Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA)
Minutes of the 64th Plenary meeting

22-24 April 2015, Leuven (Belgium)

Meeting open to Observers

OPEN SESSION
23-24 April 2015

(Agreed on 30 April 2015)

Participants

- **Panel Members:**
  Susan Fairweather-Tait, Marina Heinonen\(^1\), Sébastien La Vieille\(^2\), Rosangela Marchelli, Ambroise Martin (Chair), Androniki Naska, Monika Neuhäuser-Berthold, Grazyna Nowicka, Yolanda Sanz, Alfonso Siani, Anders Sjödin\(^1\), Martin Stern, Sean (J.J.) Strain\(^3\), Daniel Tomé, Dominique Turck and Hans Verhagen.

- **Hearing Experts\(^4\):**
  - Not Applicable

- **European Commission and/or Member States representatives:**
  - Francesco Carlucci\(^5\), Sirkku Heinimaa\(^6\), Olga Goulaki\(^7\), Marina Marini\(^7\) and Stephanie Bodenbach\(^7\) (DG-SANTE)

- **EFSA:**
  - Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Anja Bronstrup, Janusz Ciok, Wolfgang Gelbmann, Leng Heng, Emanuela Turla and Silvia Valtueña Martínez.

- **Observers:**
  - Kinga Adamaszwili (AESGP-Association of the Self-Medication Industry, BE); Andreas Kadi (EDE-Energy Drinks Europe, BE); Sara Astegiano (Istituto Zooprofilattico Sperimentale del Piemonte, IT); Marta Baffigo (Cargill R&D Centre Europe, BE); Eric Chappuis

\(^1\) Present on 22-23 April.
\(^2\) Present on 23-24 April.
\(^3\) Present on 22-23(am) April.
\(^5\) Present on 22 and 24 April.
\(^6\) Present on 24 April.
\(^7\) Present on 23 April.
(Naturalpha, FR); Patrick Coppens (Food Supplements Europe, BE); Tijmen DE Vries (ECF-European Coffee Federation, BE); Stefanie Geiser (EAS-Strategic Advice, IT); Claudia Heppner (U.S. Food and Drug Administration Europe Office, BE); Udo Herz (Danone-Nutricia Research & Development, NL); Joanna Klosowska (Specialised Nutrition Europe, BE); Sara Lewis (EU Food Law, BE); Peetz Schou Mette (Confederation of Danish Food and Drink Industries, DK); Karlheinz Niederreiter (Red Bull GmbH, AT); Marino Petracco (ISIC, IT); Stefan Ronsmans (UNESDA-Soft Drinks Europe, BE); Daniela Strohm (German Nutrition Society; Deutsche Gesellschaft für Ernährung-DGE, DE); Kate Trollope (EU Food Policy, UK); Dries Vandenbempt (Studen, BE); Marion Wolters (Yakult Europe B.V., NL).

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Carlo Agostoni, Roberto Berni Canani, Hannu Korhonen and Inge Tetens.

Anders Sjödin did not participate in agenda points 13.1 and 13.2 due to a Conflict of Interest being identified for these agenda points.

2. Brief introduction of Panel members and observers

The Chair welcomed the participants and the observers to the open plenary meeting.

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\(^8\) and the Decision of the Executive Director on Declarations of Interest\(^9\), EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the Panel Members invited for the present meeting. For further details on the outcome of the screening of the SDoI, please refer to Annex I

No other conflicts of interests 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

The code of conduct and guidelines\(^10\) for Observers, to be followed during and after attendance at the open plenary meeting, was presented.

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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 63rd Plenary meeting

There were no written procedures to report to the Panel.

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

**Dietary Reference Values**


A technical report on the Outcome of a public consultation on a draft Opinion related to the dietary reference values for calcium, which summarises the comments received during the public consultation on this opinion (which was open from 14 January to 28 February 2015), was presented and discussed, and subsequently endorsed by the Panel on 23rd April.

The technical report will be published together with the Opinion related to the dietary reference values for calcium (see also item 7.2) in the coming weeks.

7.2. Draft Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Dietary Reference Values for calcium (EFSA-Q-2011-01206)

Following the public consultation of the above-mentioned draft Opinion, relevant comments received (as outlined and discussed under item 7.1) were taking into consideration in a revised draft document (see also item 7.1). The draft opinion was adopted by the Panel on 23rd April subject to the incorporation of editorial changes.


7.3. Draft Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Dietary Reference Values for iron (EFSA-Q-2011-01214)

On 23rd April, the draft opinion was introduced and discussed. This document proposes dietary reference values for iron for adults, infants and children, pregnant and lactating women. It was endorsed by the Panel on 23rd April for release for public consultation, subject to incorporation of editorial comments.
The full text will be released for public consultation in the coming weeks.

7.4. Draft Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Dietary Reference Values for magnesium (EFSA-Q-2011-01215)

On 23rd April, the draft opinion was introduced and discussed. This document proposes dietary reference values for magnesium for adults, infants and children, pregnant and lactating women. It was endorsed by the Panel on 23rd April for release for public consultation, subject to incorporation of editorial comments.

The full text will be released for public consultation in the coming weeks.

Others

7.5. Draft technical report on outcome of the public consultation on the draft opinion on safety assessment of caffeine (EFSA-Q-2014-00915)

Following a written public consultation on the draft opinion related to the safety assessment of caffeine (which was open from 15 January to 15 March 2015) and a subsequent stakeholder meeting which was held in Brussels on 5 March 2015, EFSA received comments from 27 interested parties.

In addition, a subsequent joint-meeting was also held with ANSES, BfR and EFSA on 13 April to clarify the safety assessment of caffeine. The minutes of the meeting will be published together with the adopted Opinion.

A draft technical report, which summarises the outcome of the public consultation and includes a summary of the comments received and how the comments were addressed, was presented (see item 7.6) and endorsed by the Panel on 23rd April.

The technical report will be published together with the Opinion related to the safety of caffeine in the coming weeks.

7.6. Draft opinion on safety assessment of caffeine (EFSA-Q-2013-00220)

Following the public consultation and subsequent meetings with stakeholders and with ANSES and BfR on the safety assessment of caffeine (see 7.5), an updated version of the Opinion on the safety of caffeine was prepared taking into account the questions/comments received. A draft document outlining the changes introduced was presented and discussed. It was adopted by the Panel on 23rd April subject to the incorporation of editorial changes.

The full text will be published in the coming weeks via this link: http://www.efsa.europa.eu/en/efsajournal/pub/4102.htm


On 23rd April, the Commission Representative provided the Panel with the background of the request to update and develop scientific and technical guidance for the preparation and presentation of applications for authorisation of novel foods and to develop scientific and technical guidance for notifications for authorisations of traditional foods from third countries in the context of the new proposed EU legislative framework on Novel Foods.

The draft guidance documents elaborated by the WG on Novel Foods were presented and discussed. The guidance documents for Novel Food applications and notifications of traditional foods from third countries are intended to assist applicants in preparing and presenting their applications for authorisation of novel foods and for the notifications of traditional foods from third countries. They present a common format for the organisation of the information to be provided and outline the information and scientific and technical data which must be included in the application, as well as the key issues which should be addressed in the application or notification in order to assess the safety of a novel food or a traditional food from a third country under proposed use and use levels.

The draft guidance documents will be further elaborated by the Working Group on Novel Foods, taking into consideration the NDA Panel comments. Both guidance documents will be subject to public consultations in order to collect scientific and technical comments from interested parties, and can be finalised only once the new EU Regulation on Novel Foods has been adopted. In addition, an information session related to the Guidance on Novel Foods and Traditional Foods is planned for the first-half of 2016.

7.8. **Draft technical report on outcome of the public consultation on the draft guidance on the scientific requirements for health claims related to the gastro-intestinal tract, the immune system, and defence against pathogenic microorganisms** *(EFSA-Q-2015-00017)*

Postponed to a future plenary meeting.

7.9. **Draft guidance on the scientific requirements for health claims related to the gastro-intestinal tract, the immune system, and defence against pathogenic microorganisms** *(EFSA-Q-2014-00353)*

Postponed to a future plenary meeting.

8. **New Mandates**

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

As of 20 April 2015, 11 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. "Fabenol Max reduces the absorption of carbohydrates" *(EFSA-Q-2015-00123).*
8.2. Other mandates

Two new requests were received from the European Commission in the context of Regulation (EC) No 258/97:

- EFSA is asked to carry out additional assessment on pasteurised milk treated with UV-light as a novel food ingredient (EFSA-Q-2015-00132).

- EFSA is asked to carry out additional assessment on an extract of three herbal roots (EstroG-100) as a novel food ingredient (EFSA-Q-2015-00249).

The NDA Panel has initiated a self-task mandate to update an existing General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims (EFSA-Q-2015-00200).

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

9.1. Scientific Committee and other Scientific Panels

No Scientific Committee meeting took place since the last NDA Plenary meeting. The next Scientific Committee (SC) meeting was scheduled for 22-23 April 2015 in Parma. Of relevance to the NDA remit, members were briefed about the on-going activities of the SC’s Working Groups related to Weight of Evidence, Biological Relevance, and Uncertainty in risk assessment.

At the last Management Board (MB) meeting which took place on 19 March 2015, the MB appointed candidates to the Scientific Committee and eight of EFSA’s scientific panels, which are due for renewal for a new three-year term from 1 July 2015 (out of 807 eligible candidates, 171 experts were appointed for membership). They also established a reserve list of suitable candidates. The names of the experts will become public at the end of May 2015 once they have confirmed their wish to take up the appointment.

9.2. EFSA including its Working Groups/Task Forces

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

**WG on Claims** - At the last meeting, 5 Article 13(5) and 1 Article 14 claims opinions were discussed and elaborated. These six opinions were submitted to the Panel for adoption at this April Plenary meeting.

**WG on Novel Foods (NF)** – At the last meeting, the WG discussed and elaborated draft opinions on the following Novel Food applications: Taxifolin (EFSA-Q-2012-00961), resveratrol (EFSA-Q-2014-00232), UV treated bread (EFSA-Q-2014-00836) and two synthetic oligosaccharides Lacto-N-neotetraose (EFSA-Q-2014-00862) and 2'-O-Fucosyllactose (EFSA-Q-2015-00052). The WG also discussed sections of a draft...
guidance document for Novel Food applications and the approach for a guidance for notifications of Traditional Foods from third countries.

**WG on Dietary Reference Values (DRVs)** – The WG on DRVs for vitamins was working on vitamins B6, D, and choline, while the WG for minerals was preparing the opinions on iron, magnesium, copper, chloride, sodium, potassium and finalisation of calcium. The public consultation is closed for vitamin E (32 comments were received from interested parties), B12 (9 comments were received from interested parties) and phosphorus (19 comments were received from interested parties). The WGs are currently working on DRVs for the remaining micronutrients.

9.3. European Commission

Please refer to Sections 7.7 and 10.1.

10. Other scientific topics for information and/or discussion

10.1. Draft scientific and technical guidance for the assessment of products notified as foods for special medical purposes (FSMP) (**EFSA-Q-2014-00736**)

On 24 April, the Commission representative outlined the context and the background for the request to EFSA to provide scientific and technical guidance for the assessment of products notified as food for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013. The scope of this guidance is to ensure uniform implementation of the rules, i.e. for classification of FSMPs, and to inform the Commission for the preparation of implementing decisions pursuant to Article 3 of the Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control15.

The draft guidance document elaborated by the WG on Food for Special Medical Purposes was presented and discussed. The guidance presented in this document is for assisting in the preparation and presentation of well-structured dossiers for food products notified as foods for special medical purposes (FSMPs). It presents a common format for the organisation of the information to be provided and outlines the information and scientific data which must be included in the dossier, as well as the key issues which should be addressed in the dossier in order to assess the extent to which a food product notified as FSMP falls under the scope of Regulation (EU) No 609/2013, under the proposed use.

The draft guidance will be further elaborated by the Working Group on FSMPs, taking into consideration the NDA Panel comments. The draft guidance document will be subject of public consultation prior to finalisation.

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15 OJ L 181, 29.6.2013, p. 35
11. Questions from and answers to Observers (in application of the Guidelines for Observers)

Please refer to Annex II.

12. Any other business

Some editorial mistakes were identified in the published version of the Scientific Opinion on Dietary Reference Values for zinc (EFSA-Q-2011-01233), which do not affect the conclusions of the Panel. A corrected draft opinion was presented to the Panel, with changes highlighted. The NDA Panel agreed with the proposed changes and with republication of the corrected opinion.

The next plenary meeting of the NDA Panel is scheduled to take place on 11-12 June 2015 in Parma (and will be preceded by a meeting of WG Claims on 10 June).
CLOSED SESSION
22 April 2015
from 9.00 to 18.00

Items 13.1-13.8 were closed to observers, due to confidential business information/proprietary data.

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

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

13.1. Lallemand Health Solutions - “Bifidobacterium bifidum CNCM I-3426” and “increases the proportion of healthy days by maintaining normal immune function in healthy adults during everyday life events such as moderate stress” (Art. 13.5, 0429_FR, EFSA-Q-2014-00673)

On 22nd 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://www.efsa.europa.eu/en/efsajournal/pub/4094.htm

13.2. Synbiotec S.r.l. - “SYNBIO®, a combination of Lactobacillus rhamnosus IMC 501® and Lactobacillus paracasei IMC 502®” and “persists in the intestinal tract and favours the natural regularity contributing to maintain and improve human intestinal well-being” (Art. 13.5, 0425_IT, EFSA-Q-2014-00567)

On 22nd 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://www.efsa.europa.eu/en/efsajournal/pub/4095.htm

13.3. VAB-nutrition – “Vitamin D” and “contribution to the normal function of the immune system” (Art. 14, 0430_FR, EFSA-Q-2014-00826)

On 22nd 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://www.efsa.europa.eu/en/efsajournal/pub/4096.htm

13.4. Nerthus ApS – “Combination of pomegranate pomace extract and greater galangal rhizome powder” and “increases the number of motile spermatozoa in semen” (Art. 13.5, 0424_DK, EFSA-Q-2014-00566)

On 22nd 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://www.efsa.europa.eu/en/efsajournal/pub/4097.htm
13.5. **WILD-Valencia SAU** – “FRUIT UP®” and “induces a lower blood glucose rise than high glycaemic carbohydrates” (Art. 13.5, 0418_ES, EFSA-Q-2014-00405)

On 22nd 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://www.efsa.europa.eu/en/efsajournal/pub/4098.htm

13.6. **Tchibo GmbH** – “Regular consumption of Coffee C21 contributes to the maintenance of DNA integrity in cells of the body” (Art. 13.5, 0428_DE, EFSA-Q-2014-00624)

On 22nd 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://www.efsa.europa.eu/en/efsajournal/pub/4099.htm

**Novel Foods**

13.7. **Glycom A/S** - **Lacto-N-neotetraose** (EFSA-Q-2014-00862)

On 22nd April, an outline of the draft opinion was presented and issues encountered were discussed. The Panel considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. A request for additional information will be sent to the applicant and a clock-stop procedure will be applied.


On 22nd April, an outline of the draft opinion was presented and issues encountered were discussed. The Panel considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. A request for additional information will be sent to the applicant and a clock-stop 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. A. Sjödin declared the following interests: the applications related to “Bifidobacterium bifidum CNCM I-3426” (EFSA-Q-2014-00673, agenda point 13.1) and “SYNBIO®, a combination of Lactobacillus rhamnosus IMC 501® and Lactobacillus paracasei IMC 502®” (EFSA-Q-2014-00567, agenda point 13.2). In accordance with EFSA’s Policy on Independence and Scientific Decision-Making Processes16 and the Decision of the Executive Director on Declarations of Interest17, 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 exclusion of the expert from any discussion, voting or other processing of points 13.1 and 13.2 by the concerned scientific group.

Annex II

Questions from and Answers to Observers

Sara Lewis, EU Food Law

**Question 1:** “Does the Panel intend to consider real life situations for caffeine consumption, notably young adults drinking several energy drinks with alcohol in nightclubs (therefore combining them with dancing)?”

**Ad1 (by the Chair of the WG on Caffeine):** This question was addressed under section 7.6. It is outside of the scope of the present opinion to address possible adverse health effects of caffeine in combination with alcohol beyond alcohol doses which, by themselves, pose a risk to health (e.g. binge drinking). It is not within EFSA’s remit in the context of this opinion to provide recommendations on the consumption of caffeine from specific sources (e.g. “energy drinks”), to advise on which management measures could be put in place to avoid that excessive amounts of caffeine (i.e. beyond the levels of no concern proposed in the opinion) are consumed by particular population subgroups (e.g. adolescents, subjects performing intense physical exercise) in specific circumstances (e.g. nights out), or to comment on alcohol or other drug abuse, either alone or in combination with caffeine. Section 1 of the opinion (introduction) has been expanded to include EFSA’s interpretation of the Terms of Reference and a detailed explanation of EFSA’s remit in the safety assessment of caffeine.

**Additional question 2:** “It was asked whether researches performed on subjects going beyond the habitual dose would be helpful for risk management”

**Ad2 (by the Chair of the WG on Caffeine):** Such type of experimental studies may not get ethical committee’s approval. However, it was noted that there are studies conducted at national level, for instance using questionnaires targeted at clubbing subjects.

Stefanie Geiser, EAS-Strategic Advice

**Question 3:** “DRVs: after iron and magnesium which vitamins/minerals are next on the 2015 plan for DRV draft opinions/public consultations?”

**Ad3 (by the Chair of the WG on DRVs):** Public consultations on the draft opinions on DRVs for cobalamin, vitamin E and phosphorus have closed or will close shortly. Thus, the work will focus on preparing these for adoption in the next months, as well as finalising DRVs for copper, chloride and vitamin D. See also Section 9.2.

**Question 4:** “What are the next planned EFSA activities related to stakeholder technical meetings on health claims in 2015-2016?”

**Ad4 (by Head of Nutrition Unit):** No technical meeting related to health claims is planned for 2015/2016. However, an information session related to the Guidance on Novel Foods and Traditional Foods from third countries is scheduled for the first-half of 2016.
Question 5: “After the revision of the gut and immune function health claims guidance this summer, does EFSA have further plans to update the other claims guidance documents and which one will be next?”

Ad5 (by Head of Nutrition Unit): It will be a step-wise approach in the process of updating the claims guidance documents. The next will be the update of the “General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims”\(^{18}\), which will be followed by the update of specific “Guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations”. EFSA guidance documents will be subject to public consultation before finalisation. For the latter “Guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations”, owing to the scientific nature of the guidance, a two-step public consultation process is planned in order to collect scientific and technical comments from interested parties.

Udo Herz, Danone-Nutricia Research & Development

Question 6: “It was commented that there is a lack of guidance on how to measure allergy prevention in infant and pointed out to the absence of an identified modified risk factor. Clarifications were requested on the risk factor for development of allergies (cow’s milk allergy), obesity, and gut health”.

Ad6 (by the Panel’s vice-Chair): The identification of a risk factor is a requirement of Regulation (EC) No 1924/2006 for disease risk reduction claims. There are two possible scenarios:

1) If it is a validated risk factor (for example, elevated blood LDL-cholesterol concentrations are associated with increased risk of coronary heart disease (CHD)), i.e. there is strong evidence that there is (i) an independent association between the risk factor and the incidence of the disease, (ii) a robust biological basis through which the risk factor can contribute to the development of the disease, and (iii) evidence that a given modification of the risk factor generally reduces the risk of disease, evidence that the dietary intervention induces a given modification on the risk factor for the disease would be sufficient for the scientific substantiation of the claim.

2) For other proposed risk factors, if the evidence may not be as strong (not well validated), evidence needs to be provided that a given modification of the risk factor is accompanied by reduced incidence of the disease following a specific dietary intervention, preferably in the same studies.

Defining the conditions under which a risk factor may be acceptable in the context of a disease risk reduction claim is generally possible only in the context of specific applications. No applications for claims on the reduction (or beneficial alteration) of a risk factor for allergy or obesity have been received. Therefore no specific guidance could be provided.

Claims on gut health have not been considered sufficiently defined to be evaluated since this general term may be related to many different functions of the intestinal tract.

**Additional question 7:** “With respect to FSMPs, it was questioned whether the definition of the disease should lie with the applicant”.

**Ad7 (by the Panel’s Chair):** The burden of proof to provide studies and relevant evidence that the product fulfils the classification of FSMPs lies with the applicant.

**Kate Trollope, EU Food Policy**

**Question 8:** “The management board (MB) recently discussed EFSA taking a more proactive approach on nutrition. What sort of things do you think the NDA panel could do in terms of scientific advice, given that EFSA’s self-tasking mandate is restricted in this area?”

**Ad8 (by the Panel’s Chair):** At the MB meeting, EFSA has checked with its legal service and clarified its remit in Nutrition. EFSA’s role and responsibility on matters regarding human nutrition are limited, i.e. EFSA scientific assessment is entirely separated from risk management and public health policies, which are rather for the Commission and Member States. The Panel activity is exclusively assigned by: - a specific sectorial legal act; - a specific mandate/request of the Commission; or – by its Founding Regulation under specific provisions. It is important to note that EFSA can be asked on an *ad-hoc* basis to contribute on communications in nutrition matters upon request of the Commission.

**Question 9:** “How does the panel draw the line in the sometimes grey area between risk assessment and risk management? The GMO panel, for example, issues risk mitigation measures to reduce exposure of butterflies. Could the panel issue risk mitigation measures to reduce obesity? Example of caffeine was also given and it was questioned why the Panel is reluctant to go one step further as did ANSES and BfR”

**Ad9 (by the Panel’s Chair):** With respect to risk mitigation measures for instance, as already mentioned, the Panel activity is exclusively assigned, for example, by a specific mandate/request of the Commission. Provision of risk mitigation measures is not specified in any legislation covering the NDA remit. It should be noted that risk mitigation measures to reduce exposure of butterflies is covered in the legislative framework of the GMO Panel.

With respect to the safety assessment of caffeine, EFSA answered to the Terms of Reference as requested by the Commission. If EFSA is asked by the Commission to propose mitigation measures, EFSA will do so.

**Question 10:** “The EFSA management board also recently discussed how EFSA would work more closely with WHO on nutrition. Have any actions been taken on this, and, if so, what is in the pipeline?”

**Ad10 (by Head of Nutrition Unit):** The different remits between WHO and EFSA were highlighted, pointing to a broader role of WHO into policy matters. It was noted that the common feature between WHO and EFSA is the methodologies applied in scientific evaluations.

As part of the efforts contributing to Open EFSA, EFSA has recently launched a number of activities to further contribute to producing more robust, transparent and open scientific assessments, and to open up a discussion on methodological activities not only with WHO but with the wider scientific community –
specifically covering methods for evidence use in science, uncertainty in risk assessment, weight of evidence and biological relevance.

An editorial paper was published in March 2015 (http://www.efsa.europa.eu/en/press/news/150327.htm), and workshops will be organised (the first one is planned for June 2015) to enable scientific consultations with national and international scientific advisory bodies including WHO, EFSA’s sister agencies, the European Commission non-food committees, national agencies and international bodies throughout the timeline of these activities.

**Additional question 11:** “With respect to FSMPs, it was questioned if EFSA opinions will be published”.

**Ad11 (by Head of Nutrition Unit):** As for all EFSA’s scientific outputs, opinions on FSMP will be published.

**Additional question 12:** “With respect to safety of caffeine, it was questioned whether it is safe or unsafe if subjects go beyond the recommended dose in EFSA opinion”.

**Ad12 (by Head of Nutrition Unit):** EFSA advice is targeted to the general population and subgroups thereof but not to the individual level which may need specific individual advice. The limits proposed by EFSA are safe for the majority of population. Consuming beyond the safety limits does not mean that everyone would be at risk but some might be. The higher the amounts of caffeine consumed, the higher the risk.

**Patrick Coppens, Food Supplements Europe**

**Question 13:** “We would be interested to hear which criteria have been applied in relation to the Draft Guidance on Novel Foods and Traditional Foods and if this guidance will be open to a public consultation.”

**Ad13 (by the Chair of WG on Novel Foods):** Yes, there will be a public consultation of two documents (one for novel food applications and one for notifications of traditional foods from third countries). The finalisation of the two draft guidance documents and their submission to the Panel for endorsement for public consultation will take place only after the new Regulation for Novel Foods comes into force. The basis and criteria for the two draft guidance documents were: the SCF Guidance from 1997, harmonisation with existing EFSA Guidance, and the experience gained by EFSA over the last 12 years, for example about the most frequent limitations in novel food dossiers and reasons for applying clock-stops in the evaluation of dossiers. Regarding traditional foods from third countries, the type of data on the history of use which have been used for past novel food applications (e.g. Chia seeds) have been considered.

**Question 14:** “We would like to ask which opinions are subject to public consultation and which not and how that decision is taken. As you are aware we very welcome the opportunities given to comment on draft opinions before they are finalised.”

**Ad14 (by Head of Nutrition Unit):** In line with EFSA policy on openness and transparency, the criteria for the need to publicly consult are: (1) New type of
questions (no previously issued opinions); (2) complex/emerging scientific issues (e.g. RA approaches are still to be developed); (3) RA methodologies/principles/processes (e.g. documents of horizontal nature). The public consultation must be viewed in the context of the applicable legal framework regulating the respective EFSA domain. It may be limited by, for example, the procedures and deadlines laid down in the relevant EU legislation or set by the risk managers; the particular urgency of a question; the confidential nature or protection of data for certain outputs.

As in the example of caffeine, a public consultation is an added value to get scientific inputs from interested parties before finalisation. EFSA’s approach on public consultations on scientific outputs is published\(^\text{19}\).

**Additional question 15:** “It was pointed out that the concept of substantial equivalence is not addressed in the draft guidance on guidance on Novel Foods and Traditional Food, which could limit study requirements.”

**Ad15 (by EFSA staff):** The concept of substantial equivalence is rather for the risk manager. However, EFSA has already applied the principle in several of its opinions.

**Additional question 16:** “It was asked if the guidance dated 2011 related to claims on gut and immune function remains valid when the updated version of the guidance on the scientific requirements for health claims is adopted”

**Ad16 (by Head of Nutrition Unit):** When the updated version of the guidance on the scientific requirements for health claims is adopted, it will supersede the guidance dated 2011.

**Sylvie Binda, Danone Research (registered but not participated)**

**Question 17:** “Pre-evaluation of the eligibility of some target populations for the claims with Member states”

**Ad17 (by the Head of the Nutrition Unit):** With respect to the eligibility of the target population for claims, which target population groups under medical treatment and which relate to side effects of the treatment, it should be noted that it is outside the remit of EFSA to interpret the scope of the Claims Regulation, which is rather under the responsibility of the risk managers (i.e. Member States and European Commission). Therefore, as outlined in the “draft guidance related to health claims on GI tract, immune system and defence against pathogens”, applicants are invited to check the admissibility of the target population for the claim with the recipient Member State at the earliest possible stage.

**Question 18:** “Microbiota types of claims paragraph disappearance”.

**Ad18 (by the Panel’s vice-Chair):** It is a requirement of the claims Regulation (EC) No 1924/2006 that the use of health claims shall only be permitted if the food/constituent, for which the claim is made, has been shown to have a beneficial physiological effect (i.e. a benefit for a specific function of the body). Under this framework, the claimed effects should be defined, beneficial for the

target population, refer to a specific function of the body, and can be measured \textit{in vivo} in humans by generally accepted methods. The NDA Panel wishes to reiterate that all three of these requirements need to be met.

Claims referring to changes in outcome variable(s) that \textit{per se} (alone) do not reflect a benefit on a specific function of the body, cannot be the claimed effect. This is the case of many claims referring only to “changes in the composition of the gut microbiota” \textit{per se}, or “changes in immune markers” \textit{per se}.

Specifically regarding claims on microbiota composition, we do not know which bacterial groups and microbiota structure may confer a benefit on a specific function of the body. Therefore, this outcome variable cannot be used alone to substantiate a claim. Changes in some of these outcome variables could, however, be proposed as part of the mechanisms by which a food may exert the claimed effect, i.e. induce a beneficial change on a specific function of the body (e.g. defence against pathogens).

This aspect has been already clarified in the Technical Report on “the Outcome of a public consultation on the discussion paper for the revision of the guidance on the scientific requirements for health claims related to gut and immune function”\textsuperscript{20}.

\textbf{Question 19: “Biological markers maturity for claim substantiation”}

\textbf{Ad19 (by the Panel’s vice-Chair):} See Ad18 regarding the need to demonstrate an effect on a specific function of the body in the context of function claims and Ad16 regarding the need to demonstrate an effect on a risk factor for disease development in the context of disease risk reductions claims according to Regulation (EC) No 1924/2006.

\textbf{Eric Chappuis, Naturalpha}

\textbf{Additional question 20: “It was asked if the protection of proprietary data applies for efficacy studies submitted in the context of FSMPs”}

\textbf{Ad20 (by the Commission Representative):} Art. 3 of the FSG Regulation does not lay down specific rules for protection of proprietary data. General EFSA rules on confidentiality apply with respect to EFSA opinions on the matter.

\textsuperscript{20} \url{http://www.efsa.europa.eu/en/supporting/pub/758e.htm}