SCIENTIFIC PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGY

(NDA)

Minutes of the 52nd plenary meeting of the NDA Panel

Held on 20-22 March 2013, Parma

(Agreed on 30 May 2013)

Participants

- **Panel Members**: Carlo Agostoni, Roberto Berni Canani, Susan Fairweather-Tait, Marina Heinonen[1], Hannu Korhonen, Sébastien La Vieille, Rosangela Marchelli, Ambroise Martin (Chair), Androniki Naska, Monika Neuhäuser-Berthold, Grazyna Nowicka, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Sean Strain, Daniel Tomé, Dominique Turck[1], Hans Verhagen
- **Hearing Experts**: None
- **European Commission:** Basil Mathioudakis[1], Francesco Felice Carlucci[1]
- **EFSA:**
    - **Nutrition Unit:** Valeriu Curtui, Reinhard Ackerl, Anja Bronstrup, Janusz Ciok, Agnès de Sesmaisons Lecarré, Céline Dumas, Wolfgang Gelbmann, Leng Heng, Amy Mullee, Ariane Titz, Emanuela Turla, Silvia Valtueña Martínez
    - **Other EFSA Directorates/Units**: Andras Szoradi[2], Per Bergman[3], Liisa Valsta[4], Davide Arcella[5]
- **Observers[6]:** Shane Starling (NutraIngredients-FoodNavigator - UK), Kinga Adamaszwili (AESGP-Association of the European Self-Medication Industry - Belgium), Stefanie Geiser (European Advisory Services (EAS) – Italy), Stephanie Courau (Merck Consumer Health Care - France), Valérie de Bourayne (Kemin, Human Nutrition and Health - Portugal), Laure Normand (INNEOV - France), Polina Dombute (Rephine Balticum SIA - Latvia), Louis Vareille (Danone Baby Nutrition), Annemieke Tops (Mead Johnson Nutrition – The Netherlands), Cecilia Bender (Istituto Kurz Italia), Sara Graziano (Istituto Kurz Italia).

1 Present only on 20 and 21 March 2013
2 Present only for agenda item 5
3 Present only for agenda item 13.1
4 Present only for agenda item 13.2
5 Present only for agenda item 13.3
6 Present only on 20 March 2013

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1. Welcome and apologies for absence

The Chair opened the meeting and welcomed the participants and the observers (who were attending this Plenary meeting as part of the project underpinning EFSA's commitment to openness and transparency). Apologies were received from I. Tetens.

Participants and Observers were invited to introduce themselves.

2. Adoption of agenda

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

Four new items were added under "Any other business": - Harmonised timelines for submitting information to EFSA within the clock-stop mechanism; - Nutrient database; - EFSA Food Consumption database; - Questionnaire to Panels on the use of Scientific Committee guidance documents.

For three items (11.1, 11.5 and 11.6), the discussion was postponed to a further plenary meeting.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs)[7] and the Decision of the Executive Director implementing this Policy[8], EFSA screened the Annual Declarations of Interest (ADoIs) and the Specific Declarations of Interest (SDoIs) filled in by the experts invited to the present meeting. For further details on the outcome of the screening of the ADoIs and SDoIs, as well as the Oral Declarations of Interest (ODoIs) indicated at the beginning of the meeting, please refer to Annexes I and II.

M. Heinonen did not participate in agenda points 7.1 and 11.3.

H. Verhagen did not participate in agenda point 11.3.

S. Fairweather-Tait did not participate in agenda points 7.2 and 7.3.

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.

4. Agreement of the minutes of the 51st Plenary meeting held on 24-25 January 2013, Parma

The minutes of the 51st Plenary meeting were reviewed and agreed on 20 March 2013[9].

5. Information on the open plenary meeting: presentation of the Guidelines for observers

The code of conduct for Observers, to be followed before, during and after attendance to plenary meetings, was presented.

Observers from interested parties were given the possibility to raise questions in relation to EFSA's work when submitting their registration. The questions were recorded and will be answered in the dedicated session at the end of the first day of the Plenary meeting.

7 http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
8 http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf
9 http://www.efsa.europa.eu/en/events/event/130124-m.pdf

Observers and members of the NDA Panel were invited to fill in a feedback form at the end of the meeting. Comments and suggestions will be used to improve future open Plenary meetings organised by EFSA.

6. Report on written procedures since the 51th Plenary meeting

There were no written procedures to report to the Panel.

7. Scientific outputs submitted for discussion and/or possible endorsement for public consultation

7.1. 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 vitamin C (EFSA-Q-2011-01229)

On 20, 21 and 22 March, the draft opinion was introduced and discussed. The Draft was referred back to the Working Group on DRVs for Vitamins for further consideration.

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 fluoride (EFSA-Q-2011-01211)

On 20 March, the draft opinion was introduced and discussed. This document proposes dietary reference values for fluoride for adults, infants and children, and pregnant and lactating women. It was endorsed by the Panel for release for public consultation subject to incorporation of editorial comments.

Post-meeting notes: Public consultation is open until 13 June 2013. Interested parties are invited to submit written comments via the following link http://www.efsa.europa.eu/en/consultations/call/130502.htm

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 molybdenum (EFSA-Q-2011-01217)

On 21 March, the draft opinion was introduced and discussed. This document proposes dietary reference values for molybdenum for adults, infants and children, and pregnant and lactating women. It was endorsed by the Panel for release for public consultation subject to incorporation of editorial comments.

Post-meeting notes: Public consultation is open until 13 June 2013. Interested parties are invited to submit written comments via the following link http://www.efsa.europa.eu/en/consultations/call/130426.htm

8. New mandates

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

The Nutrition Unit informed the Panel about the status of claims applications since the last Plenary meeting.

Article 13.5 claims (claims based on newly developed science and/or which include a request for the protection of proprietary data) – 2 new applications were received:

Glycaemic carbohydrates and muscle glycogen repletion following strenuous exercise; Padina pavonica–extract and maintenance of bone mineral density.

Article 14 claims – 1 new application was received related to Risk Reduction: folic acid raises maternal red blood cell folate; low maternal red blood cell folate is a risk factor for neural tube defects in the developing foetus.

Rapporteurs have been appointed for the new applications received. EFSA NDA guidance documents on health claims will be taken into consideration for the evaluation of the new applications received.

8.2 Other mandates

Novel foods **-** Two new requests were received from the European Commission asking EFSA to carry out additional assessment related to the safety of "Rapeseed protein" (EFSA-Q-2013-00231) and of "Coriander seed oil" (EFSA-Q-2013-00232), submitted in accordance with the Novel Foods Regulation 258/97/EC as novel food ingredients. These requests have been allocated to the NDA Working Group on Novel Foods.

Safety of caffeine **-** EFSA received a request from the European Commission for a scientific opinion on the safety of caffeine (EFSA-Q-2013-00220). EFSA has already begun to work on the collection of data on the safety of caffeine, which is expected to be completed by the end of July 2013. EFSA proposes to deliver the scientific opinion on the safety of caffeine by 31 December 2013.

The NDA Panel agreed to establish an *ad-hoc* working group (WG) to deal with this request. This WG should be composed of experts from the NDA Panel and also involve experts from EFSA ANS/CEF Panels. In cooperation with the Head of Unit, the Panel Chair will appoint the WG Chair. The appointed Chair of the WG, in collaboration with the Head of Unit, will select members of the WG following the procedure as laid down in the Executive Director Decision of 2011[10].

Milk based-drinks and similar products intended for infants and young children - EFSA received a request from the Commission for a scientific opinion on milk-based drinks and similar products intended for infants and young children (EFSA-Q-2013-00263 & 00264) (see also Agenda point 9.4).

To best address the terms of reference, EFSA will issue a scientific opinion on dietary requirements of infants and young children in the framework of advice to be provided on milk based-drinks and similar products intended for infants and young children by 31 October 2013, and a scientific opinion on the composition of milk based-drinks and similar products intended for infants and young children by 31 March 2014.

Food Allergy in the framework of exemption from labelling **-** EFSA also received a request from the European Commission for scientific and technical assistance on the updating of the Commission's Guidance document for the preparation and presentation of applications for labelling exemption pursuant to Article 6, paragraph 11 of Directive 2000/13/EC (EFSA-Q-2013-00221). Owing to the scientific aspects of the guidance, the NDA Panel will address this request by providing a scientific opinion regarding the scientific data and information that could be expected to substantiate an application for labelling exemption. This request has been allocated to the NDA Working Group on Food Allergy. The opinion will be subject to public consultation and the expected date for delivery of the final opinion is 31 December 2013.

[10] http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

9. Feedback from the Scientific Committee/the Scientific Panel, Working Groups, EFSA, the European Commission

9.1 Scientific Committee and other Scientific Panels

At the last meeting, the Scientific Committee adopted a Draft opinion on hazard assessment of endocrine disruptors (EDs). The opinion addresses the scientific criteria for identification of EDs and appropriateness of existing testing methods for human health and the environment. In the framework of this opinion, a scientific meeting with stakeholders was held on 20 March 2013 (in Brussels) to inform about EFSA's work in the area of endocrine active substances (EAS) and ED (http://www.efsa.europa.eu/en/events/event/130320a.htm).

With reference to the EU's new programme for research and innovation, Horizon 2020 is managed by DG Research and Innovation (DG RI) and DG Agriculture and Rural Development (DG AGRI) and it is linked to EU 2020 strategy for smart, sustainable and inclusive growth. It is organised in three parts: excellent science, which includes food security, sustainable agriculture, marine and maritime research and bio-economy; industrial leadership and societal changes. EFSA can contribute to this programme by listing priority research areas of interests for EFSA's mandate. At the next plenary meeting, the Scientific Committee will discuss possible priority research areas identified during various consultations with the Scientific Committee, the Advisory Forum and EFSA Panels and Units. The final list of priorities will be communicated to DG RI and DG AGRI for their possible consideration.

9.2 Working groups

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

WG on Food Allergy - At the last meeting, different chapters of the opinion related to the evaluation of allergenic foods for labelling purposes were discussed, including clinical symptoms, diagnosis, epidemiology, influence of genetic, geographic, and environmental factors on food allergy, methods of detection of food allergens, effects of processing on allergenicity, celiac disease, and allergy to celery, and milk. Next, the WG will tackle issues such as prevalence of allergens, cross-reactivity, allergy to fish, egg, peanuts, lupin and nuts, emerging allergens and minimum eliciting doses.

In addition, the WG will be starting with drafting an opinion on the updating of the Commission's Guidance document for the preparation and presentation of applications for labelling exemption pursuant to Article 6, paragraph 11 of Directive 2000/13/EC (see also Agenda point 8.2).

WG on Novel Foods - The WG discussed and elaborated on draft opinions on the following Novel Food applications: "Rooster Combs Extract" (Bioiberica, EFSA-Q-2012-00613), Taxifolin (EFSA-Q-2012-00961), and Citicoline (EFSA-Q-2013-00080). For all three applications the WG requested additional information/clarifications to be provided by the applicant, thus clock-stops were applied in the evaluation of these applications.

WG on Claims - The WG discussed and elaborated on 8 draft opinions related to Article 13.5 and 14 claim applications. Among these, 2 draft opinions were submitted to this March plenary meeting for discussion and possible adoption, and 6 were subject to the clock-stop procedure for requesting supplementary information from the applicant.

WG on DRVs for vitamins - The main work was on drafting the opinion on DRVs for vitamin C. Other vitamins, such as vitamins D and B12, will be tackled during the next WG meetings.

WG on DRVs for minerals - The main work was on drafting the opinion on DRVs for fluoride and molybdenum, which were submitted to the March Plenary meeting (see Agenda points 7.2 and 7.3). Next, the WG will be working on other minerals, such as manganese, iodine and iron.

9.3 EFSA

EFSA will hold a "Technical meeting on the reporting of human studies submitted for the scientific substantiation of health claims" on **20 November 2013 in Parma**.

The objective of this meeting is to discuss with **scientists** the information required for a full scientific evaluation of human studies submitted for the scientific substantiation of health claims (i.e. the requirements for the compilation and reporting of human studies investigating the relationship between the consumption of the food/constituent for which the claim is requested and the claimed effect, which should be complete, unambiguous and well organised, in order to allow a full scientific evaluation by the NDA Panel). This meeting will NOT address the scientific requirements for the substantiation of health claims, either in general or in relation to selected areas.

Registration is foreseen to open after the summer break. Detailed information about this technical meeting is available at the following webpage: http://www.efsa.europa.eu/en/events/event/131120.htm.

9.4 European Commission

The Commission representative provided information on the mandates that the Commission recently sent to the NDA Panel. More specifically, the Commission representative focused on the mandate on the safety of caffeine and on the mandate on milk-based drinks and similar products intended for infants and young children. The Commission described the background to the decision to request EFSA's scientific advice on these matters and explained in detail the terms of reference of its requests.

With respect to the mandate on milk-based drinks and similar products intended for infants and young children, the Commission recalled that the Codex Committee on Nutrition and Food for Special Dietary Uses has recently decided to start a full revision of the standard applicable to follow-up formula and underlined the importance of this mandate in this context.

The Commission representative provided an update to the NDA Panel and the observers on recent regulatory developments of interest to the Panel. The Commission representative focused in particular on the vote that took place in the Standing Committee meeting of 4 February 2013 on a draft Regulation to amend Regulation (EU) No 432/2012 establishing the list of permitted Article 13 claims. The Commission explained that if no objection is raised during the scrutiny period by the European Parliament and the Council, the Regulation will be adopted in the next months, and certain claims will be included on the list of permitted Article 13 claims. These are claims on: alpha-cyclodextrin and the reduction of the blood glucose rise; certain omega-3 fatty acids and the maintenance of normal blood pressure and normal blood triglyceride levels; dried plums and the maintenance of normal bowel function and fructose and lower blood glucose rise.

The Commission also recalled that certain claims will remain 'on-hold' pending further consideration by the Commission: these are claims made on so-called 'botanicals' (pending the finalisation of the Commission's reflection on how to treat them); claims on caffeine (pending the finalisation of the assessment by EFSA on the safety of caffeine); claims on very low calorie diets and foods with reduced lactose content (pending finalisation of the revision of the legislation on foodstuffs for particular nutritional uses) and one claim on glycaemic carbohydrates and the maintenance of normal brain

function (pending further consideration on how to set appropriate conditions of use for the claim). The Commission explained that all the other claims will be included in the Register as non-authorised, and that the Regulation will apply six months after its entry into force.

The Commission also informed the NDA Panel and observers about forthcoming updates to the Annexes of Directive 2002/46/EC on food supplements and Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and certain other substances to food with respect to the authorised sources of chromium.

Finally, the Commission informed the Panel and observers that it intends to present to a forthcoming meeting of the Standing Committee a draft Directive amending Directive 2006/141/EC on infant formulae and follow-on formulae with regard to protein requirements for these products. This draft Directive will, on the basis of EFSA's opinions, authorise protein from goats' milk as a source of protein in infant formulae and follow-on formulae and allow, under certain conditions, follow-on formulae manufactured from protein hydrolysates to have a lower protein content than that allowed today.

10. Questions from Observers

For answers to questions received from Observers, please see **Appendix I**.

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

11.1 *Valio Ltd.* – *"Lactobacillus rhamnosus* GG" and "defence against upper respiratory tract viruses" (Art. 14, 0363_FI, EFSA-Q-2012-00750)

Discussion postponed to a further plenary meeting owing to the clock-stop-procedure.

11.2 *Leiber GmbH* - "Yestimun®" and "helps to maintain the body's defence against pathogens in the upper respiratory tract" (Art. 13.5, 0364_DE, EFSA-Q-2012-00761*)*

On 21 March, the draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The full text is published in the EFSA Journal: http://www.efsa.europa.eu/en/efsajournal/pub/3159.htm

11.3 *McNeil Nutritionals and Raisio Nutrition Ltd* - "Consumption of 2 g/day plant stanols as part of a diet low in saturated fat results in a 2-fold greater reduction in LDL-cholesterol than consuming a low saturated fat diet alone. High cholesterol is a risk factor in the development of coronary heart disease" (Art 14, 0368_UK, EFSA-Q-2012-00915*)*

On 21 March, the draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The full text is published in the EFSA Journal: http://www.efsa.europa.eu/en/efsajournal/pub/3160.htm

11.4 *Minami Nutrition Health BVBA*- "Eicosapentaenoic acid (EPA)" and "reduces the AA/EPA ratio in blood. A high AA/EPA ratio is a risk factor in the development of attention difficulties in children" (Art. 14, 0350_BE, EFSA-Q-2012-00573*)*

On 21 March, the draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The full text is published in the EFSA Journal: http://www.efsa.europa.eu/en/efsajournal/pub/3161.htm

Novel foods

11.5 *Bioiberica* – Rooster Combs Extract (EFSA-Q-2012-00613*)*

Discussion postponed to a further plenary meeting owing to the clock-stop procedure.

11.6 *Myrisana* – Cetyl Myristoleate Complex (EFSA-Q-2012-00649*)*

Discussion postponed to a further plenary meeting owing to the clock-stop procedure.

12. Other scientific topics for information and/or discussion

Not applicable (see Agenda point 13).

13. Any Other Business

13.1 Harmonised timelines for submitting information to EFSA within the clock-stop mechanism

The mechanism of stopping the clock is foreseen in many EC food and feed sectoral legislations for regulated products. The procedure consists of freezing the timeline of a scientific risk assessment to request additional or supplementary information to applicants in cases where the responsible Scientific Panel cannot conclude its evaluation based on the information available.

As this mechanism is differently described in different legislations, and since its use by EFSA varies between its different sectors, EFSA has developed a draft guideline which aims, where possible, at harmonisation of the use of the clock-stop procedure. EFSA has started to analyse the types of information typically requested to applicants under this clock-stop mechanisms and the timelines applied for collection of this information.

On 21 March, the draft document was presented by Per Bergman for discussion by the Panel. The Panel discussed the indicative timelines relevant to the NDA framework. An updated document will be tabled for discussion at the next SC plenary meeting.

13.2 EFSA Food Consumption database

On 22 March, Davide Arcella gave an overview on the food consumption database in EFSA, outlining the legal framework, the background, the network of expert groups involved, the process, the methods used for gathering, and future activities of EFSA towards harmonised food data collection across Europe.

13.3 Nutrient database

On 22 March, Liisa Valsta presented how the EFSA food composition database could be used for nutrient intake calculations, using EFSA FoodEx2 and facet descriptors to map food codes on national food composition datasets. The Panel questioned the use of nutrient database for nutrient intake calculations and the nutrients covered, as these could be helpful for the NDA activities on DRVs related to micronutrients.

13.4 Questionnaire to Panels on the use of Scientific Committee (SC) guidance documents

The questionnaire on the use of SC guidance documents in the framework of NDA mandates was sent to the Panel for comments (i.e. Claims, DRV, NF, Food Allergy, and Infant Formulae/Dietetic Products). Comments received will be submitted to the Scientific Committee secretariat.

Appendix I

Questions and Answers session for Observers

- **Shane STARLING - NutraIngredients-FoodNavigator, UK**

  Question: "How has the NDA focus changed now that the bulk of article 13.1 opinions has been published?"

  Answered by the Panel's Chair: The NDA panel is still dealing with around 20-30 health claim applications per year. In addition to the work on health claims, the Panel is now busy with establishing dietary reference values for 29 micronutrients, which need to be finalised by June 2015. The panel is also working on an opinion on allergen risk assessment including consideration on possible threshold concentrations of each allergen in food that would provide an acceptable level of protection for at-risk consumers. The Panel will continue with the safety assessment of novel foods, caffeine, and other possible requests related to the current revision of the legal framework for foods for particular nutritional uses and in view of subsequent adoption of delegated acts setting specific rules for the categories of foods covered by the Regulation, including infant formulae and follow-on formulae. One example of these is the new mandate on milk based-drinks and similar products intended for infants and young children (**see also Agenda items 8.2/9.4**).

  Question: "Does the panel still view its interpretation of the NHCR as a learning process as stated by previous chair, Professor Albert Flynn?"

  Answered by the Panel's Chair: Although we have gained more experience as health claims have been evaluated, it is still a learning process for many claims. Health claims are technically and scientifically complex and each health claim application is fairly unique, particularly related to Art 13(5) and 14, which require a case by case assessment.

  The scientific requirements for substantiation of health claims are now laid down for various areas in several guidance documents to applicants. More than 500 scientific opinions related to health claims have been published, in which the strengths and weaknesses of studies submitted in relation to the claims, and reasons for favourable and unfavourable assessment, are transparently outlined. EFSA-published opinions together with the guidance documents provide good assistance to applicants for good quality applications.

  Question: "Has the panel been asked to give input on how best to deal with botanical claim data?"

  Answer by the Commission representative: The Commission representative explained that the Commission's reflection on how to treat health claims made on 'botanicals' is currently on-going and that its outcome cannot be anticipated for the moment.

  Question: "*Has the Panel had experience with minority opinions*?"

  Answer by the panel's Chair: While this possibility has occasionally been considered, thorough scientific discussions have so far enabled all opinions to be reached by consensus.

- **Kinga ADAMASZWILI, AESGP - Association of the European Self-Medication Industry, Belgium**

  Question: "Given the negative outcome of the impact assessment on a possibility of EFSA fees, what are the EFSA views on the possibility of having scientific advice meetings with the applicants with regard to the health claims applications?"

  Answered by the Head of the EFSA Nutrition Unit: Openness and transparency are fundamental to EFSA's work and are concepts outlined in EFSA's Founding Regulation. Dialogue with applicants is a crucial aspect of EFSA's work, particularly in the evaluation of regulated products and health claims. EFSA has engaged regularly with stakeholders to outline and clarify where needed the process followed by the NDA Panel in the evaluation of claims, and has provided advice in this field since 2007 through guidance, briefing documents and the holding of scientific meetings.

  EFSA has also set up an Applications Helpdesk as a front office and support desk for applicants. The Applications Helpdesk is responsible for centralising and processing the initial administrative steps of all applications (including reception, registration and verifying the administrative and basic scientific completeness of the information submitted in the application).

  EFSA has received requests from applicants to hold pre-submission/scientific advice meetings with the NDA Panel. The NDA Panel is made up of independent experts who work on voluntary basis. The evaluation of health claims constitutes only part of their heavy workload. Their time should be used with great care. There are thousands of applicants and it would not be feasible for the experts to hold individual pre-submission meetings, nor does EFSA have the resources needed for such meetings to be conducted. Applicants are strongly encouraged to seek external advice from experts in the field of health claims substantiation.

  Question: "The companies have problems with designing a study which would be accepted by the NDA Panel to sufficiently substantiate a health claim. What would be EFSA advice to the companies in this regard?"

  Answered by the Chair of WG Claims: It should be noted that as required by the Claims Regulation, health claims should be substantiated by taking into account the totality of the available scientific data, and by weighing the evidence. There should be a body of scientific evidence for substantiation of health claims. Studies submitted for substantiation should follow sound scientific disciplines.

  As already outlined in a previous reply, more than **500** opinions related to health claims, together with various guidance documents for applicants, have been published. We recommend that applicants take advantage of these documents, which provide good assistance and valuable sources of information in order to help in the preparation of good quality applications. Furthermore, applicants are strongly encouraged to seek external advice from experts in the field of health claims substantiation.

  During the evaluation process, stop-clock procedures have been frequently used to communicate with applicants and seek clarifications on health claims applications.

  Question: "How will EFSA carry on the additional safety assessment of the caffeine claims?"

  Answered by the Panel's Chair: The Chair pointed out that this question has already been addressed under Agenda item 8.2.

- **Stefanie GEISER – European Advisory Services (EAS), Italy**

  Question: "DRVs: next steps on public consultation."

  Answered by the Panel's Chair: The deadline for finalising DRVs for vitamins and minerals is June 2015. All DRV opinions will be subject to public consultation before their finalisation, which should be seen as an opportunity for interested parties to provide comments and input to these opinions.

  Related to the draft opinions on DRVs for vitamin C, fluoride and molybdenum, thus subject to endorsement by the Panel and incorporation of points resulting from the discussion during this Plenary meeting, the draft opinions will undergo public consultation for a period of approximately 6-8 weeks (see also Agenda items 7.1, 7.2 and 7.3).

  Question: "Art 13.1 claims: status of NDA work related to Commission mandates for further EFSA work related to claims still "on hold" (e.g. status of caffeine safety assessment and/or are there any further Commission mandates in sight related to Art. 13.1 claims or any other claims "on hold" for other substances)?"

  Answered by the Commission representative: The Commission representative listed the Article 13 claims that are still 'on hold' (claims made on so-called 'botanicals'; claims on caffeine; claims on very low calorie diets and foods with reduced lactose content and one claim on glycaemic carbohydrates). He recalled that a mandate has been sent to EFSA with respect to claims on caffeine, and added that in the context of the new Regulation which revises existing legislation on food for particular nutritional uses, a scientific opinion from EFSA will be needed on total diet replacement for weight control including Very Low Calorie Diets. This mandate, however, will not focus on claims but on composition requirements for these products, in order to establish rules for them, as requested by the European Parliament and the Council in the new Regulation.

  The Commission representative also explained that an opinion from EFSA already exists on lactose intolerance and no request for additional advice is foreseen in that area. The claim on glycaemic carbohydrates will soon be submitted to the Standing Committee, and no EFSA's advice is foreseen. Claims on botanicals are undergoing a reflection and no decision for them has been taken so far.

  Question: "Art 13.5/14 claims: status of probiotic claims in progress – when finalisation of opinions foreseen?"

  Answered by the Head of the Nutrition Unit: For health claim applications including health claims on "probiotics", EFSA has a **5 month** legal deadline to deliver its opinion upon receipt of an application that is considered complete and valid. This timeline is extended whenever the Panel seeks supplementary information from the applicant during the evaluation process. The Panel is applying so-called clock-stops to clarify with the applicants open issues for the scientific substantiation of the claim. Currently, there are **2** applications related to health claims on "probiotics" undergoing the evaluation process. Their status is indicated in EFSA's Register of Questions.

  All assessments by the Panel are of confidential nature until the publication of the final opinion, and no information about ongoing discussions can be disclosed.

Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)[11]

In the SDoI filled for the present meeting, **Prof. M. Heinonen** and **Prof. H. Verhagen** declared the following interest: application related to plant stanols (EFSA-Q-2012-00915, agenda point 11.3). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs) and the Decision of the Executive Director implementing this Policy, 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 impossibility for the experts to be present when that item (agenda point 11.3) is discussed, voted on or in any way processed by that concerned scientific group.

In the SDoI filled for the present meeting, **Prof. S. Fairweather-Tait** declared the following interest: draft opinions related to Dietary Reference Values for fluoride (EFSA-Q-2011-01211, agenda point 7.2), and molybdenum (EFSA-Q-2011-01217, agenda point 7.3) (owing to tenders with EFSA to provide evidence reports identifying health outcomes upon which DRVs could potentially be based for these minerals). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs) and the Decision of the Executive Director implementing this Policy, 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 impossibility for the expert to be present when these items (agenda points 7.2 and 7.3) are discussed, voted on or in any way processed by that concerned scientific group.

In the SDoI filled for the present meeting, **Prof. A. Sjödin** declared an interest for the application on "Yestimun®", which consists of beta-glucans that derive from microorganisms (EFSA-Q-2012-00761, agenda point 11.2). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a conflict of Interest for the expert concerned as the application relates to beta-glucans and not to "beneficial bacteria".

[11] The Annual Declarations of Interests have been screened and approved before inviting the experts to the meeting, in accordance with the Decision of the Executive Director implementing the Policy on Independence regarding Declarations of Interests.

Annex II

Interests and actions resulting from the oral declarations of interests done at the beginning of the meeting

With regard to this meeting, Prof. **M. Heinonen** also declared the following interest: draft opinion related to Dietary Reference Values for vitamin C (EFSA-Q-2011-01229, agenda point 7.1) (owing to a tender with EFSA to provide evidence reports identifying health outcomes upon which DRVs could potentially be based for this vitamin). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs) and the Decision of the Executive Director implementing this Policy, 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 impossibility for the expert to be present when that item (agenda point 7.1) is discussed, voted on or in any way processed by that concerned scientific group.