Scientific Panel on Dietetic Products, Nutrition and Allergy (NDA)

Minutes of the 59th plenary meeting

Held on 25-27 June 2014, Parma

(Agreed on 18 September 2014)

Participants

- **Panel Members:** Carlo Agostoni[1], Roberto Berni Canani[2], Susan Fairweather-Tait[2], Marina Heinonen, Hannu Korhonen, Sébastien La Vieille, Rosangela Marchelli, Androniki Naska, Monika Neuhäuser-Berthold, Grazyna Nowicka, Yolanda Sanz, Alfonso Siani, Anders Sjödin[3], Martin Stern, Sean Strain (Chair), Inge Tetens[2], Daniel Tomé, and Hans Verhagen.
- **Hearing Experts:** None
- **European Commission and/or Member States representatives:** Francesco Carlucci[4]
- **EFSA:**
  - Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Anja Bronstrup, Janusz Ciok, Agnès de Sesmaisons Lecarré, Céline Dumas, Wolfgang Gelbmann, Leng Heng, Ariane Titz, Emanuela Turla, Silvia Valtueña Martínez and Aurélie Zunino
  - Other EFSA Directorates/Units: Roy Kirby[5]
- **Observers**[6]: Adriano Cattaneo (IBFAN, IT); Kinga Adamaszwili (AESGP-Association of the Self-Medication Industry, BE); Stefanie Geiser (EAS-Strategic Advice, IT); Annie Rose Harrison-Dunn (NutraIngredients, UK); Sarah Trattnig (Red Bull GmbH, AT); Sue O'Hagan (PepsiCo International, UK); Andreas Kadi (EDE-Energy Drinks Europe, BE); Sebnem Kavakli (Ege University, TR); Jozef Kočan (IDC Holding a.s., SK); Markus Lacorn (R-Biopharm AG, DE); Daniela Strohm (DGE-German Nutrition Society, DE); Kate Trollope (EU Food Policy, UK); Giorgio Tibaldi (Soremartec Italia srl, IT); Laila Lundby (Danish Agriculture and Food Council, DK); Camilla Melegari (Barilla, IT); Yassaman Shahkhalili-Dulloo, Taciana Luciano E Silvia, and Eleanor Villariño (Nestle Research Center, CH).

1 Present on 25 and 27 June; on 26 June (pm), present via teleconference.
2 Present on 25 and 26 June.
3 Present on 25-26 June; on 27 June, present via teleconference.
4 Present on 26 June.
5 Present only for Agenda item 13.
6 Attending the NDA Panel open Plenary meeting of 26-27 June.

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1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Ambroise Martin[7] and Dominique Turck[8].

2. Adoption of agenda

The agenda was adopted with changes in the order of discussion.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[9] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests[10], EFSA screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the SDoI, please refer to Annex I.

An Oral Declaration of Interest was asked at the beginning of the meeting[11] and no additional interest was declared.

S. Strain did not participate in agenda point 6.2 (this item was chaired by Y. Sanz).

4. Agreement of the minutes of the 58th Plenary meeting held on 8-11 April 2014

The minutes of the 58th Plenary meeting were reviewed and agreed on 25 June 2014[12].

5. Report on written procedures since the 58th Plenary meeting

There were two written procedures:

A 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 chromium (EFSA-Q-2011-01209) was endorsed by written procedure. In this opinion, the criteria for essentiality of a trace element were considered. It was concluded that no Average Requirement and no Population Reference Intake for chromium for the performance of physiological functions can be defined and that the setting of an Adequate Intake for chromium is also not appropriate.

A discussion paper on the revision of the guidance on the scientific requirements for health claims related to gut and immune function (EFSA-Q-2014-00409) was also endorsed by written procedure.

See also item 10.3.

7 Present on 25 (pm) and 26 (am) June via teleconference.
8 Present only on 26 June (am) via teleconference for the items 9.5 and 9.6.
9 http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
10 http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf
11 Oral DoI was provided by D. Turck before starting the discussion related to items 9.5 and 9.6, and no conflict of interest was identified.
12 http://www.efsa.europa.eu/en/events/event/140408a.htm

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

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

6.1 *DoubleGood AB* – **"Table water containing a nutrient mix"** and "**contributes to the reduction of blood glucose rise when consumed together with a carbohydrate rich meal"** (Art. 13.5, 0395_SE, EFSA-Q-2013-00756)

On 25 June, 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/3752.htm.

6.2 *DSM Nutritional and Kemin Foods* – "**Lutein together with zeaxanthin"** and **"helps maintain clarity and contrast of sight in bright light conditions"** (Art. 13.5, 0399_FR, EFSA-Q-2013-00875)

On 25 June, 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/3753.htm.

6.3 *InQpharm Europe Ltd* – **"PhaseLite™"** and **"helps to reduce body weight"** (Art. 13.5, 0403_UK, EFSA-Q-2013-00973)

On 25 June, 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/3754.htm.

6.4 *Natural Alternatives International, Inc (NAI)* **- "Beta-alanine"** and **"increase in performance during short-duration high intensity exercise"** (Art. 13.5, 0404_UK, EFSA-Q-2013-00974)

On 25 June, 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/3755.htm.

6.5 ***Clasado Limited*** **- "Regular daily consumption of 1.37g galactooligosaccharides from Bimuno®"** and **"may reduce abdominal discomfort"** (Art. 13.5, 0406_MT, EFSA-Q-2014-00022)

On 25 June, 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/3756.htm.

Novel Foods

6.6 ***Bioreal AB*-Draft Opinion on the safety of Astaxanthin-rich ingredients** (EFSA-Q-2011-00990)

On 25 June, 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/3757.htm.

6.7 *Myrisana*-Draft Statement on the safety of Cetyl Myristoleate Complex (EFSA-Q-2014-00166)

On 25 June, 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/3758.htm.

7. Brief introduction of Panel members and Observers, and presentation of the '*Guidelines for Observers*'

The Chair welcomed the participants and the observers to the open plenary meeting. Participants and Observers were invited to introduce themselves.

The code of conduct and guidelines for Observers, to be followed during and after attendance to the open plenary meeting, was presented.

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 at the end of the first day of the Plenary meeting.

Observers were informed that additional questions from observers are allowed if time permits.

8. New mandates

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

As of 24 June 2014: 18 claim application are in progress. No new claim application was received since the last Plenary meeting.

8.2 Other mandates

In the context of Regulation (EC) No 258/97, three new requests were received from the European Commission asking EFSA for: a scientific opinion on pasteurised milk products fermented with Bacteroides xylanisolvens as a novel food (EFSA-Q-2014-00295); a revision of an exposure assessment on lycopene as a novel food ingredient (EFSA-Q-2014-00301); and a scientific opinion on refined oil from the seeds of Buglossoides arvensis as a novel food ingredient (EFSA-Q-2014-00444). These requests have been allocated to the NDA Working Group on Novel Foods. Rapporteurs have been appointed for the new applications received.

In the framework of claims, EFSA has initiated a self-mandate for revising the existing guidance on the scientific requirements for health claims related to gut and immune function. To this end, a Discussion paper on the revision of the guidance was released for public consultation until 10 September, with the aim of collecting comments and suggestions from interested parties before drafting the guidance document. It proposes a plan for the revision, outlines the scope and issues to be covered in the revised guidance document, and proposes a timetable for finalising the guidance. The outcome of the public consultation together with new scientific evidence available to the NDA Panel and the experience gained with the evaluation of health claims will serve as a basis for revising the guidance document (http://www.efsa.europa.eu/en/consultations/call/140618.htm).

9. Scientific outputs submitted for discussion and/or possible adoption (cont.)

9.1 Draft technical report on the comments received during the public consultation for the draft DRVs for niacin (EFSA-Q-2013-01016)

A technical report on the Outcome of a public consultation on a draft Opinion related to the dietary reference values for niacin, which summarises and addresses the comments received during the public consultation (open from 14 February to 28 March 2014), was presented and discussed. Comments were received from two interested parties. The technical report was endorsed by the Panel on 27 June subject to editorial comments. It will be published together with the revised Opinion (see also item 9.2) via the following link: http://www.efsa.europa.eu/en/supporting/pub/632e.htm?wtrl=01.

9.2 Draft of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the dietary reference values for niacin (EFSA-Q-2011-01218)

Following the online public consultation of the above-mentioned draft Opinion (see also item 9.1), a revised draft document taking into consideration relevant comments received was discussed and adopted on 27 June subject to the incorporation of editorial changes.

The full text is published in the EFSA Journal:
http://www.efsa.europa.eu/en/efsajournal/pub/3759.htm.

9.3 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 selenium (EFSA-Q-2011-01223)

On 26 and 27 June, the draft opinion was introduced and discussed. This document proposes dietary reference values for selenium for adults, infants and children, and pregnant and lactating women. On 27 June, the Panel endorsed the Draft Opinion for release for public consultation, subject to incorporation of editorial comments.

Post-meeting note: Interested parties were invited to submit written comments by 19 August 2014 (http://www.efsa.europa.eu/en/consultations/call/140715.htm).

9.4 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 folate (EFSA-Q-2011-01212)

On 26 June, the draft opinion was introduced and discussed. This document proposes dietary reference values for folate for adults, infants and children, pregnant and lactating women. On 26 June, the Panel endorsed the Draft Opinion for release for public consultation, subject to incorporation of editorial comments.

Post-meeting note: Interested parties were invited to submit written comments by 14 September 2014 (http://www.efsa.europa.eu/en/consultations/call/140722.htm).

9.5 Draft technical report on the comments received during the public consultation for the Draft opinion on the composition of milk based-drinks and similar products intended for infants and young children (EFSA-Q-2014-00245)

Following the public consultation (open from 24 April to 29 May 2014) on the draft Opinion on essential composition of infant and follow-on formulae, EFSA received comments from 31 interested parties. A technical report which summarises the outcome of the public consultation and addresses comments received was presented. The technical report was endorsed by the Panel on 26 June subject to editorial comments. The report will be published together with the revised Opinion (see also item 9.6) via the following link: http://www.efsa.europa.eu/en/supporting/pub/633e.htm.

9.6 Draft Opinion on the composition of milk based-drinks and similar products intended for infants and young children (EFSA-Q-2013-00264)

An updated version of the Opinion, which took into account relevant comments received, was presented and discussed on 26 June.

In this document, the minimum content of a nutrient in formula is derived from the intake levels the Panel had considered adequate for the majority of infants in the first six months of life in its previous opinion and an average amount of formula consumed during this period. From a nutritional point of view, the minimum contents of nutrients in infant and follow-on formula proposed by the Panel cover the nutritional needs of virtually all healthy infants born at term, and there is no need to exceed these amounts in formulae since nutrients which are not used or stored have to be excreted, and this may put a burden on the infant's metabolism. Therefore, the Panel emphasises that maximum amounts should be interpreted not as target values but rather as upper limits of a range which should not be exceeded.

The Opinion was adopted by the Panel on 26 June 2014. The full text is published in the EFSA Journal:
http://www.efsa.europa.eu/en/efsajournal/pub/3760.htm.

9.7 Draft Opinion on health benefits of seafood (fish and shellfish) consumption in relation to health risks associated with exposure to methylmercury (EFSA-Q-2013-00167)

On 27 June, a revised draft opinion which took into account comments received (i.e. Feedback received at the previous NDA Plenary meetings, the Working Group on Fish, and the CONTAM Panel) was presented. An outline of the revised opinion structure was given and changes introduced were highlighted.

In the context of this opinion, the Panel has reviewed the role of seafood in European diets and evaluated the beneficial effects of seafood consumption in relation to health outcomes and population subgroups that have been identified by the FAO/WHO Joint Expert Consultation on the Risks and Benefits of Fish Consumption and/or the Panel on Contaminants in the context of a risk assessment related to the presence of mercury and methylmercury in food, as relevant for the assessment. These included the effects of seafood consumption during pregnancy on functional outcomes of children's neurodevelopment and the effects of seafood consumption on cardiovascular disease risk in adults. Consumption of about 1-2 servings of seafood per week and up to 3-4 servings per week during pregnancy has been associated with better functional outcomes of neurodevelopment in children compared to no

seafood consumption. Such amounts have also been associated with a lower risk of coronary heart disease mortality in adults and are compatible with current intakes and recommendations in most of the European countries considered. These associations refer to seafood *per se* and include beneficial and adverse effects of nutrients and non-nutrients (i.e. including contaminants such as methylmercury) contained in seafood. No additional benefits on neurodevelopmental outcomes and no benefit on coronary heart disease mortality risk might be expected at higher intakes.

The opinion was adopted on 27 June by the Panel subject to editorial changes. The document will be submitted to the Scientific Committee in July for further consideration about the feasibility of addressing the risks and benefits of seafood consumption to human health related to methylmercury.

The full text is published in the EFSA Journal:
http://www.efsa.europa.eu/en/efsajournal/pub/3761.htm.

9.8 Draft opinion on Safety assessment of caffeine (EFSA-Q-2013-00220)

On 26 June, a presentation was given on the content and a revised structure of the opinion on the safety assessment of caffeine, providing an overview on the mandate received from the Commission, the composition of the Working Group charged with the safety assessment of caffeine and drafting the opinion, and previous risk assessments carried out on caffeine. The approach used, the hierarchy and selections of studies, and key studies used for identifying adverse effects were presented, and issues encountered were highlighted.

The WG on Caffeine is currently working on the draft opinion, aiming for endorsement for release for public consultation by the Panel at its plenary meeting in September 2014. At least a 6-week public consultation is foreseen. Possible adoption by the Panel is foreseen in December 2014 (depending on the number of comments to be addressed after the public consultation).

Post-meeting note: New data on food consumption in Member States, including foods containing caffeine, have became available to EFSA and these data have to be considered in the intake assessment of caffeine in EU. Hence, the endorsement of the draft opinion for public consultation has been deferred to a future plenary to allow intake assessment. A new deadline for delivering the final opinion will be discussed with the Commission.

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

10.1 Scientific Committee and other Scientific Panels

No Scientific Committee plenary meeting took place since the last NDA Panel meeting.

10.2 Working groups

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

WG on Claims - At the last meeting, 10 Article 13(5) claims opinions were discussed and elaborated. Among these: 6 were put under the stop the clock procedure for requesting supplementary information from the applicants, 4 were

submitted to the Panel for possible adoption at this June Plenary meeting. The WG also discussed and elaborated the Discussion paper on the revision of the guidance on the scientific requirements for health claims related to gut and immune function.

WG on Dietetic Products - After the closing of the public consultation on 29 May, the WG met twice under a very tight deadline to review and implement comments received, and to revise the draft opinion on the composition of milk based-drinks and similar products intended for infants and young children. In addition, the WG is currently working on the draft opinion related to the essential composition of low and very low calorie diets (EFSA-Q-2013-00994).

WG on Novel Foods (NF) - Since the last plenary, the WG met and discussed two mandates received in March: review of the Safety of Cetyl myristoleate complex (CMC) in the light of additional information submitted by the applicant (see also item 6.7); and on the safety of the extension of use, basically the dose, of the authorised novel food ingredient DHA and EPA–rich algal oil from Schizochytrium. The WG has also continued to work on a new guidance document for novel food applications following the receipt of the mandate from the Commission in the light of the proposal for a new NF Regulation. This mandate also includes the preparation of a guidance document for traditional foods from third countries. A number of new mandates on NF applications have been received in the last months; these applications will add to the workload of the WG in the months ahead (see also item 8.2).

WG on Dietary Reference Values (DRVs) **-** The WG is currently working on DRVs for the remaining micronutrients, particularly DRVs for calcium and vitamin A (with target endorsement for public consultations in fall 2014), vitamin B12 and vitamin E (with target endorsement for public consultations by first quarter 2015).

10.3 EFSA

The Panel was informed that EFSA'scall for the renewal of 8 of its 10 Panels and the SC had been extended to 7 July 2014 (http://www.efsa.europa.eu/en/scpanels/memberscall2011.htm).

The Panel was provided with feedback from the 52nd Advisory Forum (AF) meeting held in Oslo on 18-19 June. Possible cooperation with Member States on activities related to the NDA Panel was discussed, particularly in the framework of novel food assessments. To enable planning for the implementation of the new novel food/traditional food regulations, it was proposed to establish an *ad-hoc* network with Terms of Reference to be discussed at the future AF meeting.

EFSA had launched several open consultations:

A draft scientific opinion on dietary reference values for chromium was open for public consultation until 3 August 2014. Interested parties were invited to submit written comments via this link: http://www.efsa.europa.eu/en/consultations/call/140606.htm

A **Discussion paper on the revision of the guidance on the scientific requirements for health claims related to gut and immune function** was open for public consultation until 10 September 2014 (see also items 5 and 8.2). Interested parties were invited to submit written comments via this link: http://www.efsa.europa.eu/en/consultations/call/140618.htm

A **draft scientific opinion on the evaluation of allergenic foods and food ingredients for labelling purposes** was open for public consultation until 8 August 2014. This document updates previous EFSA opinions relative to food ingredients or substances with known allergenic potential listed in Annex IIIa of 2003/89/EC, as amended. The document includes information on the prevalence of food allergy in unselected populations, on proteins identified as food allergens, on cross-reactivities, on the effects of food processing on allergenicity of foods and ingredients, on methods for the detection of allergens and allergenic foods, on doses observed to trigger adverse reactions in sensitive individuals, and on the approaches which have been used to derive individual and population thresholds for selected allergenic foods. Interested parties were invited to submit written comments via this link: http://www.efsa.europa.eu/en/consultations/call/140523.htm

EFSA's Assessment and Methodological Support Unit had launched an open consultation on the **draft Guidance on Statistical Reporting**. The guidance aims to assist harmonisation and standardisation in the reporting of statistical analysis. The Public Consultation will close on 23rd July 2014: http://www.efsa.europa.eu/en/consultations/call/140528.htm

10.4 European Commission

The Commission representative provided an update on the status of the Commission authorisation decisions of health claims made on foods. At its last meeting, the Standing Committee on the Food Chain and Animal Health authorised health claims related to calcium and vitamin D, and a health claim related to replacement of saturated fats with unsaturated fats. Other claims were rejected. All the adopted Commission decisions related to health claims are available on the Commission website: http://ec.europa.eu/nuhclaims/

The Commission representative also briefed the NDA Panel on recent regulatory developments of interest to the Panel. The implementing rules for the labelling of gluten-free foods (including non-pre-packed foods) were agreed and will apply from July 2016.

With respect to foods for specific groups of the population (covered by Regulation (EU) No 609/2013), delegated acts are being prepared. In addition, the Commission will be launching a public consultation to gather data on young child formulae (YCF) and a report will be issued. With respect to sport foods, the Commission intends to request an external contractor to carry out a study in order to collect data in preparation for a report to be issued.

11. Other scientific topics for information and/or discussion

None.

12. Questions from Observers

Please refer to Annex II.

13. Any other business

On 27 June, Roy Kirby presented to the Panel new changes in the framework of EFSA's Document Management System, i.e. moving from ScienceNet to OpenText, which will go live in Autumn 2014. Training will be provided.

As a closing remark, the Chair of the NDA Panel thanked the observers for their attendance.

Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)[13]

In the SDoI filled for the present meeting by **Prof. S. Strain,** the following interest was identified: an application related to ***"*Lutein together with zeaxanthin"** and **"helps maintain clarity and contrast of sight in bright light conditions"** (**EFSA-Q-2013-00875,** agenda point 6.2). 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 deemed to represent a conflict of interest.

This results in the impossibility for the expert to be present when this item of the meeting (agenda point 6.2) is discussed, voted on or in anyway processed by that concerned scientific group.

[13] 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

Questions from and Answers to Observers

Adriano CATTANEO (IBFAN-International Baby Food Action Network, IT)

*Question 1: "*Is toddlers formula a breast milk substitute?"

Answered by the Head of the Nutrition Unit: The question of whether young-child formulae should be considered to be breast milk substitutes is outside the remit of the Panel. Young-child formula (YCF) can be consumed by young children as can infant formula (IF), follow-on formula (FOF) or breast milk.

*Question 2: "*What is its role in the diet of toddlers?"

Answered by the Head of the Nutrition Unit: The Panel has already commented on the role of YCF in its Opinion on nutrient requirements and dietary intakes of infants and young children in the EU. In that Opinion it concluded that no unique role of YCF with respect to the provision of critical nutrients in the diet of young children can be identified (published in October 2013, http://www.efsa.europa.eu/en/efsajournal/pub/3408.htm).

*Question 3: "*Is there any evidence of beneficial effects?"

Answered by the Head of the Nutrition Unit: Fortified formulae (including YCF, IF and FOF) are one of several means to increase nutrient intakes in infants and young children with inadequate, or at risk of inadequate status of nutrients (mainly iron, vitamin D, DHA, ALA and iodine).

Additional question asked during the meeting: How does the Panel consider the studies financed by industry as compared to studies financed by public money (e.g. reference to DHA studies was made in the context of health claim authorisation)"?

Answer by the Panel's Chair: The Panel focuses on scientific aspects of studies. All data submitted is reviewed by the Panel taking into account the specific legislative framework. The Panel judges on the quality of the systematic review, taking into consideration the criteria used, compliance with the requirements, and any potential methodological bias, irrespective of the funding source. In the context of health claim applications, the Panel may ask the applicants to provide full reports of studies which are claimed as proprietary for the evaluation.

Patti Rundall (Baby Milk Action & IBFAN, UK) – did not attend, questions submitted upon registration

*Question 1: "*Does EFSA agree that ingredients for foods for infants and young children should be added ONLY when their efficacy is proven by independently-funded and systematically reviewed evidence. If no such evidence is available, such ingredients should not be permitted. To do otherwise is to use babies in a mass uncontrolled trial"

Answer by the Panel's Chair: It is outside the remit of the Panel to express its views on any regulatory aspects such as for example which substance should or should not be permitted in IF (Notes: Directive 2006/141/EC foresees that ingredients other than those permitted by the Directive may only be added to IF and FOF if their suitability for particular nutritional use by infants from birth has been established by generally accepted scientific data. It also states that such suitability shall be demonstrated through a systematic review of the available data relating to the expected benefits and to safety considerations).

All data submitted will be reviewed by the Panel taking into account the specific legislative framework. The Panel will judge on the quality of the systematic review, taking into consideration the criteria used, the compliance with the requirements, and any potential methodological bias, irrespective of the funding source. Each publication is evaluated separately.

*Question 2: "*In view of the findings of the technical report, is it inappropriate to permit health or nutrition claims for optional ingredients, given that no evidence of efficacy could be found, and since claims invariably undermine breastfeeding."

Answer by the Panel's Chair: It is outside the remit of the Panel to address whether or not health or nutrition claims should be allowed for IF or FOF. The decision for authorising the use of claims is under the remit of the risk managers, i.e. the European Commission (EC) together with Member States (MS). The role of the Panel is to evaluate the scientific substantiation of health claims.

*Question 3: "*Does EFSA agree that the marketing of all products for infants and young children – including formulas for older babies - should in any case be controlled in line with the International Code of Marketing of Breastmilk Substitutes and subsequent relevant WHO Resolutions?"

Answer by the Panel's Chair: The question regarding marketing aspects and authorisation for use on the EU market is outside the remit of the Panel.

Kinga Adamaszwili (AESGP-Association of the Self-Medication Industry, BE)

*Question: "*Following a successful meeting on the reporting of human studies submitted for scientific substantiation of health claims organised by EFSA in November 2013, is there an intention of organising further meetings related to health claims?"

Answered by the Head of the Nutrition Unit: Priority has been given to other activities**.** No further technical meeting related to health claims is foreseen for 2014/2015. However, this decision might be reconsidered in 2015.

Today, emphasis has been placed on the public consultation process, which is an extremely useful tool for interactions/communications with stakeholders. For instance, a discussion paper has been released for public consultation to engage at an early phase with experts/stakeholders in the process of updating existing guidance on the scientific requirements for health claims related to gut and immune function.

Stefanie Geiser (EAS-Strategic Advice, IT)

*Question 1: "*DRVs: which vitamins/minerals are next on the 2014 plan for DRV draft opinions/public consultations?"

Answered by the Head of the Nutrition Unit: The next Public consultations in fall 2014 will be held for the draft DRVs for **calcium and vitamin A; vitamin B12** and **vitamin E** which are targeted for consultation by the end of 2014.

Post-meeting notes: vitamin B12 and vitamin E (with target endorsement for public consultations by first quarter 2015).

*Question 2: "*What are the next planned EFSA activities related to stakeholder technical meetings on health claims?"

Answered by the Head of the Nutrition Unit: As addressed above, priority has been given to other activities**.** No further technical meeting related to health claims is foreseen for 2014/2015. However, this decision might be reconsidered later in 2015.

*Question 3: "*In terms of tools that would complement health claims dossier guidance: Status of the expected EFSA public consultation on the draft statistical reporting guidance? (which had been announced by EFSA to be scheduled in Spring 2014 at the Parma Nov 2013 claims meeting)"

Answered by the Head of the Nutrition Unit: The Public Consultation for the Draft Statistical Reporting guidance has been published on the EFSA web site. It started on 28 May 2014 and will close on 23 July 2014.

Annie Rose Harrison-Dunn (NutraIngredients, UK)

*Question 1: "*Why is EFSA looking at caffeine again - is it not in the hands of the member states now?"

Answered by the Head of the Nutrition Unit: As already outlined under Agenda item 9.8, the mandate on the safety assessment of caffeine was initiated in the context of health claims authorisation, particularly regarding the appropriateness of the proposed conditions of use, and regarding safety concerns raised by Member States. The health claims related to caffeine (with favourable opinions from the Panel[14]) have been put on hold by the Commission. The Commission asked EFSA to review the existing scientific data on the possible link between the intake of caffeine, from all sources, and adverse health effects.

*Question 2: "*Does EFSA have any plans to review the safety and novel status of meso-zeaxanthin? Does it need novel approval?"

Answered by the Head of the Nutrition Unit: Whether a food is considered as a Novel Food, and its authorisation process, are rather under the remit of the EC/MS. Any application in the framework of NF should undergo an initial assessment by an EU MS. If there is a disagreement among the MS, the EC may request EFSA to undertake an additional safety assessment of the NF. EFSA has not received any mandate from the Commission related to the safety assessment of meso-zeaxanthin in the framework of Novel Foods.

Sarah Trattnig (Red Bull GmbH, AT)

*Question: "*What is the expected timing for adoption of the draft opinion on the safety assessment of caffeine?"

Answered by the Head of the Nutrition Unit: As already outlined under Agenda item 9.8, the draft opinion is targeted for endorsement for release for public consultation by the Panel at its plenary meeting in September 2014. The public consultation will be open for at least 6 weeks. Possible adoption by the Panel is foreseen in December 2014 (depending on the number of comments to be addressed after the public consultation).

Sue O'Hagan (PepsiCo International, UK)

*Question: "*Given the benefits and risk associated with caffeine, would the NDA panel recommend that a risk benefit analysis be carried out on caffeine?"

Answered by the Head of the Nutrition Unit: The NDA panel addresses the Terms of Reference given, i.e. the safety assessment of caffeine. It is up to the Commission/MS to

[14] http://www.efsa.europa.eu/en/efsajournal/doc/2054.pdf; http://www.efsa.europa.eu/en/efsajournal/doc/2053.pdf.

propose such a risk benefit analysis. However, such a proposal should take into consideration methodological limitations and feasibility (i.e. availability of data).

Andreas Kadi (EDE-Energy Drinks Europe, BE)

*Question 1: "*Will the NDA Panel's opinion be in line with recent findings from FDA and Health Canada that the general population of healthy adults is not at risk for potential adverse effects from caffeine if they limit their consumption to 400 mg per day and if pregnant women limit their daily caffeine intake to 300 mg?"

*Question 2: "*Does the NDA Panel agree with findings of exposure assessments worldwide that the main sources of total caffeine intake are coffee, tea and soft drinks but not energy drinks?"

*Question 3: "*With regard to caffeine/energy drinks and alcohol, does the NDA Panel agree with the conclusions of the UK COT that the current balance of evidence does not support a harmful toxicological or behavioural interaction between caffeine and alcohol?"

Answered by the Head of the Nutrition Unit (Questions 1-2-3): As already outlined under Agenda item 9.8, it is premature to draw any conclusions. Observers are invited to wait until the Panel finalise the safety assessment of caffeine. The draft will be subject to public consultation before finalisation.

Additional question asked during the meeting: There was rather a comment in relation to the safety assessment of caffeine, requesting the Panel to be as precise as possible in answering the questions posed in the mandate, to allow the risk manager to take the final decision.

Answer by the Panel's Chair: The Panel took note of the comment.

Sebnem Kavakli (Ege University, TR)

*Question 1: "*What do you think of commercialization of nutritionally important metabolites?"

Answered by the Head of the Nutrition Unit: Marketing aspects and authorisation decisions for the use of foods (including botanicals) on the EU market is outside the remit of EFSA.
EFSA, as the European Union risk assessor in the area of food and feed safety, is responsible for providing scientific advice to EU risk managers (i.e. the European Commission, the Member States and the European Parliament).

Jozef Kočan (IDC Holding a.s., SK)

*Question 1: "*May contain labelling of possible presence of allergens have any limits for unintentional presence of allergen, but Czech Agriculture and Food Inspection authority accepts for such labelling the values only ten folds higher as is the minimum official analytical value for particular allergen, e.g. for peanuts the accepts values less as 25 mg/kg. Where is the truth?*"*

Answered by the Chair of the WG on Food Allergy: Accidental contamination of allergens, labelling aspects and the setting of threshold limits are not for EFSA. These issues are rather for the MS/EC.

*Question 2: "*Health claim for fructose - Consumption of foods containing fructose leads to a lower blood glucose rise compared to foods containing sucrose or glucose - is claim that in reality recommends the food for diabetics. In valid Slovak national directive of foods for special medical purposes is in the list of such foods also foods for diabetics, but there are

any other definitions or conditions. Is it possible to label the foods with fructose health claim also with claim - suitable also for diabetics within the recommended energy daily intake?"

Answered by the Panel's Chair: Questions related to authorised conditions of use (e.g. whether a claim could be used for diabetic patients, including labelling aspects), for health claims are outside the remit of EFSA, but rather the responsibility of EC/MS. In the framework of health claims, the Panel is in charge of the evaluation of the scientific substantiation of health claims made on foods. Such evaluations mean that we are only requested to perform efficacy assessment (i.e. relationship between food consumption and the claimed beneficial effect). Safety assessment is not foreseen. However, if there is any safety concern, the Panel in its opinions can state such concerns for the attention of the Commission.

*Question 3: "*Is it possible to label foods with claim - Dairy free, or lactose free? Which condition must be maintained in such declaration?"

Answered by the Panel's Chair: Labelling aspects of foods with claims are outside the remit of the Panel/EFSA.

Markus Lacorn (R-Biopharm AG, DE)

*Question 1: "*Are there any actions on threshold values for allergens in food at the EFSA?*"*

Answered by the Chair of the WG on Food Allergy: With respect to EFSA activities on threshold values, a draft scientific opinion on the evaluation of allergenic foods and food ingredients for labelling purposes is currently open for public consultation until 8 August 2014 (see http://www.efsa.europa.eu/en/consultations/call/140523.htm). This document updates previous EFSA opinions relative to food ingredients or substances with known allergenic potential listed in Annex IIIa of 2003/89/EC, as amended. It includes information on the prevalence of food allergy in unselected populations, on proteins identified as food allergens, on cross-reactivities, on the effects of food processing on allergenicity of foods and ingredients, on methods for the detection of allergens and allergenic foods, on doses observed to trigger adverse reactions in sensitive individuals, and on the approaches which have been used to derive individual and population thresholds for selected allergenic foods.

*Question 2: "*Are there any actions to establish "traceability" of analytical results from an allergen determination to a possible threshold value?*"*

Answered by the Chair of the WG on Food Allergy: Available analytical methods for the detection of allergens and allergenic foods, and the approaches which have been used to derive individual and population thresholds for selected allergenic foods, are addressed in EFSA's draft scientific opinion on the evaluation of allergenic foods and food ingredients for labelling purposes, which is currently open for public consultation until 8 August 2014 (http://www.efsa.europa.eu/en/consultations/call/140523.htm).

Daniela Strohm (DGE-German Nutrition Society, DE)

*Question 1: "*Which are the studies that were mainly considered in the draft for the derivation of the DRVs for folate?"

Answered by the Head of the Nutrition Unit: This question was addressed under Agenda item 9.4 for DRV on folate.

*Question 2: "*Which are the studies that were mainly considered in the draft for the derivation of the DRVs for selenium?"

Answered by the Head of the Nutrition Unit: This question was addressed under Agenda item 9.4 for DRV on folate.

Kate Trollope (EU Food Policy, UK)

*Question 1: "*What are the Panel's views on having open meetings and do they think it affects their discussion in any way?"

Answered by the Panel's Chair: The Panel members stressed the importance of science, how it is assessed, and how the Panel comes to a conclusion on the science. With respect to transparency, it was pointed out that many means are used to increase transparency, such as in the opinions and public consultation process. It should be possible for Panel members who were not involved in the WG discussions to ask naïve questions during Plenary meetings. Non-scientific reasons (e.g. individual personality aspects and language issues) could hamper open discussion on science in open sessions.
Open sessions, therefore, may not ensure open and thorough discussion on the science.

*Question 2: "*Would they be happy to have the meetings recorded and put on the website to save people travelling to Parma and to enable people to just listen to specific items of interest?"

Answered by the Panel's Chair: The Panel does not welcome recording of meetings as such recordings may hamper open discussions.

Question 3: **"**Will it ever be possible to have a draft health claims Opinion discussed in public"

Answered by the Head of the Nutrition Unit: In general, applications related to regulated products, particularly health claim applications, contain confidential information. This confidentiality prevents their disclosure in public. In the future, if a claim application does not contain any confidential information it would be possible to have it discussed at an open plenary. However, this process should not undermine the trust of applicants, e.g. discussing deficiency of a claim or a novel food application in public.
In other units under different frameworks and for some large applications, parts which are not confidential could be discussed at open sessions.

Additional question asked during the meeting: "With regards to transparency, how is this applied at the Commission?"

Answered by the Commission Representative: It was pointed out that the Agenda and minutes of the Commission Expert WG meetings are published for transparency. For instance with respect to baby milks, delegated acts will be prepared and stakeholders and MSs will be consulted. The Commission will also be launching a public consultation to gather data on young child formulae.

Additional question asked during the meeting: "What is the process for writing opinions?"

Answered by the Head of the Nutrition Unit: The bulk of the preparatory work and drafting of an opinion are undertaken a long time before the draft is available for discussion at the Panel. A Rapporteur is appointed. First it goes to the Working Group (WG) (e.g. quality of

studies submitted is reviewed). The opinion could be the subject of discussions at several WG meetings before the opinion is submitted to the Panel for discussion or possible adoption. Some opinions may be sent back to the WG for further consideration before adoption. In the context of health claim or novel food applications, opinions are structured in a standard way with well-defined questions to be addressed by the Panel, whereas for more generic *ad-hoc* mandates (e.g. Fish or Caffeine opinions) questions to be addressed are more complex and could be the subject of discussions during more than one Plenary meeting (e.g. the Fish opinion).

Additional question asked during the meeting from an Observer: It was questioned whether the use of fructose in formula would be allowed to mask the bitter taste considering the potential adverse effects"

Answered by the Panel's Chair: As already outlined under item 9.6, the Panel does not have any scientific reasons to exclude fructose from formulae.