Panel on Dietetic products, Nutrition and Allergies

25 November 2011

MINUTES OF THE 43RD PLENARY MEETING OF THE SCIENTIFIC PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES HELD FROM 23 TO 25 NOVEMBER 2011

PARTICIPANTS

Panel members:

- Carlo Agostoni
- Jean-Louis Bresson
- Susan Fairweather Tait
- Albert Flynn
- Ines Golly
- Hannu Korhonen
- Martinus Løvik
- Rosangela Marchelli
- Ambroise Martin
- Bevan Moseley
- Monika Neuhäuser-Berthold
- Hildegard Przyrembel
- Seppo Salminen[1]
- Yolanda Sanz
- Sean Strain
- Stephan Strobel[3]
- Inge Tetens[1]
- Daniel Tomé
- Hendrik van Loveren
- Hans Verhagen[2]

[1] Present on 23 and 24 November 2011 only
[2] Present on 24 and 25 November 2011 only
[3] Present on 23 November 2011 only

EFSA staff:

- Juliane Kleiner
- Reinhard Ackerl
- Kinga Wanda Adamaszwili
- Maria Astridou
- Anja Bronstrup
- Janusz Ciok
- Agnès De Sesmaisons-Lecarre
- Céline Dumas
- Wolfgang Gelbmann
- Leng Heng
- Ilkka Ojansivu
- Danai Papanastasiou
- Ariane Titz
- Emanuela Turla
- Silvia Valtueña Martínez

European Commission:

- Noel Griffin (European Commission)[2]

1. WELCOME, APOLOGIES FOR ABSENCE

The Chair welcomed all participants to the plenary meeting. Apologies were received from Pagona Lagiou.

2. ADOPTION OF THE AGENDA AND THE MINUTES OF LAST PLENARY

The agenda of the meeting and the minutes of the 42nd Plenary meeting were adopted. One new European Commission request for a scientific opinion on novel foods was added to Agenda item 6.

3. DECLARATIONS OF INTEREST

EFSA Secretariat screened the Annual Declaration of interest (ADoI) and Specific Declaration of interest (SDoI) filled in by the scientific experts invited to this meeting in accordance with EFSA's Policy on Declarations of Interests.

With regard to the items on the agenda for this meeting, no conflicts of interests have been identified during the screening process or at the beginning of this meeting.

Related to the current implementation of EFSA's policy on independence and scientific decision making processes regarding declarations of interest, Panel members expressed their views. Panel members feel more and more restricted in their scientific activities/networking with other organisations.

4. FEEDBACK FROM EFSA SCIENTIFIC COMMITTEE AND OTHER EFSA PANELS, GENERAL INFORMATION FROM EFSA

The Panel was informed that EFSA will move to its new seat by 5th January 2012 and that from January 2012 onwards all meetings will be held at the new seat.

In relation to the EFSA Scientific Committee, the guidance on repeated-dose 90-day oral toxicity study on whole food and feed in rodents was adopted following a public consultation (7 July-22 August 2011). The guidance complements the OECD Test guideline 408 and provides specific advice for performing and reporting experiments carried out with whole food/feed (http://www.efsa.europa.eu/en/efsajournal/pub/2438.htm).

The Scientific Committee was approached by the chair of the Panel on Food Additives and Nutrient Sources added to food (ANS) for guidance in relation to the risk assessment of regulated compounds voluntarily added to the diet (such as food additives) with allergenic properties or containing impurities or by-products with allergenic properties. This new possible activity by the Scientific Committee is quite distinct from the request the NDA Panel has received recently from the Food Safety Authority of Ireland for an opinion on allergen risk assessment. The NDA activity will review whether there are any new data to establish thresholds for known allergens (listed in Annex III of Directive 2007/68/EC) and will base the assessment on the existing methodologies available. It will not address the wide question on how to conduct a risk assessment based on allergenicity as the critical endpoint. In order to avoid duplication of work, a member of the Scientific Committee will be invited to join the NDA working group.

EFSA developed a draft Science Strategy 2012-2016 laying down the foundations for its long-term scientific work through a set of key strategic initiatives. It was endorsed by the Scientific Committee for public consultation until 21 November 2011 (http://www.efsa.europa.eu/en/consultationsclosed/call/111104.htm). A resulting revised draft of the

Science Strategy will be submitted to the EFSA Management Board for possible adoption before the end of 2011.

5. FEEDBACK FROM THE EUROPEAN COMMISSION ON MATTERS RELATING TO THE PANEL

The Commission Services provided feedback on the status of the Commission Decisions related to adopted health claims application opinions related to Art 14/13(5). All adopted Commission decisions are available on the Commission website: http://ec.europa.eu/food/food/labellingnutrition/claims/community_register/index_en.htm.

The Commission also provided feedback on the status of its decision-making related to the Art 13(1) health claims opinions that were adopted by the Panel. A draft Commission regulation on the authorisation of certain Article 13.1 health claims will be presented for an opinion at the meeting of the Standing Committee on the Food Chain and Animal health (General Food Law), which will be held on 5 December 2011.

For those Art 13(1) claims eligible for further assessment (microorganisms not sufficiently characterised, and claims for which EFSA concluded that there is insufficient evidence), dossiers have been received by the Commission via Member States' co-ordination; It is planned to submit the data to EFSA before the end of 2011. A deadline for finalisation of these health claims still needs to be agreed on.

6. NEW REQUESTS

EFSA received from the European Commission a new request for an additional safety assessment related to: "**Dihydrocapsiate"** as a novel food ingredient submitted in accordance with the Novel Foods Regulation 258/97/EC.

7. GENERAL ISSUES ON HEALTH CLAIMS EVALUATIONS

7.1 Update on Article 13(5) and 14 applications

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

Article 14 claims: Since the last meeting, one new application was received referring to a disease risk reduction claim (food plant sterols and Choleternorm®mix and lowers cholesterol).

Article 13(5) claims (claims based on newly developed science and/or which include a request for the protection of proprietary data): Since the last meeting, two new applications were received (glucosamine and maintenance of normal joints**;** wheat polar lipid extracts and skin hydration).

Article 19 claims (modification of authorisations): An application was received for modifying the conditions of use of an authorised claim related to plant sterols and plant stanol esters and reduction of blood cholesterol.

Rapporteurs have been appointed for the new applications received.

7.2 Update on Article 13 list claims – Further assessment

Please see item 5.

7.3 Draft guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health (EFSA-Q-2010-01182)

Following the online-public consultation of the above-mentioned draft guidance document, a revised draft guidance document taking into consideration relevant comments received was thoroughly discussed and adopted on 24 November by the Panel subject to the incorporation of editorial changes. The NDA Panel members expressed its gratitude for the many useful comments received, which helped to improve the document. Due to the specific technical nature of many of the comments received, the Panel felt that these comments could be best addressed in written form via the technical report (see 7.4).

The final text of the guidance document is published together with a Summary Report of the comments received during the online-consultation phase via the following link: http://www.efsa.europa.eu/en/efsajournal/pub/2474.htm

7.4 Technical report: Outcome of a public consultation on the Draft guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health (EFSA-Q-2011-00306)

A technical report on the Outcome of a public consultation of a draft guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health, which summarises the comments received during the public consultation of this guidance (opened from 26 April 2011 to 31 August 2011) was presented, discussed and subsequently endorsed by the Panel on 24 November. The technical report is published together with the guidance document on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health (see also item 7.3) via the following link: http://www.efsa.europa.eu/en/supporting/pub/208e.htm.

7.5 Draft guidance on the scientific requirements for health claims related to physical performance (EFSA-Q-2010-01186)

On 24 November, a draft guidance document on the scientific requirements for health claims related to physical performance was discussed and endorsed by the Panel for release for public consultation subject to the incorporation of editorial changes. The on-line public consultation is opened until 9 March 2012: http://www.efsa.europa.eu/en/consultations/call/111219.htm.

8. APPLICATIONS PURSUANT TO ARTICLES 14/13(5) OF REGULATION (EC) NO 1924/2006

8.1 "**Coffee C21"** and **"maintenance of DNA integrity in cells of the body**" (Art. 13.5: 0303_DE, EFSA-Q-2011-00783)

On 23 November, 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/2465.htm.

8.2 **Spermidine**" and "**prolongation of the growing phase (anagen) of hair cycle**" (Art 13.5: 0309_IT, EFSA-Q-2011-00896)

On 23 November, 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/2466.htm.

8.3 **"sugar beet fibre"** and **"decreasing intestinal transit time"** (Art 13.5: 0311_DK, EFSA-Q-2011-00971)

On 23 November, 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/2467.htm.

8.4 **"sugar beet fibre"** and **"increasing faecal bulk"** (Art 13.5: 0312_DK, EFSA-Q-2011-00972)

On 23 November, 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/2468.htm.

8.5 "**Diacylglycerol (DAG)"** and **"reduction of bodyweight**" (Art. 13.5: 0301_UK, EFSA-Q-2011-00751)

On 25 November, 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/2469.htm.

8.6 "**Barley beta-glucan**" and "**lowering of blood cholesterol and reduced risk of (coronary) heart disease**" (Art. 14: 0305_BE, EFSA-Q-2011-00798)

On 23 November, 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/2470.htm.

8.7 "**Barley beta-glucan**" and "**lowering of blood cholesterol and reduced risk of (coronary) heart disease**" (Art. 14: 0306_SI; EFSA-Q-2011-00799)

On 23 November, 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/2471.htm.

8.8 **"Bimuno® GOS" and "reducing of gastro-intestinal discomfort**" (Art. 13(5): 0299_UK, EFSA-Q-2011-00401)

On 24 November, 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/2472.htm.

8.9 **"Bimuno® GOS" and "reduction of pathogenic bacteria in the gastrointestinal tract, which is a risk factor for travellers' diarrhoea"** (Art. 14: 0300_UK, EFSA-Q-2011-00402)

On 24 November, the draft opinion was presented and discussed. The Panel identified a number of issues for which additional information is needed from the applicant before the Opinion can be concluded. The stop the clock procedure will be applied.

8.10 **"Glucosamine sulphate"** and **"maintenance of joints"** (Art. 13(5): 0309_HU, EFSA-Q-2011-00907)

On 25 November, 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/2476.htm.

9. NOVEL FOODS

9.1 Statement on the safety of glucosamine for patients receiving coumarin anticoagulants (EFSA-Q-2011-00770)

On 25 November, the draft statement 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/2473.htm.

10. ANY OTHER BUSINESS

The minutes of the 43rd Plenary meeting were agreed on 18 January 2012.