

Panel on Dietetic products, Nutrition and Allergies

10 September 2010

MINUTES OF THE 35TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES HELD FROM 8 TO 10 SEPTEMBER 2010

PARTICIPANTS

Panel members:

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

EFSA staff:

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

European Commission:

- Ariane Vander Stappen¹
- Sabine Osaer¹
- Christina Antoniou¹

¹ DG Health and Consumers

1. WELCOME, APOLOGIES FOR ABSENCE

The Chair welcomed all participants to the plenary meeting.

Apologies for absence were received from Pagona Lagiou.

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

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

The minutes of the 34th Plenary meeting were adopted.

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.

For agenda items 9.1 related to Danone application, Jean-Louis Bresson, Yolanda Sanz, Sean Strain, Susan Fairweather-Tait, Albert Flynn and Ambroise Martin declared an interest, however the agenda item was postponed to the next meeting.

For Agenda item 9.2 related to Yakult application, Ambroise Martin declared an interest and refrained from discussion for this agenda item.

With regard to the other 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.

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

The last meeting of the SC was held on 29 June 2010 and the minutes of that meeting are available on the EFSA website

(<http://www.efsa.europa.eu/en/events/event/scaf100629.htm>)

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

The Commission informed the Panel that EFSA may be requested to prioritise the evaluation of Article 13 claims work other than "botanicals".

6. NEW REQUESTS

Two new requests were received from the European Commission asking EFSA in accordance with the Novel Foods Regulation (EC) No 258/97 to carry out additional safety assessments related to "a novel chewing gum base" and related to "yeast beta-glucans".

In addition, two new requests were received requesting EFSA for scientific advice on labelling exemption regarding ovalbumin and casein used in the manufacture of wine as clarification processing aids. With respect to ovalbumin the Panel noted that only preliminary results have been provided by the applicant and that the NDA Panel cannot complete a scientific evaluation on the allergic potential of ovalbumin/egg white and products thereof used in the manufacture of wine in susceptible individuals on the basis of preliminary data.

7. STATUS OF HEALTH CLAIM EVALUATION

Draft guidance on the scientific requirements for health claims related to gut and immune function - A draft guidance document was discussed and endorsed by the Panel for release for public consultation.

The draft guidance is available at:

<http://www.efsa.europa.eu/en/consultationsclosed/call/nda100928.htm>.

The draft guidance together with the comments received during the public consultation (deadline for comments is 22 October 2010) will serve as the basis for the scientific meeting with experts in the field to be held on 2 December 2010 in Amsterdam. Registration to the meeting will open in September 2010.

Article 13 - Members were informed that the publication of the third series of Article 13 claims opinions is foreseen for October 2010. The third series will cover claims adopted at the February, April, July and September Plenary meetings.

Articles 14 and 13(5) applications – The secretariat informed the Panel about the status of claims applications since the last Plenary meeting.

Article 14 claims: Since the last meeting no new Article 14 claims have been received and no application has been withdrawn. By 8 September 2010, EFSA has received 267 Article 14 applications (218 referring to children's health and development and 49 referring to reduction of disease risk claims); 134 applications are under evaluation and 44 were withdrawn.

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 EFSA has received 5 new applications (assai fruit and antioxidant activity; *saccharomyces cerevisiae* and reduction of digestive comfort; *lactobacillus GG* and improvement of body resistance, active ingredient mix of soy isoflavones, fish oil, lycopene, Vitamin C and E and reduction of wrinkles and lines; zinc and prevention of bad breath). No application has been withdrawn. By 8 September 2010, EFSA has received 42 applications under Article 13(5): 5 are under evaluation, 23 were adopted and 9 were withdrawn.

Rapporteurs have been appointed for the new applications received.

8. NOVEL FOODS

8.1 “Phosphated Distarch Phosphate”

The draft opinion was discussed and adopted subject to the incorporation of modifications agreed upon by the Panel. The text of the full opinion appears on the EFSA web site, available at: <http://www.efsa.europa.eu/en/scdocs/scdoc/1772.htm>

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

9.1. “Fermented milk that contains the *Lactobacillus casei* DN 114001 / CNCM I-1518 Actimel® and reduces the presence of *Clostridium difficile* toxins in the gut, associated with the incidence of acute diarrhoea” (Art.14: 0260_FR)

The discussion and adoption of the opinion were postponed to the next Plenary meeting, as the response by the applicant related to the additional information requested by EFSA was only received end of August 2010.

9.2. “*L. casei* Shirota in a fermented milk product and maintain the normal conditions of upper respiratory tract” (Art.13(5): 0273_NL)

The draft opinion was discussed. A revised version will be submitted to the Panel for adoption by written procedure.

Post-meeting notes: The opinion was adopted by written procedure on 8 October 2010. The text of the full opinions appears on the EFSA web site, available at: <http://www.efsa.europa.eu/en/scdocs/scdoc/1860.htm>

9.3. “Sugar-free chewing gum and maintains tooth mineral which reduces the risk of dental caries” (Art.14_risk: 0276_UK)

The draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The text of the full opinion appears on the EFSA web site, available at: <http://www.efsa.europa.eu/en/scdocs/scdoc/1775.htm>

9.4. “Sugar-free chewing gum and neutralises plaque acids which reduces the risk of dental caries” (Art.14_risk: 0277_UK)

The draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The text of the full opinion appears on the EFSA web site, available at: <http://www.efsa.europa.eu/en/scdocs/scdoc/1776.htm>

9.5. “Synbio, a combination of *L. rhamnosus* IMC 501[®] and *L. paracasei* IMC 502[®] and maintenance and improvement of intestinal function” (Art.13(5): 0263_IT)

The draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The text of the full opinion appears on the EFSA web site, available at: <http://www.efsa.europa.eu/en/scdocs/scdoc/1773.htm>

9.6. “Silymarin BIO-C[®] and increases in the production of breast milk” (Art.13(5): 0265_IT)

The draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The text of the full opinion appears on the EFSA web site, available at: <http://www.efsa.europa.eu/en/scdocs/scdoc/1774.htm>

10. DRAFT ARTICLE 13(1) OPINIONS

The Panel discussed and adopted Article 13 (1) claims related to the following IDs: 41, 139, 140, 202, 203, 213, 243, 244, 245, 246, 273, 293, 301, 303, 304, 312, 338, 342, 344, 351, 352, 366, 367, 375, 376, 378, 379, 380, 381, 382, 402, 404, 405, 412, 414, 416, 418, 419, 420, 421, 422, 423, 425, 426, 427, 428, 429, 431, 433, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 520, 556, 597, 598, 605, 616, 645, 652, 665, 666, 684, 687, 714, 730, 791, 798, 800, 806, 807, 828, 829, 834, 905, 916, 930, 1107, 1112, 1115, 1123, 1124, 1237, 1244, 1327, 1372, 1384, 1391, 1451, 1467, 1478, 1506, 1507, 1508, 1511, 1512, 1519, 1529, 1544, 1545, 1557, 1558, 1624, 1635, 1644, 1645, 1683, 1720, 1743, 1745, 1776, 1838, 1851, 1854, 1891, 1895, 1912, 1916, 2334, 2622, 2716, 2890, 2914, 2959, 3083, 3143, 3191, 3196, 3331, 3526, 3527, 3658, 3698, 3799, 3901, 4224, 4238, 4293, 4297, 4307, 4321, 4668, 4685, 4686, 4690 and 4699. More details on which claims were adopted at the meeting can be found in the EFSA register of Questions:

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=NDA&foodsectorarea=26>

The adopted claims will be combined as appropriate to form coherent opinions and will be published by October 2010 together with other claims to be adopted at the previous Plenary meetings in February-July 2010.

11. DIETARY REFERENCE VALUES

Protein - The discussion and adoption of the opinion were postponed to the next Plenary meeting.

12. FOOD ALLERGY

Azo-colours - for inclusion in the list of food ingredients set up in Annex IIIa of Directive 2000/13/EC

The draft opinion was discussed and adopted subject to the incorporation of modifications agreed upon by the Panel. The text of the full opinion appears on the EFSA web site, available at: <http://www.efsa.europa.eu/en/scdocs/scdoc/1778.htm>

13. LACTOSE THRESHOLDS IN LACTOSE INTOLERANCE AND GALACTOSAEMIA

The draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The text of the full opinion appears on the EFSA web site, available at: <http://www.efsa.europa.eu/en/scdocs/scdoc/1777.htm>

14. ANY OTHER BUSINESS

The minutes of the 35th Plenary meeting were adopted on 12 November 2010.