

**MINUTES OF THE 31ST PLENARY MEETING OF THE
SCIENTIFIC PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES
HELD FROM 2 TO 4 DECEMBER 2009**

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
- Yolanda Sanz
- Sean Strain
- Stephan Strobel
- Daniel Tomé
- Hendrik van Loveren
- Hans Verhagen

EFSA staff:

- Juliane Kleiner
- Reinhard Ackerl
- Maria Astridou
- Ulla Bertelsen
- Wolfgang Gelbmann
- Leng Heng
- Danai Papanastasiou
- Ariane Titz
- Emanuela Turla
- Silvia Valtueña Martínez

European Commission:

- Lars Korsholm¹
- Sabine Osaer¹
- Ariane Van Der Stappen¹

¹ DG Health and Consumers

1. WELCOME, APOLOGIES FOR ABSENCE

The Chair welcomed all participants to the plenary meeting. Apology for absence was 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 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. With regard to the specific items on the agenda for this meeting interests were declared and actions were taken as follows:

In relation to the Agenda item on Immunofortis, Seppo Salminen indicated that the references provided in the claim application included a publication of 2005 issued by his research group but with no funding from the applicant. The EFSA secretariat did not consider these interests as conflict of interests and the expert was allowed to participate in the discussion for this Agenda item.

Also in relation to the Agenda item on Immunofortis – Jean-Louis Bresson, Susan Fairweather-Tait, Ambroise Martin, Sean Strain and Yolanda Sanz declared an interest and refrained from discussion for this item. Albert Flynn declared an interest and withdrew from the chair and refrained from discussion for this Agenda item.

No other conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

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

The secretariat informed the Panel about relevant issues discussed at the Scientific Committee. The decision concerning the establishment and operations of the Scientific Committee and Panels is currently being updated and draft will be put forward to the EFSA Management Board for possible adoption at their December meeting. The Scientific Committee will be discussing at its next meeting the Draft technical report on default assumptions used in risk assessment by the EFSA Scientific Committee and Panels.

An EFSA stakeholder consultation meeting took place on 1st December 2009. Juliane Kleiner gave a presentation about the EFSA scientific evaluation of health claims addressing key issues, outlining the experience gained and providing answers to concerns raised by stakeholders.

An EFSA Scientific Cooperation (ESCO) working group prepared a **report on analysis of risks and benefits of fortification of food with folic acid** and the report is published on the EFSA website under the following link: http://www.efsa.europa.eu/EFSA/National_Focal_Points/Scientific_Cooperation_projects/efsa_locale-1178620753812_folic_acid.htm. The NDA Panel was asked to review the report and to consider its conclusion and recommendation in light of their work programme. The Panel's comments were discussed and a reply letter outlining the Panel's views will be sent to the EFSA's Executive Director.

The Panel was provided with further information about the workshop on the “Application of **Systematic Review Methodology** to Food and Feed Safety Assessments to support Decision Making” which will take place in EFSA on 23, 24 and 25 February 2010.

5. FEEDBACK FROM EFSA’S 13TH SCIENTIFIC COLLOQUIUM ON NOVEL FOODS – AMSTERDAM, 19 NOVEMBER 2009

Bevan Moseley and Henk van Loveren reported back from the Colloquium on Novel Foods, which was an opportunity to bring together international experts and interested parties from different sectors for an open scientific debate and exchange of views on key issues related to the foreseen revision of the Novel Foods Regulation. It was felt as a very useful meeting and the outcome of the meeting will be taken into account when EFSA will revise the SCF recommendations on the scientific aspects of information and presentation necessary to support applications for placing on the European market novel foods and novel food ingredients. A summary report of the meeting will be prepared and published in the EFSA Scientific Colloquium Report Series.

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

The Commission briefed the Panel on the progress of the Commission Decision and possible timeline following the adoption and publication of the 1st batch of Article 13(1) health claims opinions.

In relation to Article 13(1) health claims, EFSA received back on 9 November 2009 clarification from the Commission/Member States on the over 2400 claims sent back in January and June 2009. The fate of product specific claims is still under discussion with Member States.

The Panel was informed about the status of the draft Commission Decision of Article 14 and 13(5) health claims opinions post-adoption by EFSA.

7. NEW REQUESTS RECEIVED FROM THE COMMISSION

A new request was received from the European Commission asking EFSA for an opinion in relation to the authorisation procedure for health claims pursuant to Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. EFSA is asked to further advise on whether conditions of use can be established both for health claims under Article 14 referring to the relationship between calcium and vitamin D and the reduction of bone loss and for health claims under Article 13(1) referring to the relationship between calcium and vitamin D and bone health. The Panel is aiming to address this request in the proposed timeframe and identified a rapporteur.

8. ARTICLE 13 HEALTH CLAIMS’ LIST – GENERAL UPDATE

In order to comply with requirements for transparency and to keep the workload manageable, EFSA will publish claims opinions in series as they are adopted at Plenary meetings of the NDA Panel. Assessments of individual claims will be combined, as appropriate, to form coherent opinions. The next publication is planned to take place in February 2010.

9. STATUS OF APPLICATIONS UNDER ARTICLE 14/13(5) HEALTH CLAIMS

Article 14 claims: By 30 November 2009, EFSA has received 260 Article 14 applications (215 referring to children’s health and development and 45 referring to reduction of disease risk claims); 10 applications are under evaluation and 29 were withdrawn.

Article 18/13(5) claims: By 30 November 2009, EFSA has received 24 applications under Article 13(5) (claims based on newly developed science and/or which include a request for the protection of proprietary data): 3 are under evaluation, 14 were adopted, 6 were withdrawn, and 1 was under validation.

10. NOVEL FOODS

The draft opinions related to the safety assessment of “*Conjugated linoleic acid (CLA)*” were discussed. The Panel identified a number of issues for which additional information is needed from the applicants before the Opinions can be concluded.

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

11.1. Combination of “*B. bifidum*, *B. breve*, *B. infantis*, *B. longum*” and decreasing potentially pathogenic intestinal microorganisms

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/doc/1420,0.pdf> .

11.2. “Immunofortis” and “to naturally strengthen your baby’s immune system”

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/doc/1430,0.pdf> .

11.3. “Uroval” and “eliminates the adhesion of harmful bacteria to the bladder wall”

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/doc/1421,0.pdf> .

11.4. “Catalgine®” and “contributes to the reduction in the number of hot flushes”

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/doc/1422.pdf> .

12. DRAFT ARTICLE 13(1) OPINIONS

The Panel discussed and adopted a number of evaluations of Article 13(1) claims related to vitamins, minerals, macronutrients, microorganisms, foods, other substances and botanicals. More details on which evaluations 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 evaluations of claims will be combined as appropriate to form coherent opinions and will be published in early 2010 together with other evaluations of claims to be adopted at the Plenary meeting in December 2009.

13. DIETARY REFERENCE VALUES

Further to the public consultations and the useful meeting with national experts in Barcelona in September 2009 to discuss five opinions related to principles for deriving and applying Dietary Reference Values (DRVs), to DRVs for fats, carbohydrates and water and to guidance

for establishing food based dietary guidelines water the opinions have been revised taking into account the comments received and discussed at the Plenary meeting. In addition technical reports have been prepared by EFSA including the comments received during the public consultations and how they were addressed in the opinions were tabled for information. The five opinions were adopted subject to the incorporation of modifications agreed upon by the Panel.

14. COMPLEMENTARY FEEDING OF INFANTS

The draft opinion related to **the appropriate age for introduction of complementary feeding of infants** 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/doc/1423,0.pdf>.

15. INFO SESSION – DOI APPLICATION

Ernesto Guisado Ferrer provided an update on the procedures and criteria for filling in experts' declaration of interests.

16. ANY OTHER BUSINESS

The minutes of the 31st Plenary meeting were adopted on 9 February 2010.