Panel on Dietetic products, Nutrition and Allergies

25 April 2008

MINUTES OF THE 20TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES HELD ON 22-24 APRIL 2008

PARTICIPANTS

Panel members:

- Albert Flynn
- Marina Heinonen
- Karin Hulshof
- Hannu Korhonen
- Pagona Lagiou
- Martinus Løvik
- Rosangela Marchelli
- Ambroise Martin
- Bevan Moseley
- Andreu Palou
- Hildegard Przyrembel
- J.J. (Sean) Strain
- Stephan Strobel
- Hendrik van Loveren
- Hans Verhagen

EFSA staff:

- Juliane Kleiner
- Wolfgang Gelbmann
- Leng Heng
- Maria Skarp
- Silvia Valtueña Martínez

European Commission:

- Sabine Osaer[1]
- Lars Korsholm[2]

[1] DG Health and Consumer Protection

[2] DG Health and Consumer Protection, only present via telephone conference in relation to Agenda item 6

1. WELCOME, APOLOGIES FOR ABSENCE

The Chair welcomed all participants to the plenary meeting. Apologies for absence were received from Jean-Louis Bresson, Henk van den Berg, Hans Verhagen and Seppo Salminen.

The Chair also welcomed Juliane Kleiner, the new acting Head of the Unit on Dietetic Products, Nutrition and Allergies (NDA).

2. ADOPTION OF THE AGENDA

The agenda was adopted without modification

3. DECLARATIONS OF INTEREST

Panel members were invited to declare possible interests by filling and signing a form linked to specific items included on the Agenda (7, 8 and 9) at the beginning of the meeting. There were no specific interests declared. Also no other declarations of interest were made in relation to the remaining items of the agenda.

4. FEEDBACK FROM EFSA SCIENTIFIC COMMITTEE AND OTHER EFSA PANELS

The Chair informed the Panel that a draft guidance document by the Scientific Committee on Transparency in risk assessment – scientific aspects will be circulated to all EFSA Panels for comments by end of July 2008. An updated version of the document will be then presented to the Scientific Committee for final endorsement..The NDA Panel members were invited to provide comments, which will be discussed at the next plenary meeting.

5. GENERAL INFORMATION BY EFSA ON MATTERS RELATING TO THE PANEL

A presentation was given on the new IT tool for annual and specific Declarations of Interest (DoI), which will be implemented in spring 2008. This electronic tool will ease the management of DoI, whereby the specific DoIs will not be published on the web.

Dr. Riitta Maijala, Director of EFSA's Risk Assessment Department, informed the Panel about the implementation (implementation date 21 April 2008) of an EFSA review system to ensure the quality of EFSA's scientific activities The review system is based on a Scientific Committee advice published in August 2007[4]. During the development of an EFSA document, e.g. opinion, respective EFSA staffs are asked to fill-in a self-review form to check compliance with best scientific assessment practices. In addition, random samples of adopted opinions will be reviewed by senior scientific staff.

6. NDA WORK PROGRAMME RELATED TO HEALTH CLAIMS

The planning for the overall NDA work programme for 2008-2009 was discussed. Priority will be given to the evaluation of Article 13 and Article 14 claims of the Regulation on Nutrition and Health Claims made on foods (EC 1924/2006).

[4] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178628825410.htm

Article 14 claims
Up to now EFSA received over 150 Article 14 applications (90% referring to children health and development and 10% referring to reduction of disease risk claims). For many of the applications additional information is awaited from applicants but 9 applications are considered complete and evaluation of these is underway.

Article 18 claims
EFSA also received two applications under Article 18 (claims based on newly developed science and/or which include a request for the protection of proprietary data), which are currently under evaluation.

Article 13 claims
Related to Article 13 health claims it is expected that the European Commission will send the consolidated list on Art. 13 claims (around 1000 – 1500 claims) by end May or June 2008. Proposals from the Working Group on Claims for the organisation of the work were discussed. All draft opinions will be agreed by the Working Group on Claims before submission to NDA Panel for consideration and possible adoption.

The Panel discussed a draft mandate by the European Commission related to Article. 13 claims.

It was agreed to elaborate some general principles for the scientific substantiation of Art.13 health claims including the identification of appropriate endpoints for the claimed effects. This will facilitate the evaluation task and ensure consistency and transparency in the process. Main areas to be covered were identified and rapporteurs were appointed to draft the various sections.

The panel also discussed and agreed on the main issues to be addressed and the general format of Article 13 and 14 opinions.

EFSA is currently increasing its pool of experts for evaluation of claims. Member States were asked via the EFSA Advisory Forum and the national Focal Points to suggest additional experts to assist EFSA in the scientific substantiation of health claims. The CVs and the declaration of interests (DOI) of the proposed experts are currently being reviewed taking into account the expertise needed and any possible conflict of interest. EFSA will engage additional experts from this pool in specific tasks as necessary and with due regard to their independence.

Due to the current heavy workload with the evaluation of health claims other activities of the NDA panel, although being continued, may be delayed.

7. NEW REQUESTS FOR SCIENTIFIC OPINIONS

7.1 Lactose intolerance (and galactosaemia)

A new request for an opinion was received from the European Commission for scientific advice for the determination of threshold(s) for lactose in a food or a food ingredient which may be tolerated by lactose intolerant people. In addition EFSA is asked to also comment on a potential tolerable threshold of lactose for galactosaemic individuals. More information about

this request can be found on the EFSA Register of Questions (http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf).
The request was allocated to the Working Group on Infant Nutrition and a rapporteur was identified.

7.2 Glucosamine Hydrochloride from *Aspergillus niger*

A new request for an opinion was received from the European Commission on a novel food application related to the safety of Glucosamine hydrochloride from *Aspergillus niger***,** submitted in accordance with the Novel Foods Regulation 258/97/EC. More information about this request can be found on the EFSA Register of Questions (http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf).

The request was allocated to the Working Group on Novel Foods.

7.3 Appropriate age for the introduction of complementary food for infants

A new request for an opinion was received from the European Commission for scientific advice on the appropriate age for the introduction of complementary foods for infants in the EU. More information about this request can be found on the EFSA Register of Questions http://registerofquestions.efsa.europa.eu/roqFrontend

The request was allocated to the Working Group on Infant Nutrition and a rapporteur was identified.

It was noted that the deadline for completion of these opinions will need to take account of the workload for the evaluation of health claims.

8. DIETARY REFERENCE VALUES

8.1 Draft opinion on Food Based Dietary Guidelines

The draft opinion prepared by the Working Group on Dietary Reference Values was introduced and discussed.

A number of revisions were proposed and agreed. The revised version will be circulated to the NDA Panel for endorsement by written procedure prior to its release for public consultation.

8.2 Draft opinion on the Principles for deriving and applying Dietary Reference Values

The draft opinion prepared by the Working Group on Dietary Reference Values was introduced and discussed.

The opinion was endorsed for public consultation subject to the incorporation of modifications agreed upon by the Panel.

The Panel noted that the data for reference weights of population groups in Europe are quite old and that it would be useful to compile new reference values.

8.3 Draft opinion on dietary reference values for Water

The draft opinion prepared by the Working Group on Dietary Reference Values was introduced and discussed.

The opinion was endorsed for public consultation subject to the incorporation of some modifications agreed upon by the Panel.

It was agreed that above-mentioned three opinions will be released for public consultation before the summer break and that the remaining opinions on macronutrients, i.e. fats, carbohydrates, protein, energy will be released for public consultation by the end of 2008. The finalisation and adoption of all opinions will be processed together by late 2009.

9. NOVEL FOODS

9.1 Draft opinion on Zeaxanthin

The draft opinion prepared by the Working Group on Novel Foods was introduced and discussed.

The opinion was adopted subject to the incorporation of modifications agreed upon by the Panel.

9.2 Draft opinion on Lycopene oleoresin from tomatoes

The draft opinion prepared by the Working Group on Novel Foods had been circulated for adoption by written procedure. Comments received related to allergy were presented.

The opinion was formally adopted by the Panel. The text of the full opinion appears on the EFSA web site, available at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178704673160.htm

9.3 Draft opinion on Fungal oil

Discussion of the draft opinion was deferred pending further consideration by the Working Group on Novel Foods. A revised version will be forwarded to the Panel for possible adoption at the next Plenary meeting.

10. ANY OTHER BUSINESS

The following meeting dates for 2009 were agreed:

24th NDA Plenary: 20-22 January 2009
25th NDA Plenary: 11-13 March 2009
26th NDA Plenary: 13-15 May 2009
27th NDA Plenary: 7-9 July 2009
28th NDA Plenary: 13-15 October 2009
29th NDA Plenary: 02-04 December 2009

11. ADOPTION OF THESE MINUTES

These minutes were adopted by written procedure on 23rd May 2008.