Parma, 17 March 2009

HK/PK/ML/AR/ST

EFSA/ANS/P_M4/MIN/3892788

MINUTES OF THE 4th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Parma on 27-29 January 2009

Adopted on 17 March 2009 at the 5th Plenary meeting

AGENDA:

MINUTES OF THE 4th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Parma on 27-29 January 2009

Panel Members:

Fernando Aguilar, Ruth Charrondiere, Birgit Dusemund, Pierre Galtier (1st and 2nd day), John Gilbert, Sandro Grilli, David Gott, Rainer Gürtler, Georges Kass (1st and 2nd day), Jürgen König, Claude Lambré, John Christian Larsen (Chair), Jean-Charles Leblanc, Alicja Mortensen, Dominique Parent-Massin (1st and 2nd day), Iona Pratt (Vice-Chair), Ivonne Rietjens (Vice-Chair), Ivan Stankovic, Paul Tobback, Tatjana Verguieva, Ruud Woutersen.

Apologies

No apologies were noted.

EFSA

Joanne Gartlon, Hugues Kenigswald, Anastasia Kesisoglou, Majlinda Lahaniatis, Federica Lodi, Kim Petersen, Ana-Maria Rincon, and Stavroula Tasiopoulou (scientific staff) – Maria Correia, Maud Pâques (administrative staff).

European Commission

Marina Marini, Olga Solomon.

1. WELCOME; APOLOGIES FOR ABSENCE

The chair welcomed the participants.

2. ADOPTION OF THE AGENDA

The agenda was adopted without changes.

3. DECLARATIONS OF INTEREST

EFSA secretariat screened the specific declarations of interests filled in by the scientific experts invited at this meeting in accordance with EFSA's Policy on Declarations of Interests. For further details on the outcome of the screening please refer to Annex I of the present minutes.

4. MATTERS ARISING FROM THE 3rd PLENARY MEETING HELD ON 25-27 NOVEMBER 2008

The draft minutes were adopted. They can be seen on:

http://www.efsa.europa.eu/cs/BlobServer/Event_Meeting/minutes_ANS_3rdplenary_25-271108rev.pdf?ssbinary=true

5. GENERAL INFORMATION FROM EFSA, THE COMMISSION AND THE CHAIR

5.1. EFSA

The participants were informed on the call launched by the European Food Safety Authority (EFSA) for the renewal of the members of its Scientific Committee and some of the Scientific Panels.

Given the fact that in 2009 the ANS Panel will be further dealing with the re-evaluation of food colours, the proposed work program was presented and discussed. A short presentation was made by H. Kenigswald on the proposed specific workflow for the re-evaluation of food colours.

5.2. Commission

M. Marini and O. Solomon informed the participants on the work in progress related to different issues:

- The revision of the "positive lists" of the nutritional substances that can be added to food supplements, PARNUTS and fortified foods will be ready soon. These lists are updated through comitology procedure based on advice of the EFSA.
- The Commission will be drafting a document on the program of re-evaluation of the permitted food additives which has to be adopted by the end of 2009.
- The Commission Directive 2008/128/EC of 22 December 2008 laying down specific purity criteria concerning colours for use in foodstuffs has entered into force.
- The implementing measures of the new regulation on food additives have to be adopted by December 2010. In relation to these implementing measures, EFSA has to define the corresponding data requirements by July 2009.

5.3. Chair

The Chair informed the participants on the activities of the Scientific Committee.

6. REPORT FROM THE WORKING GROUPS

The Chairs of the two Working Groups (WGA and WGB) on Additives and Nutrient Sources reported shortly on the outcomes of the meetings that had taken place in December 2008 and January 2009.

7. FOOD ADDITIVES

7.1. Exposure assessment for the re-evaluation of food colours

R. Charrondiere gave a brief presentation on the methodology to be used in the future in the exposure assessment in relation to the re-evaluation of food colours.

7.2. Second ERF study on aspartame

(Question N° EFSA -Q-2008-746)

The Rapporteur introduced the revised draft document. The proposed changes to the text were noted and the opinion was adopted.

The Panel concluded that:

- Evaluation of aggregated malignant tumour incidences as evidence of carcinogenic potential of the test compound can only be performed based on a thorough consideration of all tumour data including onset, and data on non-neoplastic, hyperplastic and preneoplastic lesions but these data were not provided by the authors by the time of the adoption of this opinion.
- In accordance with the previous hypothesis of the AFC Panel, the lymphomas and leukemias might have developed in a population of rats suffering from chronic respiratory disease.
- The increase in incidence of mammary gland carcinomas is not considered indicative of a carcinogenic potential of aspartame since the incidence of mammary tumours in female rats is rather high and varies considerably between carcinogenicity studies. The Panel also noted that an increased incidence of mammary gland carcinomas was not reported in the previous ERF study in which much higher doses of aspartame were used.

Overall, the Panel concluded, on the basis of all the evidence currently available from the results published from the ERF studies and previous evaluations, that there is no indication of any genotoxic or carcinogenic potential of aspartame and that there is no reason to revise the previously established ADI for aspartame of 40 mg/kg bw/day.

7.3. High viscosity white mineral oils

(Question N° EFSA -Q-2008-003)

The draft opinion was briefly discussed and was submitted to adoption by written procedure.

7.4. Resorcinol

(Question N° EFSA -Q-2006-123)

The draft document was presented and briefly discussed. Further clarifications and improvements based on the comments provided by the participants were noted. Subject to these revisions a new draft document will be scheduled for discussion in a forthcoming Panel Plenary meeting.

8. NUTRIENT SOURCES

A general discussion took place on the interpretation of the inability to assess the safety of a nutrient source due to the lack of data in the supporting dossier. The Panel considered that as the absence of evidence is not equivalent to an evidence of absence, there cannot be a presumption of safety for the nutrient source that could not be assessed. Therefore the inability to assess the safety should be regarded as an unfavourable conclusion.

8.1. Ascorbates

(Question N° EFSA-Q-2005-087, EFSA-Q-2005-104 and EFSA-Q-2006-229)

The draft document was presented and discussed. Proposed changes to the draft were noted. The opinion will be submitted to adoption by written procedure.

8.2. Taurates

(Question N° EFSA-Q-2005-217, EFSA-Q-2005-178, EFSA-Q-2006-187, EFSA-Q-2006-288)

The draft opinion was presented and discussed. The proposed changes to the text were noted and the opinion was adopted.

The Panel noted that in addition to the diet and supplement sources evaluated in this Opinion also "energy" drinks can be an important source of taurine. Intake of magnesium taurate and iron taurate at the proposed levels of use and "energy" drink at the mean intake of 8.3 mg/kg bw/day and from the diet at 0.7 to 6.7 mg/kg bw/day would result in an exposure of 52.6 to 58.9 mg taurate/kg bw/day, resulting in a margin of safety of 17 to 19. Given the facts that the NOAEL was the highest dose tested and that taurine is a natural body constituent, the Panel concluded that this margin of safety is sufficient.

The Panel concluded that the bioavailability or iron and magnesium from iron (II) taurate, magnesium taurate and magnesium acetyl taurate is expected to be similar to that of other inorganic sources of iron and magnesium in the diet.

The Panel concluded that that the use of iron (II) taurate, magnesium taurate and magnesium acetyl taurate as sources for iron and magnesium at the proposed use levels is not of safety concern.

8.3. Choline-stabilised orthosilicic acid

(Question N° EFSA-Q-2006-189)

The draft opinion was presented and discussed. The proposed changes to the text were noted and the opinion was adopted.

The Panel concluded that silicon is bioavailable from this source and that its use in supplements, at the proposed use levels of the source is of no safety concern, provided that the upper level for choline is not exceeded.

8.4. Inositol hexanicotinate

(Questions N° EFSA Q-2005-213, EFSA Q-2006-199)

The draft opinion was presented and discussed. The proposed changes to the text were noted and the opinion was adopted.

The ANS Panel concluded that nicotinic acid from inositol hexanicotinate (inositol hexaniacinate) is bioavailable and a source of niacin.

In addition the Panel concluded that the use of inositol hexanicotinate as a source for niacin when added for nutritional purposes in food supplements intended for the general population would be of no safety concern provided that use levels are in compliance with the defined upper safe use level for nicotinic acid (10 mg/day).

However, the Panel is concerned that the use levels of inositol hexanicotinate proposed by the petitioners are 40 and 495 mg/day providing 36.4 and 450 mg nicotinic acid/day. These proposed use levels provide levels of nicotinic acid that are 4 to 45 times higher than the tolerable upper intake level defined by the SCF in 2002 of 10 mg nicotinic acid/day.

8.5. Picolinates

(Questions N° EFSA Q-2005-077, EFSA Q-2006-231, EFSA Q-2005-094, EFSA-Q-2005-110)

Due to lack of time this item was not discussed.

8.6. Monomethylsilanetriol

(Questions N° EFSA-Q-2006-296, EFSA-Q-2006-198)

The draft opinion was presented and discussed. The proposed changes to the text were noted and the opinion was adopted.

Given the absence of adequate data on the bioavailability of silicon from monomethylsilanetriol and on the toxicity of monomethylsilanetriol, the ANS Panel could not assess the safety of the source and the bioavailability of silicon from this source.

8.7. Ferrous phosphate

(Question N° EFSA-Q-2006-197, EFSA-Q-2006-303)

The draft opinion was presented and discussed. The proposed changes to the text were noted and the opinion was adopted.

The ANS Panel noted that although no specific data are available on the bioavailability of iron from ferrous phosphate as a mineral substance in food supplements, iron salts are soluble in the acidic environment of the stomach and that for absorption, iron must be in the ferrous form such as in ferrous phosphate.

It is the opinion of the Panel that given the previous evaluations of ferrous iron, phosphoric acid and phosphates as food additives and as nutrient sources by the SCF, EFSA and JECFA, no additional toxicological evaluation of ferrous phosphate is required.

Therefore the Panel concluded that the use of ferrous phosphate in food supplements as a source of iron is not of safety concern at the proposed use levels.

8.8. Selenium amino-acid chelate

(Question N° EFSA-Q-2006-223)

The draft document was presented and discussed. The proposed changes to the text were noted and the statement was adopted.

The Panel concluded that due to the lack of an adequate dossier supporting the use of selenium amino acid chelate in food supplements, the safety of selenium amino acid chelate and the bioavailability of selenium from this substance cannot be assessed.

8.9. Selenious acid

(Question N° EFSA -Q-2006-278)

The draft document was presented and briefly discussed. Further clarifications and improvements based on the comments provided by the participants were noted. Subject to these revisions a new draft document will be scheduled for discussion in a forthcoming Panel Plenary meeting.

8.10. Ethanolamine phosphates

(Questions N° EFSA-Q-2008-022, EFSA-Q-2008-023)

The draft statement was presented and discussed. The proposed changes to the text were noted and the statement was adopted.

The ANS Panel noticed that the petitioner has not provided any data on the toxicity of chromium (III) ethanolamine phosphate and copper (II) ethanolamine phosphate and on the bioavailability of chromium and copper from the respective ethanolamine phosphate salts.

Therefore, the Panel concluded that due to the lack of an appropriate dossier supporting the use of chromium (III) and copper (II) ethanolamine phosphate in food supplements, the safety of chromium (III) and copper (II) ethanolamine phosphate and the bioavailability of chromium and copper from the respective ethanolamine phosphate salts cannot be assessed.

8.11. Chromium yeasts

(Questions N° EFSA-Q-2005-097, EFSA-Q-2005-120, EFSA-Q-2005-205, EFSA-Q-2006-211, EFSA-Q-2006-212, EFSA-Q-2006-213)

Due to lack of time this item was not discussed.

8.12. Discussion paper on the exposure assessment of the nutrient sources

The discussion paper on the exposure assessment was briefly presented. Further clarifications and improvements based on the comments provided by the Panel members were noted. Subject to these revisions the discussion paper will be updated.

9. ANY OTHER BUSINESS

NEXT MEETINGS

The next Plenary meetings of the ANS Panel will take place on the following dates:

17 – 19 March 2009

28 – 30 April 2009

3 – 5 June 2009

7 – 9 July 2009

22 – 24 September 2009

24 – 26 November 2009

Annex I

INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF SPECIFIC DECLARATION OF INTERESTS

Agenda point 7.2 Second ERF study on aspartame (Question N° EFSA -Q-2008-746).

D. Parent-Massin declared an interest for activities related to aspartame with private companies. In accordance with EFSA's Policy on Declarations of Interests and Implementing documents thereof, and taking into account the specific matters discussed at the meeting, the interest above was deemed to represent a conflict of Interest (level C). Pursuant to EFSA's Procedure on Identifying and Handling Declarations of Interest, the said expert as per point C.III.b[1] is excluded from participating in EFSA activities concerned by the potential conflict in question. Therefore she did not participate in the discussion.

D. Gott declared an interest as he is involved in the preparation of related research activities for the UK Food Standards Agency. This was not considered as a conflict of interests and he was invited to participate in the discussion.

F. Aguilar has declared an interest because he has been involved in the evaluation of aspartame for his employer (AFFSSA). This was not considered as a conflict of interests and he was invited to participate in the discussion.

I. Pratt has declared an interest because she has been involved in the evaluation of the first ERF study on aspartame for EFSA.. This was not considered as a conflict of interests and she was invited to participate in the discussion.

Agenda point 8.7 Ferrous phosphate (Question N° EFSA-Q-2006-197, EFSA-Q-2006-303).

J. C. Larsen declared an interest because his employer (Danish National Food Institute) has been involved in the preparation of one of the dossiers on ferrous phosphate; In accordance with EFSA's Policy on Declarations of Interests and Implementing documents thereof, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest (level B). Pursuant to EFSA's Procedure on Identifying and Handling Declarations of Interest, the said expert incurs in the limitations identified under point C.III.b[1] that is he cannot participate in the final discussion.

INTERESTS AND ACTIONS RESULTING FROM DECLARATIONS DONE AT THE MEETINGS

With regard to this meeting no other interest than those already declared in the ADoI or in a previous SDoI and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof was declared by the experts.

[1] Implementing act to the policy on declaration of interests procedure for identifying and handling potential conflicts of interest.
http://www.efsa.europa.eu/cs/BlobServer/General/mb_annex_procedure_doi_en%20221008,0.pdf?ssbinary=true