Parma, 9 March 2010

EFSA/ANS/P_M12/MIN-1/4731873

MINUTES OF THE 12th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Parma from 9 to11 February 2010

Adopted on 9 March 2010 at the 13th Plenary meeting

AGENDA:

1. *Welcome; apologies for absence* 4

2. *Adoption of the agenda* 4

3. *Declarations of interest* 4

4. *Matters arising from the 11th plenary meeting held on 24-26 November 2009* 4

5. *General information from EFSA, the European Commission and the Chair* 4

   5.1. *Chair* 4

   5.2. *EFSA* 4

   5.3. *Commission* 5

6. *Information session on internal and external evaluation and management plan 2010* 5

7. *Report from the working groups* 5

European Food Safety Authority - Largo N. Palli 5/a, I - 43121 Parma
Tel: (+39) 0521 036 111 • Fax: (+39) 0521 036 110 • ans@efsa.europa.eu • www.efsa.europa.eu

8. Food Additives 6

8.1. Re-evaluation of food additives 6
8.2. Annatto extracts (Question N° EFSA-Q-2008-395) 6
8.3. Basic methacrylate copolymer (Question N° EFSA-Q-2009-00452) 7
8.4. Calcium lignosulphonate (Question N° EFSA-Q-2009-00374) 7
8.5. Oregano and lemon balm extract (Question N° EFSA-Q-2009-00376) 7
8.6. Sucrose esters of fatty acids (Question N°EFSA-Q-2009-00451) 7
8.7. Brown HT (Question N° EFSA Q- 2008-224) 9
8.8. Brown FK (Question N° EFSA-Q-2008-243) 9
8.9. Steviol glycosides (Question N° EFSA-Q-2007-071, EFSA-Q-2008-387, EFSA-Q-2008-401) 9
8.10. Brilliant Black BN (Question N° EFSA-Q-2008-241) 9
8.11. Amaranth (Question N° EFSA-Q-2008-227) 9
8.12. Litholrubine (Question N° EFSA-Q-2008-257) 9

9. Any other business 9

Next meetings 10

MINUTES OF THE 12th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Parma from 9 to 11 February 2010

Panel Members:

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

Apologies

Apologies for absence were noted from Ruth Charrondiere, John Christian Larsen (Chair), Tatjana Verguieva.

Invited experts

Nils-Gunnar Ilback (2nd day).

EFSA

Hugues Kenigswald, Ana Maria Rincon, Kim Petersen, Stavroula Tasiopoulou and Majlinda Lahaniatis (scientific staff) – Anna Campanini, Maria Correia (administrative staff).

European Commission

Marina Marini, Olga Solomon (only for items 8.1 and 8.2 - via teleconference)

1. WELCOME; APOLOGIES FOR ABSENCE

In absence of the Chair of the Panel, Iona Pratt, Vice Chair of the Panel, chaired the meeting. The chair welcomed the participants. Apologies for absence were noted.

2. ADOPTION OF THE AGENDA

The agenda was adopted without changes.

3. DECLARATIONS OF INTEREST

In accordance with EFSA's Policy on Declarations of Interests, the EFSA secretariat screened the Specific Declarations of Interests (SDoIs) completed by the scientific experts invited to this meeting. No 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. MATTERS ARISING FROM THE 11th PLENARY MEETING HELD ON 24-26 NOVEMBER 2009

The draft minutes were discussed and some changes were suggested. The adopted minutes can be seen on:

http://www.efsa.europa.eu/en/events/event/ans091124-m.pdf

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

5.1. Chair

In the absence of the Chair no specific information was reported.

5.2. EFSA

The Panel was informed that the three on-going public calls for scientific data published on 23 November 2009 have been re-published in early February with a clarified text and extended deadlines. The public calls concerned are:

"Call for scientific data on food additives permitted in the EU and belonging to the functional classes of preservatives and antioxidants",

"Call for scientific data on miscellaneous waxes permitted as food additives in the EU", and

"Call for scientific data on food additives permitted in the EU and belonging to the functional classes of emulsifiers, stabilisers and gelling agents"

It is planned that two additional scientific officers in the field of exposure assessment and chemistry will join the unit in 2010.

5.3. Commission

The representative of the European Commission informed the Panel that a feedback document has been prepared by the Commission providing a summary overview on all the opinions adopted by the ANS Panel and the related risk management actions taken. This document will be circulated to the Panel.

The draft regulation on "setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives" was discussed and adopted by the EU member States during a meeting of the Standing Committee of the Food Chain and Animal Health on 8 February 2010. A few modifications have been introduced compared to the draft that had been circulated to the Panel.

The Panel was informed that the deadline for Member states to submit to the Commission national derogations with supporting dossiers for the nutrient sources for the fortification of food dossiers is over (20 January 2010) and that the Commission is examining the requests received to identify those that meet the legal conditions for acceptance.

6. INFORMATION SESSION ON INTERNAL AND EXTERNAL EVALUATION AND MANAGEMENT PLAN 2010

Riitta Maijala, director of the Risk Assessment Directorate, presented the EFSA management plan for 2010, the process for the external evaluation of the quality of EFSA opinions and finally, the recently adopted rules for Panels and changes in indemnities for Panel and Working Group members.

7. REPORT FROM THE WORKING GROUPS

The Chairs of the 2 working groups summarised the main issues for discussion raised during their last meetings.

8. FOOD ADDITIVES

8.1. Re-evaluation of food additives

The draft document on the strategy for the re-evaluation of the food additives first discussed in July 2009 was brought back to the plenary for further discussion.

The Commission has suggested changes to the draft strategy document based on consultations with Member States and other stakeholders. The changes proposed by the Commission were tabled during the meeting.

Olga Solomon from the Commission participated to the discussion via teleconference. The Commission's main concern when considering establishing a strategy for re-evaluation of food additives is that data gaps are identified as early as possible. This would enable the Commission and stakeholders a better chance for providing the missing data before the end of a possible deadline. The Commission suggested that possible data gaps should be established (e.g. by the WGs) before any drafts are presented to the Panel.

The Panel agreed that it would be useful to identify data gaps as early as possible but disagreed with the approach suggested by the Commission. The significance of data gaps cannot be identified before the evaluation is initiated and the first draft opinion is discussed by the working group or the Panel.

Finally the Panel decided that the draft strategy should be discussed again in the Panel. The Secretariat should transmit the draft to the Panel again before the next meeting including changes suggested during the discussion and after bilateral discussion with the Commission.

Furthermore, the Panel was encouraged to provide comments to the Secretariat before 19 February so the draft document could be further updated before it is discussed again.

8.2. Annatto extracts *(Question N° EFSA-Q-2008-395)*

For annatto extracts as well as for a number of colours under re-evaluation, limitations in the data available have been identified (e.g. insufficient chemical characterisation, data gaps). In order to approach these limitations in a consistent way, a draft discussion document related to the evaluation of natural colors has been prepared. The draft discussion document was discussed, agreement was reached on its main principles and it was decided to use it as an internal guidance and to test it using the assessment of individual natural colours on a case by case basis in order to both progress on the re-evaluations and to refine the discussion paper based on experience.

8.3. Basic methacrylate copolymer *(Question N° EFSA-Q-2009-00452)*

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

The opinion only deals with the safety of basic methacrylate copolymer for use as a glazing agent/coating agent in solid food supplements and in solid foods for special medical purposes.

The Panel concluded that the use of basic methacrylate copolymer used as a glazing agent/coating agent in solid food supplements and in foods for special medical purposes is not of safety concern at the proposed use levels.

The Panel noted that the petitioner did not provide use levels for basic methacrylate copolymer for uses in solid foods for special medical purposes (FSMPs). Therefore, the safety of this usage could not be evaluated.

8.4. Calcium lignosulphonate *(Question N° EFSA-Q-2009-00374)*

The draft opinion was discussed. The proposed changes to the text were noted and the revised draft opinion will be sent for adoption by written procedure.

8.5. Oregano and lemon balm extract *(Question N° EFSA-Q-2009-00376)*

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

The Panel noted the absence of data on genotoxicity, reproductive and developmental toxicity, and long-term toxicity of oregano and lemon balm extracts.

Altogether, with reference to the SCF Guidance on submissions for food additive evaluations, the Panel concludes that due to the lack of an appropriate dossier supporting the use of oregano and lemon balm extracts as additives, the safety of oregano and lemon balm extracts at the proposed uses and use levels cannot be assessed.

8.6. Sucrose esters of fatty acids *(Question N°EFSA-Q-2009-00451)*

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

adopted.

The Panel concludes that the lauric acid ester of sucrose should be included in the group ADI of 40 mg/kg bw/day for sucrose esters of fatty acids (E473) and sucroglycerides (E474).

The Panel notes that the vinyl fatty acid esters, present in only mg/kg levels in the sucrose esters of fatty acids, are hydrolysed in the gastrointestinal tract and the vinyl portion of the fatty acid instantly tautomerises to acetaldehyde. The Panel concludes that any exposure to the vinyl part of the vinyl fatty acid molecule will be very low and not of toxicological concern.

Acetaldehyde is similarly only present in mg/kg levels in the sucrose esters of fatty acids, and the additional average exposure of 1.4 µg acetaldehyde/kg bw/day resulting from the use of sucrose esters of fatty acids as food additive would be negligible compared to the exposure from food and endogenous formation and not of safety concern.

The Panel notes that the maximum residual level of *p*-methoxyphenol in sucrose fatty acid esters as reported by the petitioner was <0.1 mg/kg and concludes that any exposure to this impurity resulting from the use of sucrose esters of fatty acids as food additive would be negligible and not of safety concern.

The Panel therefore concludes that sucrose esters of fatty acids produced by the new manufacturing method do not present any safety concern provided the overall exposure is within the ADI of 40 mg/kg bw/day for sucrose esters of fatty acids and sucroglycerides.

However, the Panel notes that the EC specifications for sucrose esters of fatty acids may need to be amended to include the sucrose ester of lauric acid and to permit supercritical carbon dioxide as an approved solvent to be used for their preparation.

The Panel additionally concludes that an additional use of sucrose esters of fatty acids in fruit beverages would only contribute a few percent to the group ADI of 40 mg/kg bw/day for sucrose esters of fatty acids (E 473) and sucroglycerides (E 474) established by EFSA in 2006.

The Panel notes however that refined estimates calculated for Irish consumers give a mean dietary exposure to sucrose esters of fatty acids of 29.1 mg/kg bw/day, and of 64.2 mg/kg bw/day at the 95th percentile, the intake by high level adult consumers being above the ADI.

The Panel notes that the mean dietary exposure of Irish children aged 5-12 years was 51.6 mg/kg bw/day, and 117.3 mg/kg bw/day at the 95th percentile. For both groups (average intake and high level consumers), the intakes were above the ADI.

The Panel notes that in the refined estimates the main contribution to total mean dietary exposure was from fruits treated with sucrose esters of fatty acids as a glazing agent (36% and 46% for adults and children, respectively) for a more refined estimate, exact usage data of sucrose esters of fatty acids in fruit would have to be known, or in absence of the former, information on the exact depth of the application layer, the types of fruit which are treated with the glazing agent and the market share of the glazing agent in comparison to other glazing agents/waxes would have to be provided.

8.7. Brown HT *(Question N° EFSA Q- 2008-224)*

Due to lack of time this item was not discussed.

8.8. Brown FK *(Question N° EFSA-Q-2008-243)*

Due to lack of time this item was not discussed.

8.9. Steviol glycosides *(Question N° EFSA-Q-2007-071, EFSA-Q-2008-387, EFSA-Q-2008-401)*

The rapporteur introduced the draft opinion. Proposed revisions based on the comments provided by the Panel members were noted. Subject to these revisions the draft opinion will be scheduled for discussion in a forthcoming Plenary meeting.

8.10. Brilliant Black BN *(Question N° EFSA-Q-2008-241)*

Due to lack of time this item was not discussed.

8.11. Amaranth *(Question N° EFSA-Q-2008-227)*

The rapporteur introduced the draft opinion. Further clarifications and improvements based on the comments provided by the Panel members were noted. Subject to these revisions, the draft opinion will be scheduled for discussion in a forthcoming Plenary meeting.

8.12. Litholrubine *(Question N° EFSA-Q-2008-257)*

Due to lack of time this item was not discussed.

9. ANY OTHER BUSINESS

The Panel agreed to have an extra Plenary meeting in March 2010 (9 – 11 March) in replacement of the scheduled working group meetings.

H. Kenigswald presented the recently received mandates and their status.

NEXT MEETINGS

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

9 – 11 March 2010

13 - 15 April 2010

8-10 June 2010

6 - 8 July 2010

5 - 7 October 2010

7 - 9 December 2010