Parma, 1 February 2011

MINUTES OF THE 20th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Parma on 7-9 December 2010

Adopted on 1 February 2011 at the 21st ANS Panel plenary meeting

AGENDA:

MINUTES OF THE 20th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Parma on 7-9 December 2010

Panel Members:

Birgit Dusemund, Pierre Galtier, David Gott (2nd and 3rd day), Rainer Gürtler, Jürgen König (2nd and 3rd day), Claude Lambré, John Christian Larsen (Chair) (2nd and 3rd day), Alicja Mortensen (2nd and 3rd day), Dominique Parent-Massin, Iona Pratt (Vice-Chair) (1st and 2nd day/morning session), Ivonne Rietjens (Vice-Chair), Ivan Stankovic, Paul Tobback, Tatjana Verguieva, Ruud Woutersen.

Apologies

Apologies for absence were noted from Fernando Aguilar, John Gilbert, Sandro Grilli and Jean-Charles Leblanc.

EFSA

Hugues Kenigswald, Majlinda Lahaniatis, Federica Lodi, Ana Maria Rincon, Kim Petersen, Stavroula Tasiopoulou, Alexandra Tard (1st day), Maria Luisa Escudero Hernandez (1st day) (scientific staff), Maria Correa and Maud Paques (administrative staff).

European Commission

Stéphane Brion and Josiane Houins-Roulet.

1. WELCOME; APOLOGIES FOR ABSENCE

In the absence of John Christian Larsen, Ivonne Rietjens (Vice-Chair) chaired the meeting on the first day. 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, EFSA screened the Annual Declaration of interest (ADoI) and Specific Declaration of interest (SDoI) filled in by the experts

invited for the present 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. ADOPTION OF THE MINUTES OF THE 19TH ANS PLENARY MEETING ON 9-10 NOVEMBER 2010

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

http://www.efsa.europa.eu/en/science/

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

5.1. Chair

No information was reported by the Chair.

5.2. EFSA

A few matters regarding the organization of the work were briefly discussed. The Panel was informed that the procedure concerning the renewal of the ANS Panel is ongoing and will be finalized by EFSA in March 2011.

H. Kenigswald informed the Panel members about the work programme 2011.

It was confirmed that no change should be introduced directly during the proofreading.

H. Kenigswald informed the Panel members that Alexandra Tard and Maria Luisa Escudero Hernandez have joined the ANS unit in November and introduced them to the Panel members.

5.3. European Commission

No information was reported by the Commission.

6. REPORT FROM THE WORKING GROUPS

6.1. Working Group A on Food Additives and Nutrient Sources

The Chair of Working Group A summarized the outcome of the discussions during the 19th Working Group A meeting held in Brussels, 11 November 2010.

6.2. Working Group B on Food Additives and Nutrient Sources

The Chair of Working Group B informed the Panel that several natural colours were discussed at the last meeting in November.

6.3. Working Group "Guidance on Food Additives"

The Chair of Working Group "Guidance on Food Additives" reported on the progress achieved during the last meeting in November. A new draft is expected in December and it is planned that the draft is discussed thoroughly by the Panel in March 2011. The Panel acknowledged that it was unlikely that the guidance document could be finalised by July 2011 and that the deadline should be extended to the end of 2011 or beginning of 2012. Accordingly, the guidance will probably be adopted by the renewed ANS Panel.

6.4. Working Group "Exposure assessment"

The vice-Chair of the Working Group "Exposure assessment" presented the proposal of the WG to include in the Annex A of the future food colour opinions the related decision trees. The Panel agreed to this proposal.

6.5. Working Group "Chemistry and specifications"

No meeting has taken place since the last Panel Plenary meeting.

7. FOOD ADDITIVES

7.1. Caramels (E 150 a-d)

(Question N° EFSA-Q-2008-237; EFSA-Q-2008-238; EFSA-Q-2008-239; EFSA-Q-2008-240)

The draft opinion was discussed. Further clarifications and improvements were suggested. The revised draft opinion will be scheduled for discussion in a forthcoming ANS Panel plenary meeting.

7.2. Allyl isothiocyanate

(Question N°EFSA-Q-2009-00377)

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

The present opinion deals with the safety of allyl isothiocyanate (AITC) for the proposed uses as a food additive (preservative). The volatilisation of the AITC from the packaging materials provides exposure of the food to AITC vapours for the purpose of protection from spoilage, resulting in a longer preservation of the food. The safety evaluation of the use of AITC in food contact materials is outside the remit of the Panel.

The Panel derived an ADI of 0.018 mg/kg bw/day which was rounded up to 0.02 mg/kg bw/day, based on the LOAEL of 9 mg/kg bw/day established for transitional cell papillomas of the urinary bladder observed in the carcinogenicity study in male rats and applying an uncertainty factor of 500.

The Panel noted that intakes of AITC resulting only from application as an antispoilage agent could be estimated for children ranging from 0.3 up to 2.8 times the ADI and for adults ranging from 0.2 up to 1.6 times the ADI, based on a market share of 20% and 100%, respectively.

Furthermore, the Panel noted that the mean daily total exposure to AITC from all sources including natural occurrence in food, use as flavouring and application as an antispoilage agent results in a two to four-fold exceedance of the ADI in children (3-5 fold exceedance at the 95th percentile for the 20% and 100% market share, respectively), and up to eight-fold exceedance in the case of 95th percentile adult consumers.

7.3. Polyvinylpyrrolidone-vinyl acetate copolymer

(Question N°EFSA-Q-2010-00037)

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

The Panel noted that the petitioner did not provide data on reproductive toxicity, chronic toxicity and carcinogenicity of PVP/VA. In the absence of these data, chronic effects in the gastrointestinal tract following oral administration cannot be excluded. Therefore, the Panel considered that an ADI should not be established and that a Margin of Safety (MOS) approach is appropriate. The Panel considered the calculated Margins of Safety for PVP/VA copolymer sufficient.

The Panel concluded that the residual level of hydrazine, proposed to be up to a maximum of 1.0 mg/kg in the final product, is unlikely to be of safety concern.

Overall, the Panel concluded that the use of PVP/VA copolymer in solid food supplements as a binding/coating agent is unlikely to be of safety concern at the proposed uses and use levels.

The Panel noted that it would be prudent to lower the level of hydrazine as far as reasonably achievable.

7.4. Indigotine, Indigo Carmine (E 132)

(Question N°EFSA-Q-2008-232)

The draft opinion was discussed. Due to lack of sufficient data on genotoxicity the Panel decided to launch a public call for scientific data on Indigotine, Indigo Carmine (E 132). Therefore, the draft opinion will be scheduled for discussion in a future ANS Panel plenary meeting.

7.5. Sodium ascorbate

(Question N° EFSA-Q-2010-01011)

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

The opinion deals with the safety of sodium ascorbate for its proposed use as a food additive in vitamin D preparations intended to be used in formulae and weaning foods for infants and young children.

The Panel concluded that the proposed extension of use of the food additive sodium ascorbate (E 301), intended to be used as an antioxidant for the vitamin D preparations for use in infant formulae and follow-on formulae, is not of safety concern.

7.6. Vegetable carbon (E 153)

(Question N° EFSA-Q-2008-242)

The draft opinion was discussed. Further clarifications and improvements were suggested and the draft opinion was sent back to the working group.

8. NUTRIENT SOURCES

8.1. Potassium and sodium sulphate

(Question N°EFSA-Q-2010-00818)

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

Based on the available data, the Panel concluded that potassium and sodium from respectively potassium sulphate, sodium sulphate and sodium sulphate decahydrate are bioavailable.

The Panel noted that, at the proposed level of use in food supplements, the additional supply of potassium from the source amounts to a maximum of 4% of the average intake level of potassium from the diet.

The Panel also noted that at the proposed level of use in food supplements, the additional supply of sodium from the source amounts to a maximum of 7% of the mean intake level of sodium from the diet.

The Panel concluded that the proposed use and use levels of potassium sulphate, sodium sulphate and sodium sulphate decahydrate in food supplements as a source of potassium and sodium are not of safety concern.

9. ANY OTHER BUSINESS

The Panel discussed the request from the Commission to answer a question received from the petitioner on erythritol. The Panel concluded that a letter from EFSA would be adequate to address the request.

NEXT MEETINGS

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

1 - 3 February 2011	5 - 7 July 2011
1 - 2 March 2011	20 - 22 September 2011
12 - 14 April 2011	25 - 27 October 2011
24 - 26 May 2011	6 - 8 December 2011