

Parma, 9 November 2010
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**MINUTES OF THE 18th PLENARY MEETING
OF THE SCIENTIFIC PANEL ON
FOOD ADDITIVES AND NUTRIENT SOURCES
ADDED TO FOOD (ANS)**

Held in Parma on 5-7 October 2010

Adopted on 9 November 2010 at the 19th ANS Panel plenary meeting

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Held in Parma on 5-7 October 2010

Panel Members:

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

Apologies

Apologies for absence were noted from Fernando Aguilar, John Christian Larsen (Chair), Sandro Grilli and Paul Tobback.

EFSA

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

European Commission

Josiane Houins-Roulet and Stéphane Brion.

1. WELCOME; APOLOGIES FOR ABSENCE

In the absence of John Christian Larsen, Ivonne Rietjens (Vice-Chair) 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, 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 17TH ANS PLENARY MEETING ON 24 SEPTEMBER 2010

The ANS unit has received comments that were inserted in the minutes. 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

A few matters regarding the organisation of the work were discussed. The Chair stressed the importance that both the rapporteurs and the ANS unit try to provide the drafts as early as possible.

5.2. EFSA

A few matters regarding the organisation of the work were briefly discussed. The Panel was informed that the deadline for applying to the ANS Panel is now closed.

5.3. European Commission

A few matters regarding the on-going work were presented and discussed.

6. REPORT FROM THE WORKING GROUPS

6.1. Working Group A on Food Additives and Nutrient Sources

The Chair of the Working Group A reported on the outcome of the latest meeting of the working group, held in September 2010.

6.2. Working Group B on Food Additives and Nutrient Sources

The Chair of the Working Group B reported on the outcome of the latest meeting of the working group, held in September 2010.

6.3. Working Group “Guidance on Food Additives”

The Chair of the Working Group “Guidance on Food Additives” reported on on-going work and the planned activities in the next few weeks.

6.4. Working Group “Exposure assessment”

The Chair of the Working Group “Exposure assessment” reported on the outcome of the latest meeting of the working group, held in September 2010.

6.5. Working Group “Chemistry and specifications”

The Chair of the Working Group “Chemistry and specification” reported on the outcome of the latest meeting of the working group, held in July 2010.

J. Gilbert informed that one teleconference has taken place in July and useful input has been gathered for the revised guidance document on food additives.

7. FOOD ADDITIVES

7.1. Lutein (E 161b)

(Question N°EFSA-Q-2008-787)

The Panel discussed the issues raised by NATCOL and CEFIC in their letter of 30 August on the opinion on the re-evaluation of lutein adopted by the Panel in July 2010.

The Panel considered that the studies on lutein esters that can be made available by NATCOL might partially address the gaps identified by the Panel in the toxicological database for lutein preparations other than lutein with high concentrations of total saponified carotenoids at levels of at least 80%. Therefore the Panel will propose to EFSA a self-mandate to evaluate the safety of these other lutein preparations.

The Panel noted that the studies on lutein esters that can be made available by NATCOL would not address the absence of multigeneration reproductive toxicity study and of chronic toxicity/carcinogenicity study for lutein. Therefore the Panel concluded that there is no reason to reconsider the overall additional uncertainty factor of 200 applied by the Panel to establish the ADI of 1 mg/kg bw/day for lutein.

The apparent discrepancies between the values on use levels of lutein provided to EFSA by NATCOL and the figures reported in the opinion originate from an error in the reference given in the title of the Table 3 in the opinion which should read “Usage levels provided by Industry” rather than “Outcome of NATCOL usage survey for lutein” since data originating from other stakeholders have also been taken into account. The title of Table 3 should be modified in order to provide the appropriate reference.

7.2. Allyl isothiocyanate

(Question N°EFSA-Q-2009-00377)

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

7.3. Polyvinylpyrrolidone-vinyl acetate copolymer

(Question N°EFSA-Q-2010-00037)

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

The opinion deals with the safety of PVP/VA copolymer for use in food supplements in tablet form as a binding/coating agent in an amount of up to 10% of weight per tablet, for a tablet weight of 1000 mg.

7.4. 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 Plenary meeting.

7.5. Green S (E 142)

(Question N°EFSA-Q-2008-236)

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

The Panel considered that the present dataset on the absorption, distribution, metabolism and excretion, subchronic, reproductive, developmental and long-term toxicity and carcinogenicity do not give reason to revise the ADI of 5 mg/kg bw/day allocated by SCF in 1984. For Green S, the lack of adequate genotoxicity data is balanced by the negative results from carcinogenicity and reproductive toxicity studies.

The Panel noted that the issue whether lacking genotoxicity data could be balanced by cancerogenicity and reproductive toxicity studies is currently a matter of discussion in the Scientific Committee.

The Panel concluded that at the maximum levels of use of Green S, intake estimates for children at the high percentiles (95th/97.5th) are above the ADI of 5 mg/kg bw/day at Tier 2, but not at the refined intake estimate at Tier 3. The Panel noted that the ADI for adults is not exceeded at Tier 2 and 3.

The Panel noted that the specifications for Green S need to be updated with respect to the percentage of material not accounted for that may represent sodium chloride and/or sodium sulphate as the principal uncoloured components.

The Panel noted that the JECFA specification for lead is < 2 mg/kg whereas the EC specification is <10 mg/kg.

The Panel noted that the aluminium lake of the colour could add to the daily intake of aluminium for which a TWI of 1 mg aluminium/kg bw/week has been established and that therefore specifications for the maximum level of aluminium in the lakes may be required.

7.6. Canthaxanthin (E 161g)

(Question N°EFSA-Q-2008-249)

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

Canthaxanthin is a carotenoid pigment allowed as a food additive in the EU and previously evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1974, 1987, and 1995, and the EU Scientific Committee for Food (SCF) in 1983, 1987 and 1997. Both committees have established an ADI of 0.03 mg/kg bw/day.

Based on

- the NOAEL of 0.25 mg/kg bw/day for scotopic b-wave changes (without impairment of vision) in a human study by Arden et al. (1989) and
- the BMDL05 of 12-20 mg/day, amounting to 0.20-0.33 mg/kg bw/day for a 60 kg person, derived in a worst case BMD analysis of the data from the meta-analysis reported by Köpcke et al. (1995) on the crystal incidence in human eyes with increasing daily doses of canthaxanthin,

the Panel derived a point of departure of 0.30 mg/kg bw/day and allocated an ADI of 0.03 mg/kg bw/day using an uncertainty factor of 10. This ADI is in line with the ADI derived previously by JECFA and the SCF.

For both adults and children, total anticipated combined exposure to canthaxanthin from application as food and feed additive is unlikely to exceed the ADI.

The Panel noted that the specifications of canthaxanthin need to be updated with respect to the heavy metal levels. The Panel noted that the JECFA specification for lead is ≤ 2 mg lead/kg, whereas the EC specification is ≤ 10 mg/kg. In addition, the Panel noted that canthaxanthin used as a food additive is manufactured synthetically and that the EC specifications should be modified accordingly.

7.7. Erythrosine (E 127)

(Question N°EFSA-Q-2008-229)

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

Erythrosine (E 127) is a xanthene-dye authorised to be used as a food additive in the EU and previously evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1980 and the EU Scientific Committee for Food (SCF) in 1984 and 1989. Both committees have established an ADI of 0-0.1 mg/kg bw/day.

The Panel concluded that the present database does not provide a basis to revise the ADI of 0.1 mg/kg bw/day.

The Panel concluded that at the current levels of use intake estimates for adults on average is 0.0031 mg/kg bw/day and 0.01 mg/kg bw/day at the 95th percentile, and consequently are below the ADI of 0.1 mg/kg bw/day. The Panel considered there would be no safety concerns at current levels of exposure including other sources of exposure (e.g. toothpaste, pharmaceuticals).

The Panel also noted that the limit test for heavy metals (expressed as lead) is considered obsolete and is being replaced with limits for individual metals of concern.

The Panel noted that the aluminium lake of the colour could add to the daily intake of aluminium and that therefore specifications for the maximum level of aluminium in the lakes are required.

7.8. Brilliant Blue FCF (E 133)

(Question N°EFSA-Q-2008-233)

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

Brilliant Blue FCF (E 133) is a triarylmethane dye authorised as a food additive in the EU and has been previously evaluated by JECFA in 1970 and the SCF in 1975. Both committees have established an ADI of 12.5 mg/kg bw/day. In 1984, the SCF revised the ADI to 10 mg/kg bw/day, according to new long-term studies.

The Panel concluded that the present data set on the absorption, distribution, metabolism and excretion, genotoxicity, subchronic, reproductive, developmental and long-term toxicity, and carcinogenicity give reason to revise the ADI of 10 mg/kg bw/day allocated by SCF in 1984.

The Panel considered that the NOAEL of 631 mg/kg bw/day from the chronic toxicity study in rat can be used to allocate a new ADI to Brilliant Blue FCF. By application of an uncertainty factor of 100, the Panel established a new ADI to Brilliant Blue FCF equal to 6 mg/kg bw/day.

The Panel concluded that at the maximum reported levels of use of Brilliant Blue FCF, refined intake estimates (Tier 3) are lower than the ADI of 6 mg/kg bw/day. The Panel concluded that at Tier 2 the intake estimates are below the ADI at the mean for both adults and children and at the higher level for adults, but above the ADI at the higher level (95th percentile) for children.

The Panel further noted that the specifications for Brilliant Blue FCF need to be updated with respect to the percentage of material not accounted for that may represent sodium chloride and/or sodium sulphate as the principal uncoloured components.

8. ANY OTHER BUSINESS

A few matters were discussed.

9. NEXT MEETINGS

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

9- 10 November 2010
7 - 9 December 2010
1 - 3 February 2011
12- 14 April 2011
24-26 May 2011

5 – 7 July 2011
20- 22 September 2011
25 -27 October 2011
6 – 8 December 2011