Parma, 22 September 2010

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MINUTES OF THE 16th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Parma on 6-8 July 2010

Adopted by written procedure on 22 September 2010

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MINUTES OF THE 16th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Parma on 6-8 July 2010

Panel Members:

Fernando Aguilar, Birgit Dusemund, Pierre Galtier, David Gott, Sandro Grilli, 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, Tatjana Verguieva, Ruud Woutersen.

Apologies

Apologies for absence were noted from John Gilbert and John Christian Larsen (Chair).

EFSA

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

Apologies for absence were noted from Hugues Kenigswald.

European Commission

Stephane Brion.

1. WELCOME; APOLOGIES FOR ABSENCE

In the absence of John Christian Larsen, Ivonne Rietjens (Vice-Chair) chaired the first and third days of the meeting. Iona Pratt (Vice-Chair) chaired the second 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 15TH ANS PLENARY MEETING ON 22-24 JUNE 2010

The Secretariat 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/events/event/ans100622-m.pdf

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

5.1. Chair

No information was reported by the Chair.

5.2. EFSA

The Panel was informed that the adopted opinion on monomethylsilanetriol was published on 6 July 2010.

5.3. Commission

No information was reported by the Commission.

6. INFORMATION SESSION ON THE LIBRARY SUPPORT FOR THE PANEL MEMBERS

Lara Congiu, from EFSA Library gave a presentation of the services and resources available to the users of EFSA library support.

7. REPORT FROM THE WORKING GROUPS

No meeting of Working Group A or B has taken place since the last Plenary.

The Chair of the Working Group on 'Guidance on food additives' summarised the results of the discussions during the meeting held in June 2010.

8. FOOD ADDITIVES

8.1. Polyvinylpyrrolidone-vinyl acetate copolymer

(Question N°EFSA-Q-2010-00037)

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 meeting of the Working Group and the subsequent Plenary meeting.

8.2. Patent Blue V (E 131)

(Question N°EFSA-Q-2008-231)

The draft document was discussed. Further clarifications and improvements were suggested. The Panel noted several data gaps for which data would be needed to finalise the evaluation and it was decided to launch a public call for data. Subject to these revisions a new draft document will be scheduled for discussion in a forthcoming Plenary meeting.

8.3. Lycopene

(Question N°EFSA-Q-2009-00895)

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

The Panel concluded that the divergence of scientific opinions is not based on data that were not available to EFSA during its evaluation of lycopene in 2008, but rather to a diverging interpretation of the toxicological relevance of the effects seen on aspartate transaminase (AST) and alanine transaminase (ALT) levels in a one-year rat study.

The ANS Panel agrees with the evaluation of the one-year rat study by the AFC Panel, and the NOAEL of 50 mg/kg bw/day identified from that study based on a non-reversible increase in ALT at the higher dose level.

8.4. Lutein

(Question N°EFSA-Q-2008-787)

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

Lutein (E 161b) is a natural carotenoid dye authorised as a food additive in the EU (E 161b) and previously evaluated by the EU SCF in 1975 and JECFA in 2006. JECFA established a group ADI of 0-2 mg/kg bw/day for lutein from *Tagetes erecta* and for zeaxanthin. The SCF could not establish an ADI, but concluded that xanthophylls prepared from natural foods by physical processes are acceptable for use in food (SCF, 1975).

The Panel concluded, based on the NOAEL of 200 mg/kg bw/day (the highest dose level tested) in a 90-day rat study, the absence of developmental toxicity at dose levels up to 1000 mg/kg bw/day (the highest dose level tested), the fact that lutein is not genotoxic, the fact that in 90-day studies no effects

on reproductive organs were observed, and the fact that lutein is a normal constituent of the diet, that an ADI can be derived. Given the absence of a multigeneration reproductive toxicity study and of chronic toxicity/carcinogenicity studies the Panel applies an uncertainty factor of 200 and establishes an ADI of 1 mg/kg bw/day.

The Panel noted that this ADI refers to lutein derived from *Tagetes erecta* containing at least 80% carotenoids consisting of lutein and zeaxanthin (79 and 5% respectively). The ADI does not refer to lutein preparations of lower purity or from other sources.

The Panel concluded that at the current levels of use Tier 3 intake estimates are above the ADI of 1 mg/kg bw/day at the upper end of the range.

The Panel concluded that the average intake for adults from the regular diet amounts to 1-4 % of the ADI of 1 mg/kg bw/day. High level intakes from the regular diet would amount to 28% of this ADI for children (assuming an intake of lutein present in food of 7 mg/day and a body weight of 25 kg, equal to 0.28 mg/kg bw/day).

The Panel concluded that the existing specifications need to be extended to include the material not accounted for and to match the material tested in the toxicological studies.

The Panel noted that the JECFA specifications for lead are ≤ 5 or ≤ 3 mg/kg whereas the EC specification is ≤10 mg/kg.

The Panel noted that, if available, the aluminium lake of the colour could add to the daily intake of aluminium for which a Tolerable Weekly Intake (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.

8.5. Curcumin (E 100)

(Question N°EFSA-Q-2008-220)

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

The Panel concluded that the present database supports an ADI of 3 mg/kg bw/day based on the NOAEL of 250-320 mg/kg bw/day from the reproductive toxicity study for a decreased body weight gain in the F2 generation observed at the highest dose level, and an uncertainty factor of 100.

The Panel concluded that at the maximum levels of use of curcumin, intake estimates for 1- to 10-year old children at the mean and the high percentiles (95th) are above the ADI of 3 mg/kg bw/day in some European countries.

When the exposure assessment takes into account the use of turmeric (Curcuma longa) as a spice in cooking in one country (Irish adults and children), it was found to contribute to the dietary exposure of curcumin in consumers of the spice. Therefore, it can be concluded that the combined exposure to curcumin through its use as a food colour and as a spice will exceed the ADI for both adults and children, especially at the higher percentiles.

The Panel concluded that intake from the normal diet amounts to less than 7% of the ADI of 3 mg/kg bw/day, resulting from an average exposure to curcumin of 0.1 mg/kg bw/day from the intake of turmeric and curry powder each for both children and adults.

The purity of curcumin is specified as not less than 90% total colouring matters. The Panel noted that the specifications for curcumin should be updated to define the residual 10%.

The Panel noted that specifications for curcumin according to Commission Directive 2008/128/EC and JECFA differ with regard to the solvents that are allowed for extraction and purification of curcumin and their maximum levels in the material of commerce and with regard to the maximum allowed lead concentration (which is given as ≤ 10 mg/kg and ≤ 2 mg/kg respectively) and with regard to other metals.

The Panel noted that the aluminium lake of the colour could add to the daily intake of aluminium for which a Tolerable Weekly Intake (TWI) of 1 mg aluminium/kg bw/week has been established (EFSA, 2008) and that therefore specifications for the maximum level of aluminium in the lakes may be required.

8.6. Canthaxanthin (E 161g)

(Question N°EFSA-Q-2008-249)

The draft document was discussed. Further clarifications and improvements were suggested. Subject to these revisions a new draft document will be scheduled for discussion in a forthcoming Plenary meeting.

8.7. Brilliant Blue (E 133)

(Question N°EFSA-Q-2008-233)

Due to lack of time this item was not discussed.

8.8. Green S (E 142)

(Question N°EFSA-Q-2008-236)

Due to lack of time this item was not discussed.

8.9. Erythrosine (E 127)

(Question N°EFSA-Q-2008-229)

The draft document was discussed. Further clarifications and improvements were suggested. Subject to these revisions a new draft document will be scheduled for discussion in a forthcoming Plenary meeting.

8.10. Allyl isothiocyanate

(Question N°EFSA-Q-2009-00377)

The Panel discussed and clarified a few issues related to the further revision of the draft document, which will be scheduled for discussion in a forthcoming Plenary meeting.

9. ANY OTHER BUSINESS

The Panel proposed that the scheduled working group meetings of WGA and WGB planned for November 2010 would be converted into a Plenary meeting in order to discuss the opinions that have already been finalised by the WGs.

Finally the Panel stressed that teleconferences should only be initiated when there is real need for them.

NEXT MEETINGS

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

24 September 2010

5 - 7 October 2010

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