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MINUTES OF THE 3rd PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Parma on 25-27 November 2008

Adopted on 27 January 2009 at the 4th Plenary meeting

AGENDA:

MINUTES OF THE 3rd PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Parma on 25-27 November 2008

PARTICIPANTS

Panel Members:

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

Apologies

Jean-Charles Leblanc

EFSA

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

European Commission

Marina Marini (2nd and 3rd day)

1. WELCOME; APOLOGIES FOR ABSENCE

The chair welcomed the participants and the secretariat noted apologies.

2. ADOPTION OF THE AGENDA

The agenda was adopted.

3. DECLARATIONS OF INTEREST

The declarations concerning items on the agenda of this meeting are noted under the specific items (10.2, 10.5 and 11.5).

4. MATTERS ARISING FROM THE 2ND PLENARY MEETING HELD ON 23-25 SEPTEMBER 2008

The minutes of the 2nd Plenary Meeting were adopted and can be seen on: .

http://www.efsa.europa.eu/cs/BlobServer/Event_Meeting/Minutes_ANS_%202nd%20Plenary.pdf?ssbinary=true

The opinion on calcium L-threonate for use as a source of calcium in food supplements has been adopted by written procedure on 24 October 2008.

5. GENERAL INFORMATION FROM EFSA AND THE COMMISSION

5.1. ANS UNIT

The two new scientific officers (M. Lahaniatis and K. Petersen) who joined the ANS Unit were introduced.

6. POTENTIAL RISKS ARISING FROM NANOSCIENCE AND NANOTECHNOLOGIES ON FOOD AND FEED SAFETY AND THE ENVIRONMENT

The Draft Opinion of the Scientific Committee on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed safety and the Environment is still open for public consultation.

7. THE 4TH MEETING OF THE CHAIRS AND SECRETARIATS OF COMMISSION AND AGENCY SCIENTIFIC COMMITTEES AND PANELS

The 4th Meeting of the Chairs of the EFSA Panels and EFSA Panel Secretariat with the Scientific Committees of the Commission, the European Medicines Agency (EMEA) and the European Centre for Disease Prevention and Control (ECDC) was held in Parma on the 4th and 5th of November 2008.

8. COMMISSION

The new Regulation on Food additives was adopted by the Council and it is foreseen to be published at the end of 2008 or the beginning of 2009.

9. REPORT FROM THE WORKING GROUPS

The Chairs of the two Working Groups on Additives and Nutrient Sources reported shortly on the outcomes of the meetings that had taken place from 28 to 30 October 2008.

10. FOOD ADDITIVES

10.1. EXPOSURE ASSESSMENT FOR THE RE-EVALUATION OF FOOD COLOURS

This item was not discussed.

10.2. 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 and 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 Food Standards Agency. This was not considered as a conflict of interests and he was invited to participate in the discussion.

Furthermore, it was mentioned that the following Panel members have been also involved in the ad hoc working group that has prepared the evaluation of the 1st Ramazzini study on aspartame by the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC):.A. Mortensen, I. Pratt.

The draft opinion was presented by the rapporteur. It was discussed and changes were suggested. The draft opinion will be forwarded to a forthcoming Plenary meeting.

10.3. NATAMYCIN - (QUESTION N° EFSA -Q-2006-009)

Due to lack of time this item was not discussed.

10.4. HIGH VISCOSITY WHITE MINERAL OILS - (QUESTION N° EFSA -Q-2008-003)

The draft opinion was briefly presented and discussed. The proposed changes to the text were noted. The draft opinion will be forwarded to a forthcoming Plenary meeting.

10.5. TAURINE AND D-GLUCURONO-γ-LACTONE IN "ENERGY" DRINKS - (QUESTION N° EFSA-Q-2007-113)

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

B. Dusemund declared an interest because she has been involved in the evaluation of energy drinks for her institute (BfR). This was not considered as a conflict of interests and she was invited to participate in the discussion.

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

10.6. RESORCINOL - (QUESTION N° EFSA-Q-2006-123)

Due to lack of time this item was not discussed.

10.7. MODIFIED ACACIA GUM - (QUESTION N° EFSA-Q-2008-002)

Due to lack of time this item was not discussed.

11. NUTRIENT SOURCES

11.1. CALCIUM FLUORIDE - (QUESTION N° EFSA-Q-2005-088)

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 the use of calcium fluoride as food supplement would be of no safety concern provided that fluoride upper level values established in Europe are not exceeded by the combined exposure from food supplements and the diet.

The Panel noticed that the foreseen supplementation with calcium fluoride will not exceed fluoride ULs established in Europe for different populations. Furthermore, the potential added contribution of this supplementation, at the levels considered in this opinion, to the total fluoride daily exposures estimates available for adults should not exceed the established UL for this population. The Panel concludes that the use of calcium fluoride as food supplement at the proposed use levels would be of no safety concern for adults and children above the age of 8–year-old.

11.2. ASPARTATES SOURCES - (EFSA-Q-2005-129, EFSA-Q-2006-260, EFSA-Q-2005-215, EFSA-Q-2005-101, EFSA-Q-2006-253, EFSA-Q-2006-294, EFSA-Q-2005-109, EFSA-Q-2006-282, EFSA-Q-2006-283, EFSA-Q-2006-284, EFSA-Q-2006-285, EFSA-Q-2006-305, EFSA-Q-2006-254, EFSA-Q-2005-161, EFSA-Q-2006-259)

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

In view of its reported insolubility, the magnesium aspartate complex source proposed for use in food supplements could not be considered as its bioavailability and its potential aspartate exposure could not be evaluated. For zinc aspartate it has been assumed that its reported solubility in diluted hydrochloric acid will allow its dissociation and absorption in the stomach although it was not clear to the Panel if further absorption could take place in the intestine considering its reported insolubility in water.

The Panel considered that the individual or combined use of zinc and copper aspartates as sources of zinc and copper, at the proposed use levels, are not of safety concern. On the other hand, the Panel concluded that the individual use of calcium, magnesium, potassium aspartates as food supplements at the levels proposed in this opinion could be of safety concern because the margins of safety towards a NOAEL from a 90-days rat study are considered too low.

Furthermore, based on the cumulative exposure estimates arising from use of a multi-mineral combination, the Panel considered that the proposed use levels for all aspartate sources could be of safety concern given that the margin of safety between the estimated exposure and the NOAEL in the 90-day rat study is too low. Furthermore the estimated exposure would be above the levels reported to induce amino acid imbalance in intervention trials, taking into consideration aspartate exposure from the diet.

11.3. SILVER HYDROSOL - (QUESTION N° EFSA-Q-2005-169)

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

The Panel noted that the application was for a nanoparticulate material. The Panel considered that the data provided by the petitioner are insufficient to adequately characterise silver hydrosol for risk assessment. The Panel considered that data on ionic silver cannot be used to establish the safety of silver hydrosol. The Panel considered that the toxicological data provided by the petitioner are insufficient to allow hazard characterisation of silver hydrosol. Therefore, the Panel concluded that due to the lack of an appropriate dossier supporting the use of silver hydrosol, the safety of silver hydrosol and the bioavailability of silver from silver hydrosol cannot be assessed.

11.4. TIN CHLORIDE - (QUESTIONS N° EFSA Q-2006-224)

The draft statement 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 appropriate dossier supporting the use of stannic chloride in food supplements, the safety of stannic chloride and the bioavailability of tin from this substance cannot be assessed.

11.5. SODIUM MONOFLUOROPHOSPHATE - (QUESTIONS N° EFSA Q-2006-277, EFSA Q-2006-295)

S. Grilli declared an interest because he has contributed to a risk assessment of sodium monofluorophosphate in cosmetics for a private company. This was not considered as a conflict of interests and he was invited to participate in the discussion.

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 the use of sodium monofluorophosphate as food supplement would be of no safety concern provided that fluoride upper level values established in Europe are not exceeded by the combined exposure from food supplements and the diet.

The ANS Panel noticed that most of these proposed levels of supplementation are below upper levels established for different populations in Europe. However, when the potential fluoride contribution of sodium monofluorophosphate supplementation is added to the total fluoride daily exposure estimates in Europe for children, fluoride upper level values will be exceeded in most cases. For adults, the proposed fluoride supplementation levels will not exceed the upper level value with the exception of the supplementation value of 2 mg/day.

11.6. ASCORBATES - (QUESTION N° EFSA-Q-2005-087, EFSA-Q-2005-104 AND EFSA-Q-2006-229)

Due to lack of time this item was not discussed.

11.7. TAURATES - (QUESTION N° EFSA-Q-2005-217, EFSA-Q-2005-178, EFSA-Q-2006-187, EFSA-Q-2006-288)

Due to lack of time this item was not discussed.

11.8. METHIONATES - (QUESTIONS N° EFSA-Q-2005-2005-138, EFSA-Q-2005-143, EFSA-Q-2005-076)

The draft opinion was presented by the rapporteur and discussed. The proposed changes to the text were noted. It was decided to submit the draft opinion to an adoption by written procedure.

11.9. CHROMIUM POLYNICOTINATE - (EFSA-Q-2005-079)

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

The Panel noted that the simultaneous use of nicotinate as a source of chromium (III) in both foods intended for particular uses and in foods supplements both at use levels up to 200 µg/day could amount to use levels of 400 µg/day. This would be equivalent to 4 mg chromium nicotinate daily containing 2.2 mg nicotinate/day. This amount of chromium would be above the level of 250 µg chromium/day considered by the WHO as a value for supplementation that should not be exceeded.

The dose of 2.2 mg nicotinate/day would amount to 22% of the tolerable upper level for nicotinate established by the SCF and thus the Panel concludes that this intake of nicotinate would not be of safety concern.

Therefore, even though the amount of nicotinate that would be consumed as a result of these proposed uses would be safe, the Panel could not conclude that these uses of chromium (III) nicotinate are of no safety concern.

The Panel noted that recent reviews and evaluations of chromium (III)(including Eastmond *et al.*, 2008; Levina and Lay, 2008) point at conflicting outcomes of genotoxicity assays and report diverging views and conclusions on the consequences of this genotoxicity issue for the ultimate safety assessment of chromium (III). The Panel is aware that given this situation the safety of chromium (III) might need to be re-evaluated in light of the recent findings.

12. ANY OTHER BUSINESS

None

13. NEXT MEETINGS

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

27 – 29 January 2009

17 – 19 March 2009

28 – 30 April 2009

3 – 5 June 2009

7 – 9 July 2009

22 – 24 September 2009

24 – 26 November 2009