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MINUTES OF THE 7th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Parma on 13-14 May 2009

Adopted on 2 June 2009 at the 8th Plenary meeting

AGENDA:

MINUTES OF THE 7th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Parma on 13-14 May 2009

Panel Members:

Fernando Aguilar (1st day AM only), Birgit Dusemund, Pierre Galtier, John Gilbert, David Gott, Rainer Guertler, Georges Kass, Jürgen König, Claude Lambré, John Christian Larsen (Chair), Alicja Mortensen, Dominique Parent-Massin, Iona Pratt (Vice-Chair), Ivan Stankovic, Paul Tobback, Tatjana Verguieva,

Apologies

Ruth Charrondiere, Sandro Grilli, Jean-Charles Leblanc, Ivonne Rietjens and Ruud Woutersen.

EFSA

Joanne Gartlon, Hugues Kenigswald, Majlinda Lahaniatis, Federica Lodi, Ana-Maria Rincon and Stavroula Tasiopoulou (Scientific Staff) – Maria Correia, Maud Pâques (Administrative Staff).

European Commission

Marina Marini

1. WELCOME; APOLOGIES FOR ABSENCE

The chair welcomed the participants. Apologies for absence were noted.

2. ADOPTION OF THE AGENDA

The agenda was adopted without changes.

3. DECLARATIONS OF INTERESTS

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. For further details on the outcome of this screening please refer to Annex I of these minutes.

4. MATTERS ARISING FROM THE 6th PLENARY MEETING HELD ON 28-30 APRIL 2009

The participants were asked to confirm their agreement with the minutes of the 6th ANS Plenary meeting. The draft minutes were discussed, revised and adopted. They can be viewed online at:

http://www.efsa.europa.eu/cs/BlobServer/Event_Meeting/ans_minutes_6th_plenary_meeting_en.pdf?ssbinary=true

5. INFORMATION FROM EFSA, THE CHAIR AND THE COMMISSION

5.1. EFSA

The Panel was informed on the following issues:

- A call for recruiting a senior scientific officer (toxicologist) in the ANS Unit will be launched in June 2009.
- A call for the preparation of pre-evaluation documents for the evaluation of preservatives is scheduled to be launched in June 2009.
- A call for the establishment of a database which will include the main metabolites of all permitted food additives is planned to be launched in June 2009.

5.2. Commission

The Commission informed the Panel that the deadline for the re-evaluation of the colours of the "Southampton study" is postponed to September 2009, in order to allow the Panel to take into account the new data that will be provided in May 2009.

5.3. Chair

No new information since the last meeting in April 2009.

6. REPORT FROM THE WORKING GROUPS

The Chair of the Working Group A on Additives and Nutrient Sources (WG A) reported briefly on the outcome of the meeting that had taken place on 12 May 2009.

The Chair of WG A suggested that in the future the meetings of WG A and Working Group B (WG B) should take place, if possible in parallel, or on dates as close as possible in order to facilitate the exchange of views and harmonisation of work between the two WGs.

No meeting of WG B has taken place since the last Plenary meeting in April 2009.

7. NUTRIENT SOURCES

7.1. L-Selenomethionine

(Question N° EFSA-Q-2005-103, EFSA-Q-2006-195, EFSA-Q-2006-196 and EFSA-Q-2006-304)

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

The Panel noted that the Tolerable Upper Intake Level (UL) defined by the Scientific Committee on Food (SCF) of 300 µg selenium/day is the current basis for assessing the safety of inorganic selenium compounds, for example selenious acid (EFSA, 2009) and that the AFC Panel (EFSA) considered that this UL should also apply to organic selenium compounds from selenium-enriched yeasts (EFSA, 2008).

The Panel noted however that the findings of the recent SELECT trial (Selenium and Vitamin E Cancer Prevention Trial) using L-selenomethionine indicate that in humans, selenium-related effects might be observed at a supplemental level of 200 µg selenium/day, in individuals also having a high dietary intake of selenium. The Panel considered that, because of these data and given the greater bioavailability of selenium from L-selenomethionine, the safety of L-selenomethionine can only be established at use levels in food supplements up to 250 µg L-seleomethionine/day in food supplements (corresponding to up to 100 µg selenium/day).

The Panel concluded that the use of L-selenomethionine as a source for selenium in food supplements would not be of safety concern in adults at use levels up to 250 µg /day (supplying up to 100 µg selenium/day). At this use level the combined intake from diet and supplement use will be below the SCF's UL, even for individuals also having a high dietary intake of selenium (greater than 100 µg selenium/day from the diet).

The Panel considered, however, that the current database on selenium and the new data provided by the recent SELECT trial indicate the need for a integrated reconsideration of the UL for selenium from all sources, and recommends that this also considers systemic selenium levels rather than external dose in characterising dose-response relationships, in order to allow a comparison of selenium-containing compounds with different bioavailabilities.

7.2. Chromium-enriched yeasts

(Questions N° EFSA-Q-2005-097, EFSA-Q-2005-120, EFSA-Q-2005-205, EFSA-Q-2006-211, EFSA-Q-2006-212, EFSA-Q-2006-213)

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

The Panel concluded that information is available demonstrating that chromium(III) is bioavailable from chromium-enriched yeasts, and that there was no evidence of adverse effects in a number of studies in humans that have examined effects of chromium-enriched yeast supplementation at levels of up to 1000 µg chromium(III)/day). However, these studies were not designed to study the safety of chromium(III)-enriched yeast.

The Panel concluded that the petitioners have insufficiently chemically characterised their products and therefore have not demonstrated that the chromium from chromium-enriched yeasts has a metabolic fate and biological distribution similar to those of other sources of chromium in the diet.

Therefore, the Panel is not able to reach a conclusion regarding the safety of the chromium-enriched yeasts under consideration.

7.3. Vanadium-enriched yeasts

(Question N° EFSA-Q-2005-171, EFSA-Q-2005-190)

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

The Panel concluded that the safety of vanadium-enriched yeasts and the bioavailability of vanadium from these sources cannot be assessed on the basis of the dossiers supporting the use of vanadium-enriched yeasts in food supplements.

However, the Panel considered that the conclusions and risk characterisation in the opinion of the NDA Panel on vanadium (EFSA, 2004), based on the toxicity of the vanadium sources vanadyl sulphate, vanadium pentoxide, ammonium monovanadate and some other vanadium compounds, are relevant, not only for vanadium itself, but also for the vanadium sources (vanadium-enriched yeasts) under consideration in the present opinion.

7.4. Strontium-enriched yeast

(Question N° EFSA-Q-2005-193)

The draft statement was 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 strontium-enriched yeast in food supplements, the bioavailability of strontium from strontium-enriched yeast and the safety of strontium-enriched yeast cannot be assessed.

7.5. Lithium-enriched yeast

(Question N° EFSA-Q-2005-192)

The draft statement was 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 lithium-enriched yeast in food supplements, the bioavailability of lithium from lithium-enriched yeast and the safety of lithium-enriched yeast cannot be assessed.

7.6. Iron-enriched yeasts

(Question N° EFSA-Q-2005-095, EFSA-Q-2005-206; EFSA-Q-2006-214)

Due to lack of time the item was not discussed.

7.7. Magnesium-enriched yeasts

(Question N° EFSA-Q-2005-092, EFSA-Q-2005-204)

Due to lack of time the item was not discussed.

7.8. Molybdenum-enriched yeast

(Question N° EFSA-Q-2005-203)

The draft statement was 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 molybdenum-enriched yeast in food supplements, the bioavailability of molybdenum from molybdenum-enriched yeast and the safety of molybdenum-enriched yeast cannot be assessed.

7.9. Calcium acetate, calcium and magnesium succinate, calcium and magnesium pyruvate, potassium malate.

(Questions N° EFSA-Q-2006-230, EFSA-Q-2005-137, EFSA-Q-2005-131, EFSA-Q-2005-136, EFSA-Q-2005-141, EFSA-Q-2008-025)

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

The Panel concluded the following:

- Calcium is expected to be bioavailable from the three sources of calcium (calcium succinate, calcium pyruvate and calcium acetate) to be used as nutritional substances in food supplements;
- Magnesium is expected to be bioavailable from the two sources of magnesium (magnesium succinate and magnesium pyruvate) to be used as nutritional substances in food supplements;
- Potassium is expected to be bioavailable from potassium malate which is to be used as a nutritional substance in food supplements;
- The use of calcium acetate, calcium succinate, calcium pyruvate, magnesium succinate, magnesium pyruvate and potassium malate, as sources of calcium, magnesium and potassium, in food supplements for the uses and at the use levels proposed by the petitioners is not of safety concern, provided that the UL for intake of the cations is not exceeded. However, the Panel noted that when the dietary intake is also taken into consideration, with supplementation of calcium succinate, calcium pyruvate or calcium acetate at the proposed daily use levels of up to 800 mg calcium, the UL defined by the SCF for calcium would be exceeded for the 97.5 percentile European adult population;
- The intake of pyruvate, succinate, malate and acetate from the corresponding sources is not of safety concern.

7.10. Copper oxide

(Questions N° EFSA-Q-2005-156, EFSA-Q-2006-219, EFSA-Q-2006-286, EFSA-Q-2006-287)

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

The Panel considered that copper(II) oxide shows lower bioavailability compared to other inorganic sources of copper(II) due to its low solubility. However, the Panel noted that copper from copper(II) oxide is expected to be bioavailable to some extent.

The Panel concluded that, provided that the Tolerable Upper Intake Level for copper is not exceeded, the use of copper(II) oxide as a source of copper at the proposed use levels is not of safety concern.

7.11. Iron and potassium amino-acid chelates

(Questions N° EFSA-Q-2006-221, EFSA-Q-2006-222)

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

The Panel concluded that due to the lack of an adequate dossier supporting the use of potassium amino acid chelate and of iron amino acid chelate, the safety of potassium amino acid chelate and of iron amino acid chelate and the bioavailability of potassium or iron from the respective sources, cannot be assessed.

7.12. Tocopherols and tocotrienols

(Questions N° EFSA-Q-2006-262, EFSA-Q-2006-263, EFSA-Q-2006-264, EFSA-Q-2006-266, EFSA-Q-2006-267, EFSA-Q-2006-268, EFSA-Q-2006-269, EFSA-Q-2006-270)

Due to lack of time the item was not discussed.

7.13. Sodium hyaluronate

(Question N° EFSA-Q-2006-190)

Due to lack of time the item was not discussed.

7.14. Folic acid-enriched yeast (biotransformed folic acid)

(Question N° EFSA-Q-2005-197))

The draft statement was 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 folic acid-enriched yeast in food supplements, the bioavailability of folic acid from folic acid-enriched yeast and the safety of folic acid-enriched yeast cannot be assessed.

7.15. Vitamin C-enriched yeast)

(Questions N° EFSA-Q-2005-194)

Due to lack of time the item was not discussed.

7.16. Vitamin D-enriched yeast

(Questions N° EFSA-Q-2005-198)

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

7.17. Biotin-enriched yeast

(Questions N° EFSA-Q-2005-199)

Due to lack of time the item was not discussed.

7.18. Riboflavin-enriched yeast

(Questions N° EFSA-Q-2005-210)

Due to lack of time the item was not discussed.

8. ANY OTHER BUSINESS

None

NEXT MEETINGS

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

2 – 5 June 2009

7 – 9 July 2009

22 – 24 September 2009

24 – 26 November 2009

Annex I

INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF SPECIFIC DECLARATION OF INTERESTS

With regard to this meeting no other interest than those already declared in the ADoI and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof was declared by the experts.

INTERESTS AND ACTIONS RESULTING FROM DECLARATIONS DONE AT THE MEETINGS

With regard to this meeting no other interest than those already declared in the ADoI or in a previous SDoI and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof was declared by the experts.