

Parma, 23 September 2009

EFSA/ANS/P_M9/MIN/4363942

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

Held in Parma on 7-9 July 2009

Adopted on 23 September 2009 at the 10th Plenary meeting

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PARTICIPANTS

Panel Members:

Fernando Aguilar (1st and 2nd day morning), Birgit Dusemund, Pierre Galtier, John Gilbert (1st and 2nd day), David Gott, Sandro Grilli, Rainer Guertler, Georges Kass, Jürgen König, Claude Lambré, John Christian Larsen (Chair), Jean-Charles Leblanc, Alicja Mortensen, Dominique Parent-Massin (1st and 2nd day), Ivonne Rietjens (Vice-Chair), Ivan Stankovic, Paul Tobback, Tatjana Verguieva, Ruud Woutersen.

Apologies

Apologies for absence were noted from Ruth Charrodiere and Iona Pratt.

EFSA

Hugues Kenigswald, Kim Petersen, Ana-Maria Rincon, Stavroula Tasiopoulou and Majlinda Lahaniatis (3rd day) (scientific staff) – Maria Correia (administrative staff).

European Commission

Marina Marini, Olga Solomon (via teleconference – only for item 6.2).

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 INTEREST

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 8th PLENARY MEETING HELD ON 2-5 JUNE 2009

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/cs/BlobServer/Event_Meeting/ans_minutes_8th_Plenary_meeting_2_5_June_2009.pdf?ssbinary=true

4.1. EFSA

The Secretariat reminded the Panel that the annual declaration of interests has to be updated at least once a year and that therefore the members who have not yet had the opportunity to update it in the last 11 months will automatically receive a request to submit an updated declaration.

H. Kenigswald informed the Panel that he had participated to the meeting organised by the European Commission with the Member States on the programme for the re-evaluation of the food additives.

4.2. Commission

With regard to food additives, a meeting with the Member States and in the presence of the ANS Secretariat has taken place in June where the re-evaluation program for food additives was discussed. EFSA will receive the working document related to the re-evaluation programme and will provide comments by 15 September 2009.

4.3. Chair

The Chair informed the Panel members that he has participated in the latest JECFA meeting.

5. REPORT FROM THE WORKING GROUPS

No meeting of working group A had taken place since the last plenary meeting in June 2009.

The chair of working group B informed that in the June meeting eight additives were discussed. Furthermore the Panel was informed that K. Hulshof has now stopped her participation to the working group.

6. FOOD ADDITIVES

6.1. Data requirements for food additives

(Question N° EFSA-Q-2007-188)

A draft opinion prepared by the Secretariat was thoroughly discussed and the Panel concluded that detailed data requirements and specific scientific approaches should not be described in this document but rather in the guidance document. It was thus decided to replace the draft opinion by a more summarised draft statement that was prepared during the meeting.

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

The statement defines the general data requirements, while specific scientific approaches are suggested in the guidance for food additives applications applicable at the time of the application. In order to reflect current thinking in risk assessment, the Panel will commence a detailed reappraisal of the guidance in September 2009. It is anticipated that, following a period of public consultation, this new guidance will be finalised in July 2011.

The Panel also advises the applicants to take into consideration the opinions adopted in 2009 by the Scientific Committee of EFSA on Nanoscience and Nanotechnologies, on the use of the Benchmark Dose approach in risk assessment and on the replacement and reduction of animal testing, as well as the guidance on transparency in the scientific aspects of risk assessments adopted in 2009 and the guidance on the safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements adopted in 2008.

6.2. Re-evaluation of food additives

A draft document on the strategy for the re-evaluation of the food additives was presented and discussed. Proposed changes to the draft document were noted. Subject to these revisions a new draft document will be scheduled for discussion in a forthcoming ANS Plenary meeting.

6.3. Ethyl lauroyl arginate

(Question N° EFSA-Q-2009-00609)

Due to the late availability of the draft document, the draft document was not discussed.

6.4. Resorcinol

(Question N° EFSA-Q-2006-123)

The draft document was presented and discussed. Proposed changes to the draft document were noted. Subject to these revisions a new draft document will be scheduled for discussion in a forthcoming ANS Plenary meeting.

6.5. Natamycin

(Question N° EFSA-Q-2006-009)

The draft document was presented and discussed. Proposed changes to the draft document were noted. Subject to these revisions a new draft document will be scheduled for discussion in a forthcoming ANS Plenary meeting.

6.6. Polyglycitol syrup

(Question N° EFSA-Q-2007-072)

The draft document was presented and discussed. Proposed changes to the draft were noted. Subject to these revisions a new draft document will be scheduled for discussion in a forthcoming ANS Plenary meeting.

6.7. Modified acacia gum

(Question N° EFSA-Q-2008-002)

This item was not discussed due to lack of time.

7. NUTRIENT SOURCES

7.1. Orotates

(Questions N°EFSA-Q-2005-135, EFSA-Q-2005-139, EFSA-Q-2005-163, EFSA-Q-2005-148, EFSA-Q-2006-232, EFSA-Q-2006-233, EFSA-Q-2006-234, EFSA-Q-2006-235, EFSA-Q-2006-236, EFSA-Q-2006-237, EFSA-Q-2006-238, EFSA-Q-2006-239, EFSA-Q-2006-240, EFSA-Q-2006-241, EFSA-Q-2006-242, EFSA-Q-2006-243, EFSA-Q-2006-244, EFSA-Q-2006-245, EFSA-Q-2006-246, EFSA-Q-2006-247, EFSA-Q-2006-248, EFSA-Q-2006-251)

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

The Panel concluded that little documentation on the bioavailability of the mineral salts of orotic acid has been submitted, but one study reveals that the bioavailability of zinc from zinc orotate is comparable to that of zinc from another organic source as well as an inorganic salt. The Panel concluded that this would probably also be the case for the bioavailability of the cations from the other orotate salts, for which no documentation has been supplied.

In view of the tumour promotion adverse effect of orotates, the Panel considered that it is not appropriate to conclude on the safety for a combination between chromium and a tumour promotor as long as it is not clear whether chromium is genotoxic or not.

Furthermore the Panel concluded that in light of the tumour promoting effect of orotic acid in animal experimentation, the small margin of safety to this effect from foreseeable exposure and the absence of any relevant studies on genotoxicity and of any developmental studies the use of orotate as a source of the eight other minerals and choline at the proposed levels of use is of safety concern.

8. ANY OTHER BUSINESS

The Panel discussed and agreed to the following dates for Plenary meetings in 2010:

9 – 11 February 2010
13 - 15 April 2010
8 - 10 June 2010
6 - 8 July 2010
5 - 7 October 2010
7 - 9 December 2010

NEXT MEETINGS

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

22 – 24 September 2009
24 – 26 November 2009

Annex I

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

J.C. Larsen declared an interest related to the evaluation of modified acacia gum by JECFA. This was not considered as a conflict of interests and he was invited to participate in the corresponding discussion.

J. C. Leblanc declared an interest related to the evaluation of ethyl lauroyl arginate and natamycin by JECFA. This was not considered as a conflict of interests and he was invited to participate in the corresponding discussion.

I. Stankovic declared an interest related to the evaluation of modified acacia gum by JECFA . This was not considered as a conflict of interests and he was invited to participate in the corresponding discussion.

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.