

**MINUTES OF THE 28th PLENARY MEETING
OF THE SCIENTIFIC PANEL ON
FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS
AND MATERIALS IN CONTACT WITH FOOD**

Held in Brussels on 6-7 March 2008

Adopted on 2 April 2008 at the 29th Panel meeting

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FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS
AND MATERIALS IN CONTACT WITH FOOD (AFC)
Held in Brussels on 6-7 March 2008**

PARTICIPANTS

Panel Members:

Fernando Aguilar, Herman Autrup, Susan Barlow (Chair), Laurence Castle, Riccardo Crebelli (1st day), Wolfgang Dekant (2nd day), Karl-Heinz Engel (Vice Chair), Nathalie Gontard, David Gott, Rainer Gürtler (1st day), John Christian Larsen (Vice Chair), Catherine Leclercq, F. Xavier Malcata, Wim C. Mennes, Iona Pratt, Ivonne Rietjens, Paul Tobback, Fidel Toldrá.

Experts: Jørn Gry (item 9)

Apologies

Sandro Grilli, Jean-Charles Leblanc, Maria Rosaria Milana

EFSA

AFC Unit: Dimitrios Spyropoulos, Hugues Kenigswald, Kim Rygaard Nielsen, Anne Theobald (scientific staff) - Maud Pâques (administrative staff)

Assessment Methodology Unit:

Billy Amzal (scientific support on item 7.1)

Communication Department – Press Unit:

Stephen Pagani

European Commission:

Fabbio D'Atri, Xavier Pavard, Olga Solomon, Mark Willis

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 on Food additives (7.1) and Flavourings (9).

4. MATTERS ARISING FROM THE 27TH PLENARY MEETING HELD ON 29-31 JANUARY 2008

4.1. Adoption of the minutes

The draft minutes were adopted. They can be seen on:

http://www.efsa.europa.eu/en/science/afc/afc_meetings/afc_27th_meeting.html

5. GENERAL INFORMATION FROM EFSA AND THE COMMISSION

None

6. FEEDBACK FROM RECENT MEETINGS OF THE SCIENTIFIC COMMITTEE, MANAGEMENT BOARD AND ADVISORY FORUM

The chair's note of the February Plenary of the Scientific Committee had been circulated for information.

7. FOOD ADDITIVES

7.1. Study from the Southampton University on the effect of some colours and benzoic acid on hyperactivity (EFSA-Q-2007-171)

Sue Barlow declared an indirect interest in this item as her partner has been a consultant on natural colours and therefore the Vice Chair, John C. Larsen, chaired this part of the meeting. She did not participate in the discussion.

Fernando Aguilar, Rainer Guertler, John C. Larsen and Iona Pratt declared an interest because they have been involved in preliminary discussions in their national institutes on the study. It was found that this was not a conflict of interest and they were invited to participate in the discussion.

David Gott declared a direct interest because he works for the Food Standards Agency (FSA) who commissioned the study and has participated in the Secretariat to the meetings of the Committee on Toxicity of the FSA where the results of the study were discussed. He did not participate in the discussion but was present to answer questions.

The rapporteur presented the draft opinion. An extensive and detailed discussion took place. Following suggested changes to the draft, the text was modified and adopted.

The Panel concluded that the McCann *et al.* study provides limited evidence that the two different mixtures of synthetic colours and sodium benzoate tested had a small and statistically significant effect on activity and attention in children selected from the general population excluding children medicated for ADHD, although the effects were not statistically significant for the two mixtures in both age groups.

Since mixtures and not individual additives were tested in the study by McCann *et al.*, it is not possible to ascribe the observed effects to any of the individual compounds.

The clinical significance of the observed effects also remains unclear, since it is not known whether these small alterations in attention and activity would interfere with schoolwork and other intellectual functioning.

In the context of the overall weight of evidence and in view of the considerable uncertainties, such as the lack of consistency and relative weakness of the effect and the absence of information on the clinical significance of the behavioural changes observed, the Panel concluded that the findings of the study cannot be used as a basis for altering the ADI of the respective food colours or sodium benzoate.

The Vice-Chair thanked the members of the ad hoc Working Group that had prepared the draft opinion.

7.2. Rosemary extracts (EFSA-Q-2003-140)

The rapporteur presented the draft opinion on rosemary extracts proposed for use as antioxidants. It was discussed, some changes were suggested and it was adopted.

The Panel concluded that toxicological data on the rosemary extracts are insufficient to establish a numerical ADI because the toxicity data set does not provide reproduction and developmental toxicity or long-term studies. On the other hand, the existing data, including the absence of effects in the 90-day studies on reproductive organs and a lack of genotoxicity, do not give reason for concern.

Potential dietary exposure to the main antioxidant components, carnosol plus carnosic acid, from rosemary extracts at the proposed uses and use levels have been estimated for adults and pre-school children (aged 1.5 to 4.5 years) and amount to respectively 0.04 and 0.11 mg carnosol plus carnosic acid/kg bw/day at the mean, 0.10 and 0.20 mg carnosol plus carnosic acid/kg bw/day at the 95th percentiles and 0.12 and 0.23 mg carnosol plus carnosic acid/kg bw/day at the 97.5th percentile.

The Panel noted that the margin between the NOAEL range in rat studies with all five extracts, of 180 to 400 mg extract/kg body weight/day amounting to 20-60 mg /kg bw /day of carnosol plus carnosic acid, and the exposure estimates for adults would range between 500-1500 for the mean intake values, between 200-600 for the 95th percentile values and between 167-500 for the 97.5th percentile values. For pre-school children these margins would amount to respectively at least 182-546, 100-300 and 88-261. The Panel noted that these margins of safety are conservative estimates since the NOAELs from the different studies were generally the highest dose levels tested, and the estimates of dietary exposure were conservative.

Based on the margins of safety identified the Panel concluded that the use of the rosemary extracts described in this opinion at the proposed uses and use levels would not be of safety concern.

8. NUTRIENT SOURCES

8.1. Processing of inadequate dossiers

A proposed draft statement on the inadequate dossiers that have been submitted on a large number of nutrient sources was discussed and will be considered for adoption at the next meeting.

9. FLAVOURINGS

Ivonne Rietjens declared that she is a member of the FEMA (Flavour and Extract Manufacturers Association) Expert Panel. Although this was not considered a direct conflict of interest for the

particular flavouring groups under evaluation at this meeting, it was decided that she should not participate in the discussion on these flavouring group evaluations.

9.1. Flavouring Group Evaluations (FGE)

9.1.1. *FGE.46 (EFSA-Q-2008-50)*

Ammonia and two ammonium salts from chemical group 30

The draft opinion was presented, discussed and proposed changes to the text were noted. As the Plenary was not in quorum at the time of finalisation, the opinion will be adopted, taking into account the proposed changes, by written procedure.

The full opinion will be published on:

http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm

9.1.2. *FGE.57 (Part of EFSA-Q-2004-049)*

Consideration of four substances structurally related to pulegone evaluated by JECFA (55th meeting)

The opinion was deferred back to the working group to address remarks from the Panel. The reference to pulegone has to be re-considered.

9.1.3. *FGE.73 (Part of EFSA-Q-2004-049)*

Consideration of alicyclic primary alcohols, aldehydes, acids and related esters evaluated by JECFA (59th meeting)

The draft opinion was presented and discussed. Minor revisions were proposed.

For three substances [FL-no: 02.141, 09.488 and 09.534] the JECFA evaluation is only based on Maximised Survey-derived Daily Intake (MSDI) values derived from production figures from the USA and two of these [FL-no: 02.141 and 09.534] are based on anticipated production figures. EU production figures are needed in order to finalise the evaluation of these substances.

For eight substances [FL-no: 02.114, 02.141, 05.098, 05.119, 05.123, 08.067, 09.289 and 09.615] information on the stereoisomeric composition is lacking and for another substance [FL-no: 05.112] further information on the composition is requested.

Thus, for 11 substances [FL-no: 02.114, 02.141, 05.098, 05.112, 05.119, 05.123, 08.067, 09.289, 09.488, 09.534 and 09.615] the Panel has reservations (only USA production volumes available and/or missing data on isomerism/composition). For the remaining four substances [FL-no: 08.034, 08.060, 09.028, 09.536] evaluated using the Procedure the Panel concluded that they would present no safety concern at the levels of intake estimated on the basis of the MSDI.

The opinion was adopted subject to the proposed changes. The full opinion will be published on:

http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm

9.1.4. ***FGE.78 (Part of EFSA-Q-2004-049)***

Consideration of Aliphatic and alicyclic and aromatic hydrocarbons evaluated by JECFA (63rd meeting)

The draft opinion was presented, discussed and proposed changes to the text were noted. As the Plenary was not in quorum at the time of finalisation, the opinion will be adopted, taking into account the proposed changes, by written procedure.

The full opinion will be published on:

http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm

9.1.5. ***FGE.88 (Part of EFSA-Q-2004-049)***

Consideration of Phenol and Phenol Derivatives evaluated by JECFA (55th meeting).

The draft opinion was presented, discussed and proposed changes to the text were noted. As the Plenary was not in quorum at the time of finalisation, the opinion will be adopted, taking into account the proposed changes, by written procedure.

The full opinion will be published on:

http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm

10. OTHER AREAS WITHIN THE REMIT OF THE AFC PANEL

10.1. Aluminium (EFSA-Q-2006-168)

Due to the lack of time this item was not discussed.

11. ANY OTHER BUSINESS

None