

Parma, 19 December 2007
EFSA/AFC/P_M25/MIN

**MINUTES OF THE 25th PLENARY MEETING
OF THE SCIENTIFIC PANEL ON
FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS
AND MATERIALS IN CONTACT WITH FOOD**

Held in Parma on 25-27 September 2007

Adopted on 27 November 2007 at the 26th plenary meeting

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**MINUTES OF THE 25th PLENARY MEETING
OF THE SCIENTIFIC PANEL ON
FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS
AND MATERIALS IN CONTACT WITH FOOD (AFC)
Held in Parma on 25-27 September 2007**

PARTICIPANTS

Panel Members:

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

Experts:

Alicja Mortensen

Apologies

Jean-Charles Leblanc, Catherine Leclercq, Ivonne Rietjens

EFSA

Torben Hallas-Møller (scientific co-ordinator of AFC Panel), Alexandre Feigenbaum (assistant scientific co-ordinator of AFC Panel), Hugues Kenigswald (assistant scientific co-ordinator of AFC Panel), Kim Rygaard Nielsen (assistant scientific co-ordinator of AFC Panel), Dimitrios Spyropoulos (assistant scientific co-ordinator of AFC Panel), Anne Theobald (assistant scientific co-ordinator of AFC Panel); Ilse Koenig (administrative assistant of AFC Panel), Stavroula Tasiopoulou, Maud Pâques (administrative secretary of AFC Panel).

Commission

Annette Schaefer (1st day via videoconference), (DG Health and Consumer Affairs).

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 item on food additives (7.1) and food contact materials (9.1 and 9.3).

4. MATTERS ARISING FROM THE 24TH PLENARY MEETING HELD ON 3-5 JULY 2007

4.1. Adoption of the minutes

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

http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Meetings424.htm

5. GENERAL INFORMATION FROM EFSA AND THE COMMISSION

The Panel was informed about the decision of 11 September of the Management Board asking the European Commission to split the AFC Panel into two separate Panels to overcome the ever increasing workload.

Following the decision EFSA has sent a request to the Commission to initiate the legal measures to make the split possible.

The Commission informed that the proposal would get priority.

The MB proposal can be seen on:

http://www.efsa.europa.eu/EFSA/DocumentSet/mb_32ndmeet_panel_afc_split_en_4_2.2.pdf

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

None

7. FOOD ADDITIVES

7.1. Study from the Southampton University on the effect of some colours and benzoic acid on hyperactivity

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.

John C. Larsen declared an interest because he has been involved in preliminary discussions in his Institute on the study. This was not considered as a conflict of interest.

Fernando Aguilar declared an interest because he is involved in the work on the study at AFSSA. This was not considered as a conflict of interest.

David Gott declared a direct interest because he works for the Food Standard 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.

Rainer Guertler declared an interest because he has been involved in the preparation of a statement by BfR on the study. This was not considered as a conflict of interest.

Iona Pratt declared an interest because she has been involved in discussions in the Food Safety Authority of Ireland on the study. This was not considered as a conflict of interest.

A preliminary discussion took place and it was concluded that a further detailed assessment of the study was necessary and that an ad hoc Working Group should be set up, to include additional expertise in the following fields: psychology and ADHD (Attention Deficit Hyperactivity Disorder), behaviour testing, statistics and allergy. The Panel identified a number of central issues which will be studied in depth, including the robustness of the study design and methodology, the statistical analysis, the role of genetic predisposition, and the clinical significance of the findings for individuals or the population in general. The Panel noted that the study carried out by Southampton University was the largest conducted so far on whether certain food additives may affect behaviour in children and has the potential to shed new light on this important question.

It was agreed that the re-evaluation of the 6 individual colours involved in the study will be taken as the first priority among all food colours unless serious concerns are identified for other food colours during the re-evaluation process.

7.2. Neotame (EFSA-Q-2003-137)

The Chair reminded the Panel of the history of the dossier and the extensive discussion that had taken place in February 2005 (10th meeting of the AFC Panel) and the need for further experimental studies on the possible formation of nitrosamine that had been expressed on that occasion.

The draft opinion was discussed and several modifications were suggested. With these modifications the opinion was adopted.

The hypothetical formation of nitrosamines in the gastrointestinal tract from reaction of nitrite with neotame and its major degradation product and/or metabolite NC-00751 has been considered by the Panel. No nitrosated neotame (NC-00799) and no nitrosated de-esterified neotame (NC- 00800) could be detected under simulated gastric juice conditions. Furthermore, both nitrosated compounds were synthesised and shown to be without mutagenic activity in the Ames test. In view of the high sensitivity of the Ames test, as performed, to genotoxic nitroso compounds, the Panel considered that nitrosation of neotame is unlikely and should it occur, is of no safety concern.

After considering all the data on stability, degradation products and toxicology for the proposed uses, the Panel concluded that neotame is not of safety concern with respect to the proposed uses as a sweetener and flavour enhancer.

The Panel established an Acceptable Daily Intake (ADI) of 0-2 mg/kg bw/day based on application of a 100-fold safety factor to the NOAEL of 200 mg/kg bw from a 52-week dog study where the adverse effect observed was the increased activity of alkaline phosphatase of hepatic origin.

Conservative estimates of dietary exposure both in adults and children suggest that it is very unlikely that the ADI would be exceeded at the proposed use levels.

The full opinion can be seen on:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178659409273.htm

7.3. **Beeswax (EFSA-Q-2006-021)**

This item was not discussed because of lack of time.

8. FLAVOURINGS

8.1. **Flavouring Group Evaluations (FGE)**

8.1.1. **FGE.25 (EFSA-Q-2003-168)**

Aliphatic and aromatic hydrocarbons from chemical group 31

The draft opinion was presented by J. Gry.

There was a discussion of the draft and it was referred back to the Flavouring Working Group Meeting and will be discussed again at the next Plenary Meeting in November 2007.

8.1.2. **FGE.05 Revision 1 (EFSA-Q-2003-148 revised)**

Esters of branched- and straight-chain aliphatic saturated primary alcohols and of one secondary alcohol, and branched- and straight-chain unsaturated carboxylic acids from chemical groups 1, 2 and 5

J. Gry presented the draft opinion, which was discussed and revisions were proposed. The opinion was adopted subject to these revisions.

The opinion was adopted. The full opinion will be published on:
http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm as an update of the previously adopted opinions on the respective FGEs.

8.1.3. **FGE.07 revision 1 (EFSA-Q-2003-150 revised)**

Saturated and unsaturated aliphatic secondary alcohols, ketones and esters of secondary alcohols and saturated linear or branched chain carboxylic acids from chemical group 5

The draft opinion was discussed and revisions were proposed. The opinion was adopted subject to these revisions.

The opinion was adopted. The full opinion will be published on:
http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm as an update of the previously adopted opinions on the respective FGEs.

8.1.4. **FGE.23 Revision 1 (EFSA-Q-2003-166 revised)**

Aliphatic, alicyclic and aromatic ethers including anisole derivatives from chemical groups 15, 16 and 26

J. Gry presented the draft opinion, which was discussed and minor editorial changes were proposed.

The opinion was adopted. The full opinion will be published on:
http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm as an update of the previously adopted opinions on the respective FGEs.

8.1.5. **FGE.24 Revision 1 (EFSA-Q-2003-167 revised)**

Pyridine, pyrrole, indole and quinoline derivatives from chemical group 28

J. Gry presented the draft opinion, which was discussed and minor editorial changes were proposed. The opinion will be adopted by written procedure, as the Plenary was not in quorum at the time of finalisation.

The full opinion will be published on:
http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm

8.1.6. **FGE.27**

One aromatic lactone from chemical group 11

J. Gry presented the draft opinion, which was discussed and minor revisions were proposed. The opinion was adopted subject to these revisions.

The opinion was adopted. The full opinion will be published on:
http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm

8.1.7. **FGE.34**

One quinoline derivative from chemical group 28

J. Gry presented the draft opinion, which was discussed. The FLAVIS Working Group was asked to take the Opinion back and search for any literature references for structural alerts for genotoxicity, due to lack of supporting substances, as well as lack of toxicity data and information on metabolism.

9. FOOD CONTACT MATERIALS

9.1. 2-isopropyl thioxanthone (ITX)

The following declarations of interest were made:

Sandro Grilli declared an interest because he had advised an Italian distribution company on ITX. He did not participate in the discussions.

Maria Rosaria Milana and Riccardo Crebelli declared an interest as they had advised their national risk management Authority. This was not considered as a conflict of interest and they were invited to participate in the discussions.

The Panel had been asked to revisit its previous opinion because of submission of a new 28-day study on the substance. Noting the short duration of the study and the effects observed, the Panel adopted a statement concluding that:

Bearing in mind the Panel's previous opinion that the existing *in vivo* genotoxicity studies do not indicate a genotoxic potential for ITX, an assessment of potential health risks in relation to the possible presence of ITX in food would require additional data on ITX effects after longer term administration in rodents.

The full statement can be seen at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178654267426.htm

9.2. Guidelines on submission of a dossier for evaluation by the EFSA of a recycling process aimed to produce safe recycled plastic materials and articles for food contact uses

The draft document was discussed and suggested changes were noted. A new draft will be re-discussed at the next Panel meeting.

9.3. Evaluation of substances for the 16th list of monomers and additives

Following declarations were made to this section:

Sandro Grilli declared an interest for the substance REF. No. 66755, 2-Methyl-4-isothiazolin-3-one because he had advised an Italian distribution company. He did not participate in the discussions.

Wolfgang Dekant declared an interest for the substances REF. No. 76723 and 76725 because he had discussions with the petitioner on a possible future collaboration. He did not participate in the discussions of these substances.

The draft opinions on the following substances were discussed, modified and adopted:

Ref. No.:	34130
Name of the substance:	Alkyl, linear with even number of carbon atoms (C12-C20) dimethylamines
CAS number:	-
Classified in list:	2
Restriction:	TDI = 0.5 mg/kg bw
Ref. No.:	37520
Name of the substance:	1,2-Benzisothiazolin-3-one
CAS number:	002634-33-5
Classified in list:	3
Restriction:	0.5 mg/kg food
Ref. No.:	39815
Name of the substance:	9,9-Bis(methoxymethyl)fluorene
CAS number:	182121-12-6
Classified in list:	3

Restriction:	0.05 mg/kg food
Ref. No.:	45703
Name of the substance:	cis-1,2-Cyclohexanedicarboxylic acid, calcium salt
CAS number:	491589-22-1
Classified in list:	3
Restriction:	5 mg/kg food
Ref. No.:	66755
Name of the substance:	2-Methyl-4-isothiazolin-3-one
CAS number:	2682-20-4
Classified in list:	3
Restriction:	0.5 mg/kg food
Ref. No.:	76463
Name of the substance:	Polyacrylic acid, sodium salt
CAS number:	9003-04-7
Classified in list:	3
Restriction:	None
Ref. No.:	76723
Name of the substance:	Polydimethylsiloxane, 3-aminopropyl terminated, polymer with dicyclohexylmethane- 4,4'-diisocyanate
CAS number:	167883-16-1
Classified in list:	3
Restriction:	None
Ref. No.:	76725
Name of the substance:	Polydimethylsiloxane, 3-aminopropyl terminated, polymer with 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane
CAS number:	661476-41-1
Classified in list:	3
Restriction:	None
Ref. No.:	86430
Name of the substance:	Silver chloride (20% w/w) coated onto titanium dioxide (80% w/w)
CAS number:	TiO ₂ : 013463-67-7 AgCl: 007783-90-6
Classified in list:	3
Restriction:	Group restriction of 0.05 mg Ag/kg food

The full opinions can be seen on the EFSA website at:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178652695290.htm

The opinions on the following substances were deferred to the next meeting:

REF. No 60027, Hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-decene and/or 1-dodecene and/or 1-tetradecene (MW: 440-12000) and

REF No 92475, 3,3',5,5'-tetrakis(tert-butyl)-2,2'-dihydroxybiphenyl, cyclic ester with [3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propyl]oxyphosphonous acid.

10. ANY OTHER BUSINESS

None