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THM/DS/HK/AT
EFSA/AFC/P_M19/MIN

**MINUTES OF THE 19TH PLENARY MEETING
OF THE SCIENTIFIC PANEL ON
FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS
AND MATERIALS IN CONTACT WITH FOOD**

Held in Parma on 26-28 September 2006

Adopted on 29 November 2006 in the 20th Plenary

AGENDA:

1.	Welcome; apologies for absence	3
2.	Adoption of the agenda	3
3.	Meeting with the Executive Director Catherine Geslain-Lanéelle	3
4.	Declarations of interest	4
5.	Matters arising from the 18th plenary meeting held on 13-15 June.....	4
6.	General information from EFSA and the Commission.....	4
7.	Feedback from recent meetings of the Scientific Committee, management board and advisory forum .	4
8.	Food additives	4
8.1.	<i>Cassia gum (EFSA-Q-2003-134)</i>	<i>4</i>
8.2.	<i>Polyethylene glycol (EFSA-Q-2005-277).....</i>	<i>5</i>
8.3.	<i>Nisin (addendum to EFSA-Q-2005-031).....</i>	<i>5</i>
8.4.	<i>L-cysteine as a flour treatment agent in bakery wares for infants and young children (EFSA-Q-2005-083).....</i>	<i>5</i>
8.5.	<i>Neotame (EFSA-Q-2003-137).....</i>	<i>5</i>
8.6.	<i>Re-evaluation of food colours</i>	<i>6</i>
9.	Nutrient Sources	6

9.1. Calcium, magnesium and zinc malate as a source of calcium, magnesium and zinc in food supplements and calcium malate as a source of calcium in PARNUTS and foods intended for the general population (EFSA-Q-2005-134, 145, 159 and EFSA-Q-2006-140	6
9.2. Magnesium potassium citrate (EFSA Q-2006-131)	7
10. Flavourings.....	7
10.1. FGE.22 (EFSA-Q-2003-165)	7
10.2. Smoke flavourings	7
11. Food contact materials	8
11.1. Bisphenol-A (EFSA-Q-2005-100)	8
11.2. Activated alumina treatment for the removal of fluoride from natural mineral waters. (EFSA-Q-2005-069).....	8
11.3. 12 th list of substances for food contact materials	8
12. Meeting days for 2007	10
13. Any other business.....	10

**MINUTES OF THE 19TH PLENARY MEETING
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FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS
AND MATERIALS IN CONTACT WITH FOOD (AFC)
Held in Parma on 26-28 September 2006**

PARTICIPANTS

Panel Members:

Fernando Aguilar, Susan Barlow (Chair), Riccardo Crebelli; Wolfgang Dekant (1st and 2nd day), Karl-Heinz Engel (Vice Chair), Nathalie Gontard, David Gott, Sandro Grilli (1st and 2nd day), Rainer Gürtler, John Christian Larsen (Vice Chair), Catherine Leclercq, Wim C. Mennes, Maria Rosaria Milana (1st and 2nd day), Iona Pratt (1st and 3rd day), Ivonne Rietjens, Paul Tobback, Fidel Toldrá (1st and 2nd day).

Experts:

J. Gry (item 10).

Apologies

Herman Autrup, Laurence Castle, Jean-Charles Leblanc, F. Xavier Malcata.

EFSA

Torben Hallas-Møller (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), Hanne Pedersen (administrative secretary of AFC Panel), Maud Pâques (administrative secretary of AFC Panel).

Commission

Xavier Pavard (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. MEETING WITH THE EXECUTIVE DIRECTOR CATHERINE GESLAIN-LANÉELLE

This part was postponed to the next Plenary meeting of the Panel in November.

4. DECLARATIONS OF INTEREST

The declarations concerning items on the agenda of this meeting are noted under the specific item on cassia gum (item 8.1), flavouring group evaluation (item 10.1) and food contact materials (bisphenol-A (item 11.1) and polyvinylpyrrolidone (11.3).

5. MATTERS ARISING FROM THE 18TH PLENARY MEETING HELD ON 13-15 JUNE

None.

The minutes can be seen on http://www.efsa.europa.eu/en/science/afc/afc_meetings/1529.html

6. GENERAL INFORMATION FROM EFSA AND THE COMMISSION

The Panel was informed that Hugues Kenigswald and Kim Rygaard Nielsen had joined the secretariat and they were briefly introduced.

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

The chair informed the Panel on the meeting of the Scientific Committee held on 14-15 September 2006.

The secretariat informed the Panel about the recent meetings of the Management Board and the Advisory Forum.

Minutes from the meetings of the Scientific Committee can be found on:

http://www.efsa.europa.eu/science/sc_committee/sc_meetings/catindex_en.html

Minutes from the Management Board meetings can be found on:

http://www.efsa.europa.eu/mboard/mb_meetings/catindex_en.html

Minutes from the Advisory Forum meeting held on 3 March can be found on:

http://www.efsa.europa.eu/advisory_forum/adv_meetings/catindex_en.html

8. FOOD ADDITIVES

8.1. Cassia gum (EFSA-Q-2003-134)

W. Dekant declared that he had advised the petitioner on the content on anthraquinones in cassia gum and it was therefore decided that he should not participate in the discussion on this substance.

The draft opinion was discussed and a number of revisions were agreed on the text. The opinion was adopted.

While the toxicological data on cassia gum are insufficient to establish an ADI, the Panel concluded that the use of cassia gum with the newly defined specifications as an additive for the proposed food uses (gelling agent and thickener) is not of safety concern.

The full opinion can be seen on http://www.efsa.europa.eu/en/science/afc/afc_opinions.html

8.2. **Polyethylene glycol (EFSA-Q-2005-277)**

The item was deferred to next meeting because of lack of time.

8.3. **Nisin (addendum to EFSA-Q-2005-031)**

The draft opinion was not discussed because of lack of time.

It was decided that because it is only a minor addendum to a previous opinion, the opinion will be adopted by written procedure.

The opinion can be seen on http://www.efsa.europa.eu/en/science/afc/afc_opinions.html

8.4. **L-cysteine as a flour treatment agent in bakery wares for infants and young children (EFSA-Q-2005-083)**

The draft opinion was discussed and a number of revisions were agreed on the text. The opinion was adopted.

The Terms of Reference referred to the use for technological purposes of L-cysteine in processed cereal based foods and foods for infants and young children but it appeared to the Panel that the use would be restricted to biscuits.

Based on the consideration that the estimated intake of L-cysteine by infants aged 3 – 12 months would be very low in comparison with the intake provided by the remainder of the child's diet, the Panel concluded that the use of L-cysteine for technological purposes in processed cereal-based foods and foods (specifically baby biscuits) for infants and young children is of no safety concern.

The Panel considers that the proposed use of L-cysteine to improve the texture of biscuits for infants and young children is not incompatible with previous advice of the SCF (that the addition of amino acids to foods intended for infants and young children should only be permitted for the purpose of improving the nutritional value of the foodstuff), given its intended application in achieving a product of suitable nutritional composition including a controlled content of sugar and fat.

The full opinion can be seen on http://www.efsa.europa.eu/en/science/afc/afc_opinions/ej390_L-Cysteine.html

8.5. **Neotame (EFSA-Q-2003-137)**

F. Aguilar declared an interest because he was a member of the secretariat of the French scientific committee which evaluated neotame as a food additive but it was considered not a conflict of interest.

The Panel discussed the additional data received and requested that the petitioner be informed of the discussion.

8.6. Re-evaluation of food colours

The general scheme of re-evaluation of food colours was discussed and the format for future reviews was approved.

The Panel agreed a list of data it would be useful to receive on the currently permitted colours during the re-evaluation process. A public call for such data will be launched by EFSA based on this recommendation:

1. Information concerning the availability of original study reports as evaluated by the SCF and JECFA. In first instance the actual reports should not be submitted, but where a specific study could be crucial for the re-evaluation the Panel may wish to request it at that stage.
2. Information on studies, concerning the safety of the colours, not forming part of the opinions of the SCF and JECFA; but only with respect to either data not published or data published in the open literature that would not be picked up by the most common search engines.
3. Information on the actual use of the food colours, including lakes (which food categories and subcategories, proportion of foods within categories/subcategories in which it is used, normal use levels as well as any maximum use levels, especially for those uses which are only limited by *quantum satis* (q.s.)).
4. Information on production methods (general description).
5. Information on the purity of colours currently in use (percentage of main content as well as impurities - special attention should be given to the content of aromatic amines when relevant (a mere reference to present specifications in the Directive is of no relevance)); also information on the content of aluminium (total as well as free and bound) in aluminium lakes is needed.
6. Information on analytical methods for determination in food.

9. NUTRIENT SOURCES

9.1. Calcium, magnesium and zinc malate as a source of calcium, magnesium and zinc in food supplements and calcium malate as a source of calcium in PARNUTS and foods intended for the general population (EFSA-Q-2005-134, 145, 159 and EFSA-Q-2006-140)

The draft opinion was discussed and a number of revisions were agreed on the text. The opinion was adopted.

The Panel concluded that the use of malates as a source of calcium, magnesium and zinc in food supplements and as a source of calcium in food for particular nutritional uses and foods intended for the general population is of no safety concern.

The Panel also concluded that the bioavailability of calcium, magnesium and zinc from malates is expected to be similar to their bioavailability from other dissociable calcium, magnesium and zinc salts permitted to be used in food supplements.

The full opinion can be seen on

http://www.efsa.europa.eu/en/science/afc/afc_opinions/ej391_malates.html

9.2. **Magnesium potassium citrate (EFSA Q-2006-131)**

The draft opinion was discussed and a number of revisions in accordance with the approach taken for the assessment of ferrous bisglycinate were agreed on the text. The opinion was adopted.

The Panel concluded that the use of magnesium potassium citrate as a source of magnesium and potassium in food supplements, food for particular nutritional uses and foods intended for the general population is of no safety concern.

The Panel also concluded that the bioavailability of magnesium and potassium from magnesium potassium citrate is expected to be similar to their bioavailability from other dissociable magnesium and potassium salts permitted to be used in food for particular nutritional uses and food supplements.

The full opinion can be seen on

http://www.efsa.europa.eu/en/science/afc/afc_opinions/ej392_potassium_magnesium_citrate.html

10. **FLAVOURINGS**

10.1. **FGE.22 (EFSA-Q-2003-165)**

I. Rietjens declared that she is a member of the FEMA (Flavour and Extract Manufacturers Association) Expert Panel. Although this was not considered of direct conflict it was decided that she should not participate in the discussion on this issue.

The draft opinion was presented by Dr. Gry and extensively discussed and several changes were suggested. Subject to these changes the draft opinion was adopted. The full opinion will be published on

http://www.efsa.eu.int/science/afc/afc_opinions/catindex_en.html

10.2. **Smoke flavourings**

The chairperson of the Working Group (WG) gave an overview of the current status of the evaluation process. After the completion of the validity check on the 16 submitted dossiers in November 2005 the applicants had been addressed with a request for additional clarification. The majority of responses were received by February 2006 and, following discussion with the Commission on application of the validity criteria, 13 dossiers were eligible for evaluation. The list of valid applications can be found at the Commission website:

http://ec.europa.eu/food/food/chemicalsafety/flavouring/list_valid_applications.pdf

The chairperson also brought forward the wish of the Working Group to prepare further clarifications and interpretation on the requirements for toxicological testing. The present

guidance document on the submission of a dossier on a Smoke Flavouring Primary Product requires three *in vitro* genotoxicity studies and one study on subchronic toxicity. It states also that in the event of positive results in any of the genotoxicity studies additional *in vivo* genotoxicity data may be required without referring explicitly to particular studies.

The Working Group will report back to the Panel at a later state on this issue.

11. FOOD CONTACT MATERIALS

11.1. Bisphenol-A (EFSA-Q-2005-100)

The following members of the Panel declared an interest:

Ivonne Rietjens because her associate professor carries out research on bisphenol-A funded by the Netherlands Organization for Health Research and Development. David Gott was a member of the secretariat in the English scientific committee which evaluated bisphenol-A. Maria Rosaria Milana has provided scientific advice to her national management authority on bisphenol-A.

None of these was considered as a conflict of interest and they were all invited to participate in the discussions.

The draft opinion was discussed and changes were proposed. Since a new 2-generation reproductive study on mice is expected to be submitted to the EFSA very shortly, the Panel decided to defer adoption of the opinion to the next meeting so that this study can also be included.

11.2. Activated alumina treatment for the removal of fluoride from natural mineral waters. (EFSA-Q-2005-069)

The draft was discussed and changes were introduced and the opinion was adopted.

The Panel concluded that the removal of fluoride from natural mineral waters by filtration over activated alumina can be safely applied provided the critical steps of the process are implemented and monitored appropriately.

The full opinion as adopted can be seen on the EFSA website at:

http://www.efsa.europa.eu/en/science/afc/afc_opinions/afc_op_ej394_fluoride.html

11.3. 12th list of substances for food contact materials

Fernando Aguilar declared an interest because he is a member of the secretariat of the French scientific committee which evaluated polyvinylpyrrolidone as a food processing aid.

This was not considered as a conflict of interest and he was invited to participate in the discussions.

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

Ref. No.:	45705
Name of the substance:	1,2-cyclohexyldicarboxylic acid, diisononyl ester
CAS number:	166412-78-8

Classified in list: 2
Restriction: TDI = 1 mg/kg bw/day

Ref. No.: 81500
Name of the substance: Polyvinylpyrrolidone
CAS number: 9003-39-8
Classified in list: 3
Restriction: None

Ref. No.: 86432/20, 86432/40 and 86432/60
Name of the substance: - Silver containing glass (silver-magnesium-aluminium-phosphate-silicate), silver content less than 2%.
- Silver containing glass (silver-magnesium-aluminium-sodium-phosphate-silicate-borate), silver content less than 0.5%
- Silver containing glass (silver-magnesium-sodium-phosphate), silver content less than 3 %
CAS number: -
Classified in list: 3
Restriction: In accordance with other silver biocides these biocides will be subject to a group SML of 0.05 mg Ag/kg food

In accordance with other boron compounds the biocide Ref No 86432/40 will be subject to a group SML of 6 mg B/kg food

Ref. No.: 95020
Name of the substance: 2,2,4-Trimethyl-1,3-pentanediol diisobutyrate
CAS number: 6846-50-0
Classified in list: 3
Restriction: 5 mg/kg food

Ref. No.: 95420
Name of the substance: 1,3,5-tris(2,2-dimethylpropanamido)benzene
CAS number: 745070-61-5
Classified in list: 3
Restriction: 0.05 mg/kg food

The full opinion as adopted can be seen on the EFSA website at:
http://www.efsa.europa.eu/en/science/afc/afc_opinions/ej395-401_12FCM_list.html

The opinions on the following substances were deferred to the next meeting due to the lack of time:

REF No 72081/10	Petroleum hydrocarbon resins (hydrogenated)
REF No 79985	Poly(ethylene propylene)glycol tridecyl ether
REF No 19180	Isophthalic acid dichloride
REF No 48960	9,10-dihydroxy stearic acid and its oligomers

12. MEETING DAYS FOR 2007

The following meeting dates were agreed for 2007 (Panel and working groups)

These dates may be subject to modification.

AFC Panel Plenary	6-8 Feb	17-19 Apr	3-5 July	25-27 Sep	27-29 Nov
Additive WG	27 Feb – 1 Mar	29-31 May	17-19 July	4-6 Sep	6-8 Nov
Flavouring WG	17-19 Jan	27-28 Mar	5-7 June	10-12 Sep	13-15 Nov
Smoke flavouring WG	11-12 Jan	13-14 Mar			
Food Contact Material WG	16-17 Jan	19-21 Feb	22-24 May	12-14 Sep	13-15 Nov
FLAVIS WG	30 Jan – 1 Feb	14-16 Mar	21-23 May	29-31 August	29-31 Oct

13. ANY OTHER BUSINESS

None