



**MINUTES OF THE 15TH PLENARY MEETING
OF THE SCIENTIFIC PANEL ON
FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS
AND MATERIALS IN CONTACT WITH FOOD**

**Held in Parma on 24-26 January 2006
Adopted on 14 February by written procedure**

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AND MATERIALS IN CONTACT WITH FOOD (AFC)
Held in Parma on 24-26 January 2006**

PARTICIPANTS

Panel Members:

Susan Barlow (Chair); Dimitrios Boskou, Laurence Castle; Riccardo Crebelli; Wolfgang Dekant; Karl-Heinz Engel; Stephen Forsythe (2nd and 3rd day); Werner Grunow (2nd vice chair), John Christian Larsen (1st vice chair) (2nd and 3rd day); Catherine Leclercq; Wim C. Mennes; Ivonne Rietjens; Kjetil Svendsen; Paul Tobback; Fidel Toldrá

Apologies

Robert Anton, Marina Heinonen; Maria Rosaria Milana; Iona Pratt

EFSA

Torben Hallas-Møller (scientific co-ordinator of AFC Panel), Dimitrios Spyropoulos (assistant scientific co-ordinator of AFC Panel); Anne Theobald (assistant scientific co-ordinator of AFC Panel); Maud Pâques, (administrative secretary of AFC Panel); Ilse Koenig (administrative assistant of AFC Panel), Carola Sonderman (senior press officer) (item 4 and 10.1), Marta Hugas (BIOHAZ) (item 7.1)

Commission (DG Health and Consumer Affairs)

Lucia Pena Alberdi. Telephone conference: Helen Lee (item 7.1)

1. WELCOME, APOLOGIES FOR ABSENCE

The Chair welcomed the Participants.

Apologies were noted.

2. ADOPTION OF THE AGENDA

The agenda was adopted.

3. DECLARATIONS OF INTEREST

These are noted under the specific item on ITX (item 4.) and bisphenol-A (item 10.1).

4. MATTERS ARISING FROM THE 14TH PLENARY MEETING ON 5-7 DECEMBER 2005

Action points were noted. The minutes were adopted and can be seen on http://www.efsa.eu.int/science/afc/afc_meetings/1239_en.html

The following issues were raised concerning matters on the agenda of the 14th meeting:

4.1. **Isopropylthioxanthone (ITX) and 2-ethylhexyl-4-dimethylaminobenzoate (EHDAB) (Q-2005-240 and 241)**

Ivonne Rietjens declared an interest because she acts as a consultant to the company Nestlé. This was considered a conflict of interest and she was asked to leave the room during the discussions. Boskou, Forsythe, Larsen and Svensson were not yet present at this part of the meeting

The Panel had a discussion on the risk communications aspects of the ITX opinion.

4.2. **10th list of FCM substances (REF No 80480):**

REF No 80480, Poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)-imino]

The Panel was informed by the petitioner of a proposed testing plan to address the issues that were raised by the Panel in its opinion of September 2005. On the understanding that this work will progress quickly the Panel reclassified the substance into List 7 pending submission of the new data.

5. GENERAL INFORMATION FROM EFSA AND THE COMMISSION

The secretariat informed about a recent meeting between EFSA and DG RTD. Members were encouraged to send in any comments on the proposed 7th Framework Programme to be passed on to the SC secretariat.

L. Pena Alberdi informed the Panel of the changes in the structure of DG SANCO. Of changes most relevant to the Panel she mentioned that the unit dealing with food additives, flavourings and food contact materials is now called E3 Chemicals, contaminants, pesticides; and the unit dealing with nutrient substances E4 Food law, nutrition and labelling. The previous Interface unit (D5) is now called 03 Science and Stakeholder relations.

The new structure can be seen on http://europa.eu.int/comm/dgs/health_consumer/chart.pdf

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

The Chair reported on the meeting of the Scientific Committee held on 12-13 December.

Minutes from the Scientific Committee can be seen on:

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

The secretariat reported on the meetings of the Management Board taking place on 15 December and on the same day as the Panel's meeting (24 January).

Minutes from the MB meetings can be found on:

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

There have been no meetings of the Advisory Forum since the last Plenary meeting of the Panel.

7. FOOD ADDITIVES

7.1. Nisin as a food additive (Q-2005-031)

The draft opinion was presented by the rapporteur and the working group Chair and was extensively discussed. With the inclusion of the suggested changes the opinion was adopted.

The Panel re-evaluated the available toxicity data and concluded that nisin can be used safely. The Panel did not find any new data that would warrant any change of the previously established SCF ADI of 0.13 mg nisin/kg bw/day.

Nisin is only used as a food preservative and has currently no therapeutic use. Sporadic nisin resistant mutants do not show any cross-resistance to therapeutic antibiotics. The Panel considered that this is probably due to the differences in the antimicrobial mode of action between therapeutic antibiotics and nisin and that the development of antibiotic resistance is not of concern in relation to the use of nisin in food.

The full opinion can be seen on

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

7.2. Aspartame (Q-2005-122)

The Panel was informed that the Working Group had had its first meeting and that it is anticipated that a draft opinion will be presented at the Panel's meeting scheduled for 2-4 May. The item was not discussed.

7.3. E 473 sucrose esters of fatty acids – revision (Q-2003-139)

The Panel has been requested to reconsider the basis for its opinion of October 2004, in which an ADI was allocated covering products containing no more than 1% of tetra and higher esters. While the product tested in the human tolerance study contained only 1%, the product used as a basis for setting the ADI contained up to 10% tetra and higher esters. The Panel therefore agrees that the ADI should cover products of sucrose esters of fatty acids with a content of up to 10% tetra and higher esters. The opinion will be modified accordingly.

The Panel also noted that at one place in the summary of the opinion it is stated that the ADI was set at 30 mg/kg bw/day. This is a printing error and will be corrected to 40 mg/kg bw/day, the value given in the conclusion of the opinion.

8. SUBSTANCES USED AS NUTRIENT SOURCES

8.1. Lutein for use in food for particular nutritional uses (EFSA-Q-2003-128)

The question had been on hold for some time while the legal status of its use was clarified by the Commission and the Member States.

The draft opinion was presented by the rapporteur and was extensively discussed. Based on the fact that it is presently permitted as a food colour and on the submitted further data, the Panel concluded that the use of lutein in food for special medical purposes (FSMP) is not of concern from a safety point of view, provided that it is in compliance with the existing EU specifications for the food additive, and with the use levels suggested by the petitioner, which would result in intakes that are in the range of a regular dietary intake of lutein.

The Panel was not able to evaluate the general use of lutein in foods for particular nutritional uses since no information was provided on proposed uses and use levels other than for FSMP.

The full opinion can be seen on

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

8.2. **Status of incoming food supplement dossiers to date**

The Additives Working Group informed about the progress in the WG.

An updated list of submitted requests can be found on the Commission website:

http://europa.eu.int/comm/food/food/labellingnutrition/supplements/food_supplements.pdf

9. **FLAVOURINGS**

9.1. **Flavouring group evaluations**

9.1.1. *FGE.26. Amino acids from chemical group 34*

The working group chair highlighted areas of special interest, but the draft was not discussed in detail because of lack of time.

9.2. **Smoke flavourings**

The chair of the Working Group on Smoke Flavourings informed that all applications have had a preliminary evaluation and the petitioners have been contacted for supplementary information. A meeting in the WG is planned for 23 February, where the dossiers will be discussed in detail.

10. **FOOD CONTACT MATERIALS**

10.1. **Bisphenol-A (Q-2005-100)**

The following members expressed an interest: Wim Mennes participated at EU level in discussions for the Existing Substances Regulation (EC 793/93). Ivonne Rietjens because her associate professor carries out research on bisphenol-A funded by national science foundation. Laurence Castle because his laboratory has performed analyses on bisphenol-A. None of these were considered as a conflict of interest and they were all invited to participate in the discussions.

A first discussion of the draft opinion, focusing on the toxicological aspects, took place. Proposed changes were noted and the rapporteur will present the new draft to the next Plenary. Due to the large number of studies from the international literature examined in the opinion and the need to consider also the exposure section in detail at the next Plenary, it is envisaged that the opinion is unlikely to be adopted at the March meeting, as initially planned, but rather at the May Plenary.

10.2. 11th list of substances for food contact materials

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

Ref. No.:	21970
Name of the substance:	N-Methylolmethacrylamide
CAS number:	00923-02-4
Classified in list:	3
Restriction:	0.05 mg/kg food
Ref. No.:	62020
Name of the substance:	12-Hydroxystearic acid, lithium salt
CAS number:	7620-77-1
Classified in list:	3
Restriction:	In accordance with other lithium compounds this will be subject to a group SML of 0.6 mg Li/kg food
Ref. No.:	79920
Name of the substance:	Poly(ethylene propylene) glycol
CAS number:	009003-11-6 and 106392-12-5
Classified in list:	3
Restriction:	None

The full opinion as adopted can be seen on
http://www.efsa.eu.int/science/afc/afc_opinions/catindex_en.html

11. WORKING PROGRAMME

The updated register of questions can be seen on the EFSA website at
http://www.efsa.eu.int/register/qr_panels_en.html.

12. ANY OTHER BUSINESS

There was no further business.