



Parma, 12 December 2005  
EFSA/THM/AT/DS  
EFSA/AFC/P\_M13/MIN-final

**MINUTES OF THE 13<sup>TH</sup> PLENARY MEETING  
OF THE SCIENTIFIC PANEL ON  
FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS  
AND MATERIALS IN CONTACT WITH FOOD  
Held in Parma on 4-6 October 2005**

(The minutes were adopted on 5 December 2005 at the 14<sup>th</sup> Plenary meeting)

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OF THE SCIENTIFIC PANEL ON  
FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS  
AND MATERIALS IN CONTACT WITH FOOD (AFC)  
Held in Parma on 4-6 October 2005**

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**PARTICIPANTS**

Panel Members:

Susan Barlow (Chair); Laurence Castle; Riccardo Crebelli; Wolfgang Dekant (from 2<sup>nd</sup> day); Karl-Heinz Engel; Marina Heinonen (1<sup>st</sup> and 2<sup>nd</sup> day); John Christian Larsen (1<sup>st</sup> vice chair); Catherine Leclercq (1<sup>st</sup> and 2<sup>nd</sup> day); Wim C. Mennes; Maria Rosaria Milana; Iona Pratt; Ivonne Rietjens, Kettil Svensson; Paul Tobback; Fidel Toldrá (1<sup>st</sup> and 2<sup>nd</sup> day)

Experts

Jørn Gry (2<sup>nd</sup> and 3<sup>rd</sup> day)

Apologies

Robert Anton, Dimitrios Boskou, Werner Grunow, Stephen Forsythe

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, Hanne Pedersen (administrative secretaries of AFC Panel); Ilse Koenig (administrative assistant of AFC Panel)

Commission

Not present

**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 the 10<sup>th</sup> list of substances for food contact materials (item 10.2)

**4. MATTERS ARISING FROM THE 12<sup>TH</sup> PLENARY MEETING ON 28-30 JUNE 2005**

Action points were noted. The minutes were adopted and can be seen on  
[http://www.efsa.eu.int/science/afc/afc\\_meetings/991/afc\\_minutes\\_plen12\\_en\\_web1.pdf](http://www.efsa.eu.int/science/afc/afc_meetings/991/afc_minutes_plen12_en_web1.pdf)

## **5. GENERAL INFORMATION FROM EFSA AND THE COMMISSION**

The Members of the Plenary meeting were informed on current calls for expression of interest for recruitment of the Executive Director since G. Podger will be leaving EFSA at the end of November. Calls have also been launched for additional scientific staff to reinforce the AFC Secretariat. All calls were recently published and the expected time line for recruitment of the Executive Director as well as the AFC additional scientific staff will be the first semester of 2006.

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

The Chair informed Members of the 14<sup>th</sup> meeting of the Scientific Committee (SC) held on 15-16 September 2005.

Main issues were:

The presentation of the progress report on the identification and creation of a network of key sources to support EFSA in the identification of emerging risks.

Continuing concern on the extensive travel for meetings back and forth to Parma.

The representative from DG SANCO Interface Unit informed about the problems with setting deadlines and that within SANCO they are trying to streamline and fine-tune the setting of Commission deadlines.

In accordance with Art. 36 of Regulation (EC) No. 178/2002 a call for tender has been launched for organisations and institutes wishing to be registered as part of the cooperative network assisting EFSA in its tasks.

A number of new mandates and working groups for the Scientific Committee has been discussed and approved.

Further details can be found in the minutes from the SC meeting:

[http://www.efsa.eu.int/science/sc\\_committee/sc\\_meetings/1132\\_en.html](http://www.efsa.eu.int/science/sc_committee/sc_meetings/1132_en.html)

Members were informed of the MB held on 13 September in Parma.

Members were informed of the AF of 29 September held in Cyprus where the illegal dyes issue was discussed. Also the presence of lead and cadmium in ceramics was a topic for consideration.

## **7. FOOD ADDITIVES**

### **7.1. Lycopene from *Blakeslea trispora* as a food colour (EFSA-Q-2004-102)**

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

Whilst the toxicity data on lycopene from *B. trispora* and on lycopene from tomatoes do not give indications for concern it should be borne in mind these data are limited and do not allow establishing of an Acceptable Daily Intake (ADI). The Panel notes that the range for potential additional intake from the proposed use levels as a food colour exceeds the range for the mean intake from natural dietary sources by a considerable margin. Therefore, without further safety data, the Panel is unable to conclude whether the proposed use levels of lycopene from *B. trispora* as a food colour would be safe.

The full opinion can be found at

[http://www.efsa.eu.int/science/afc/afc\\_opinions/1231\\_en.html](http://www.efsa.eu.int/science/afc/afc_opinions/1231_en.html)

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

The Panel was informed about the difficulties in obtaining direct answers to its latest queries. The general view was that without a direct answer an opinion could be adopted leaving this question open.

### **7.3. Aspartame (EFSA-Q-2005-122)**

The Panel was informed that the Ramazzini Institute had held a conference where the results on the aspartame study were presented, but no data were presented which were not already presented earlier this year. It will therefore be necessary to await the promised raw data from the institute before an evaluation of the new data can be performed. An ad hoc working group under the Food Additive working group is being created and the secretariat is contacting external experts to ask for their willingness to participate in such a working group as soon as the promised data will be transmitted.

## **8. SUBSTANCES USED AS NUTRIENT SOURCES**

### **8.1. Ferrous bisglycinate as a source of iron for use in food and food supplements (EFSA-Q-2004-039)**

The rapporteur introduced a draft opinion and there was extensive discussion of this draft. A number of modifications were suggested and several clarifications of the draft opinion were requested. The members were asked to send their comments and suggestions to the rapporteur, who would revise the draft in line with these comments for discussion at the next Plenary in December.

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

Since the last Plenary meeting more requests for evaluation of food supplements were submitted by the Commission. It is understood that all dossiers have been sent to EFSA and the secretariat will provide an overview of the ca. 200 dossiers received as well as the around 200 substances for which names were also submitted, but without a proper dossier. It is

foreseen that EFSA will set priorities for the evaluation process after consultation with the Commission.

An up-dated list of submitted requests can be found on the Commission website:  
[http://europa.eu.int/comm/food/food/labellingnutrition/supplements/food\\_supplements.pdf](http://europa.eu.int/comm/food/food/labellingnutrition/supplements/food_supplements.pdf)

## **9. FLAVOURINGS**

### **9.1. Flavouring group evaluations**

#### **9.1.1. *FGE16 Furfuryl and furan derivatives with and without additional side-chain substituents and heteroatoms from chemical group 14***

The draft opinion was introduced by the Flavis Chair. There was extensive discussion of the draft. A number of substantive changes to the text were agreed, together with a number of editorial changes. The draft opinion will be revised in the light of the discussions and will be sent for final adoption at a later Plenary meeting.

### **9.2. Smoke flavourings**

The chair of the newly formed Working Group reported back from the first meeting on smoke flavourings. After initial consultations among the rapporteurs it has been decided to complete the assessment of the validity of the dossiers only after response from the petitioners. The information contained in the dossiers required often explanatory notes and the petitioners will be given the opportunity to clarify certain points.

The Working group will report back at the next Plenary meeting.

## **10. FOOD CONTACT MATERIALS**

### **10.1. REF No 25552 Epoxy Phenolic Novolac Resins (NOGE)**

The draft opinion was discussed and a number of revisions were agreed to the text on the first day of the meeting. On the third day the document was re-discussed and subject to the introduction of other revisions the opinion was adopted.

The Panel had been asked to advise the Commission on the implications for human health of the use of Epoxy Phenolic Novolac Resins (Novolac Glycidyl Ether, NOGE) as starting substance only for special coatings, called “heavy duty coatings”, applied to containers having a capacity of more than 10000 liters and to pipelines connected to them.

In this opinion the Panel considered three recent *in vivo* mutagenicity studies carried out with a low molecular weight commercial NOGE containing high percentages of oligomers with molecular weight below 1000 Daltons (D) and bisphenol-F-diglycidyl ether (BFDGE), which

can be considered as the lowest molecular weight component of NOGE. The material was tested in a transgenic rodent system with the analysis of mutations in the liver and the forestomach, in the rat liver unscheduled DNA synthesis (UDS) assay and in the mouse bone marrow micronucleus test. Negative results were obtained in all three studies following the administration of NOGE oligomers and BFDGE up to the highest recommended dose level.

Based on the examined data, the Panel concluded that the oligomeric fraction of NOGE with molecular weight below 1000 D and BFDGE are not genotoxic *in vivo*. Considering the lack of genotoxicity and the information on specific migration from heavy duty coatings provided by the applicant showing that migration is  $\leq 50 \mu\text{g/kg}$  food, the Panel concluded that the use of NOGE as a starting substance in heavy duty epoxy coatings is not of concern from a safety point of view.

The full opinion can be found at:

[http://www.efsa.eu.int/science/afc/afc\\_opinions/1184\\_en.html](http://www.efsa.eu.int/science/afc/afc_opinions/1184_en.html)

## 10.2. 10<sup>th</sup> list of substances for food contact materials

S. Barlow, L. Castle and M. R. Milana declared an interest for the opinion on the substance tri-n-butyl acetyl citrate, REF No. 93760 because in the past they had advised their national authorities. In addition, L. Castle had also published, more than 10 years ago, studies on the migration of the substance into foodstuffs.

None of these was considered conflict of interest and they were invited to participate in the discussion.

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

Ref. No.:	12786
Name of the substance:	3-Aminopropyltriethoxysilane
CAS number:	000919-30-2
Classified in list:	3
Restriction:	0.05 mg/kg food when used for the surface treatment of materials and articles
Ref. No.:	13618
Name of the substance:	1,2-Bis(triethoxysilyl)ethane
CAS number:	016068-37-4
Classified in list:	3
Restriction:	0.05 mg/kg food; used for the surface treatment of materials and articles
Ref. No.:	16450
Name of the substance:	1,3-Dioxolane
CAS number:	00646-06-0
Classified in list:	3
Restriction:	5 mg/kg food
Ref. No.:	19112

Name of the substance:	1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane homopolymer, methyl ethyl ketone oxime-blocked
CAS number:	103170-26-9
Classified in list:	3
Restriction:	0.05 mg/kg food for the blocked trimer Only to be used for thermoset can coatings
Ref. No.:	24886
Name of the substance:	5-Sulphoisophthalic acid, monolithium salt
CAS number:	46728-75-0
Classified in list:	3
Restriction:	5 mg/kg food
Ref. No.:	25900
Name of the substance:	1,3,5-Trioxane
CAS number:	110-88-3
Classified in list:	3
Restriction:	5 mg/kg food
Ref. No.:	38885
Name of the substance:	2,4-Bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine
CAS number:	002725-22-6
Classified in list:	3
Restriction:	0.05 mg/kg food
Ref. No.:	80480
Name of the substance:	Poly(6-morpholino-1,3,5-triazine-2,4-diyl)-(2,2,6,6-tetramethyl-4-piperidyl)imino)hexa-methylene-(2,2,6,6-tetramethyl-4-piperidyl)imino)
CAS number:	90751-07-8
Classified in list:	5
Restriction:	
Ref. No.:	93760
Name of the substance:	Tri-n-butyl acetyl citrate
CAS number:	000077-90-7
Classified in list:	2
Restriction:	TDI: 1.0 mg/kg bw
Ref. No.:	93970
Name of the substance:	Tricyclodecane dimethanol-bis(hexahydrophthalate)
CAS number:	-
Classified in list:	3
Restriction:	0.05 mg/kg food

The full opinion can be found at:  
[http://www.efsa.eu.int/science/afc/afc\\_opinions/1192\\_en.html](http://www.efsa.eu.int/science/afc/afc_opinions/1192_en.html)



## **11. OTHER ISSUES**

### **11.1. Procedure**

Because of the large and ever increasing workload for the AFC Panel various options for introducing a simplified procedure for presenting draft opinions to the Plenary was discussed. It was agreed that draft opinions, not expected to be of special concern, could be sent in advance to the members for written comments thus reducing the time of discussions during the adoption of the opinion at the Plenary.

## **12. WORKING PROGRAMME AND MEETING DAYS IN 2006**

The Panel endorsed the suggestions from the working groups for meeting days in the first half of next year until the end of the present mandate. The meeting days of the Panel (together with the Plenary meetings, which were decided at previous meeting) will thus be:

AFC Panel Plenary	24-26 January	28 February-2 March	2-4 May
Additive WG	10-12 January	21-23 March	
Flavouring WG	5-6 January	8-10 March	10-12 May
Smoke flavouring WG	23 February	To be decided	
Food Contact Material WG	8-10 February	17-19 May	
FLAVIS WG	15-17 February	5-7 April	

The updated register of questions can be seen on the EFSA website at [http://www.efsa.eu.int/register/qr\\_panels\\_en.html](http://www.efsa.eu.int/register/qr_panels_en.html).

## **13. ANY OTHER BUSINESS**

There was no further business.