



**MINUTES OF THE 9<sup>TH</sup> PLENARY MEETING  
OF THE SCIENTIFIC PANEL ON  
FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS  
AND MATERIALS IN CONTACT WITH FOOD  
Held in Brussels on 7-9 December 2004  
(the minutes were adopted on 22 February 2005)**

**AGENDA:**

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<b>1. Welcome, apologies for absence .....</b>	<b>3</b>
<b>2. Adoption of the agenda .....</b>	<b>3</b>
<b>3. Declarations of interest .....</b>	<b>3</b>
<b>4. Matters arising from the 8<sup>th</sup> plenary meeting on 5-7 October 2004.....</b>	<b>4</b>
<b>5. General information from EFSA and the Commission.....</b>	<b>4</b>
<b>6. Feedback from recent meetings of the Scientific Committee, Management board and advisory forum.....</b>	<b>4</b>
<b>7. Food additives.....</b>	<b>5</b>
7.1. <i>Propan-2-ol</i> .....	5
7.2. <i>Neotame</i> .....	5
7.3. <i>Titanium dioxide</i> .....	5
<b>8. Substances used as nutrient sources .....</b>	<b>6</b>
8.1. <i>Boric acid and sodium borate</i> .....	6
8.2. <i>Magnesium aspartate</i> .....	6
<b>9. Flavourings .....</b>	<b>6</b>
9.1. <i>Pulegone and menthofuran</i> .....	6
9.2. <i>Flavouring group evaluations</i> .....	7
9.2.1. FGE07 Saturated and unsaturated aliphatic secondary alcohols, ketones and esters of secondary alcohols and saturated linear or branched-chain carboxylic acids from chemical group 5	7

9.2.2.	FGE.09 Secondary alicyclic saturated and unsaturated alcohols, ketones and esters containing secondary alicyclic alcohols from chemical groups 8 .....	8
9.2.3.	FGE11 Aliphatic dialcohols, diketones, and hydroxyketones from chemical group 10 9 .....	9
9.2.4.	FGE.19 Draft proposal for alpha,beta-unsaturated carbonyl substances and their precursors in the Register .....	10
<b>10.</b>	<b>Food contact materials .....</b>	<b>10</b>
10.1.	<i>Mineral oils in jute and sisal bags.</i> .....	10
10.2.	<i>Di-butyl phthalate (DBP) REF No 74880.</i> .....	11
10.3.	<i>Butylbenzyl phthalate (BBP) REF No 74560.</i> .....	11
10.4.	<i>Bis (2-ethylhexyl) phthalate (DEHP) REF No 74640.</i> .....	11
10.5.	<i>6<sup>th</sup> list of substances for food contact materials.</i> .....	11
10.5.1.	Acrylic acid, methyl ester, telomer with 1-dodecanethiol, C16-C18 alkyl esters; REF No 31542 .....	11
10.5.2.	2,4-Bis(dodecylthiomethyl)-6-methylphenol; REF No 38940 .....	12
10.5.3.	Iron Phosphide; REF No 62245 .....	12
10.5.4.	Maleic anhydride-styrene, copolymer, sodium salt; REF No 64990 .....	12
10.5.5.	Mono-n-dodecyltin tris(isooctyl mercaptoacetate)/ Di-n-dodecyltin bis(isooctyl mercaptoacetate); REF No 67360/47600 .....	12
10.5.6.	Petroleum hydrocarbon resins (hydrogenated); REF No 72081/10 .....	12
10.5.7.	Polyester of adipic acid with glycerol or pentaerythritol, esters with even numbered unbranched C12-C22 fatty acids; REF No 76815 .....	12
10.5.8.	Polyethyleneglycol tridecyl ether phosphate; REF No 79600 .....	12
10.5.9.	Silver Zeolite A (Silver zinc sodium ammonium alumino silicate), silver content 2 – 5 %; REF No 86437 .....	12
10.5.10.	Silver-zinc- aluminium – boron – phosphate glass, mixed with 5-20% barium sulphate, silver content 0.35 – 0.6 %; REF No 86437/50 .....	12
<b>11.</b>	<b>Semicarbazide .....</b>	<b>12</b>
<b>12.</b>	<b>Working programme .....</b>	<b>13</b>
<b>13.</b>	<b>Any other business .....</b>	<b>13</b>

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FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS  
AND MATERIALS IN CONTACT WITH FOOD (AFC)  
Held in Brussels on 7-9 December 2004**

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## **PARTICIPANTS**

### Panel Members:

Robert Anton (1<sup>st</sup> day and 2<sup>nd</sup> day), Susan Barlow (chair); Dimitrios Boskou; Laurence Castle; Riccardo Crebelli; Wolfgang Dekant (1<sup>st</sup> day); Karl-Heinz Engel; Werner Grunow (2<sup>nd</sup> vice chair); Marina Heinonen; John Christian Larsen (1<sup>st</sup> vice chair); Wim C. Mennes; Maria Rosaria Milana, Iona Pratt; Ivonne Rietjens (2<sup>nd</sup> day), Kjetil Svendsen; Paul Tobback; Fidel Toldrá (3<sup>rd</sup> day).

### Experts

Jean-Claude Lhuguenot (2<sup>nd</sup> day); Jørn Gry; Detlef Woefle (2<sup>nd</sup> day); Alicja Mortensen (1<sup>st</sup> day).

### Apologies

Stephen Forsythe; Catherine Leclercq;

### EFSA

Torben Hallas-Møller (scientific co-ordinator of AFC Panel), Dimitrios Spyropoulos (assistant scientific co-ordinator of AFC Panel); David Gott (assistant scientific co-ordinator of AFC Panel); Hanne Pedersen and Sandra Desmedt; (administrative secretaries of AFC Panel); Ilse Koenig (administrative assistant of AFC Panel).

### Commission

Almut Bitterhof; Annette Schäfer (1<sup>st</sup> day); Wim Debeuckelaere (2<sup>nd</sup> and 3<sup>rd</sup> day); Helen Lee (3<sup>rd</sup> day); Olga Solomons (1<sup>st</sup> and 3<sup>rd</sup> day); Rosella Brazzi (1<sup>st</sup> day) (DG Health and Consumer Protection).

## **1. WELCOME, APOLOGIES FOR ABSENCE**

The Chair welcomed the members and others attending from EFSA and the Commission.  
Apologies were noted.

## **2. ADOPTION OF THE AGENDA**

The agenda was adopted.

## **3. DECLARATIONS OF INTEREST**

These are noted under the specific items on boron (item 8.1) and phthalates (item 10.2-4). Members were reminded of the need to complete their annual declaration of interest at their earliest opportunity. Members were informed that Friends of the Earth had recently published a report on the interests declared by the GMO Panel and that this report was scheduled to be discussed by the Management Board. EFSA's position continued to be that a declaration of

interest did not necessarily indicate a conflict of interest. Members pointed out that certain EU research funding required industrial participation in the project and the Secretariat would raise this issue with EFSA Management.

#### **4. MATTERS ARISING FROM THE 8<sup>TH</sup> PLENARY MEETING ON 5-7 OCTOBER 2004**

Action points were noted.

The Chair informed Members of EFSA's rationale for the release of a press release on the flavouring group evaluations.

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

The relocation of EFSA to Parma had commenced in November and the AFC Secretariat was still scheduled to move in March.

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

A brief report was tabled to inform members of the main items discussed at the meetings of the Scientific Committee held since AFC last met. Members' attention was particularly drawn to two points in this report of the last Scientific Committee meeting, namely suggestions for research proposals for the 7<sup>th</sup> Framework Programme of DG Research and the progress on botanicals. The botanicals paper had been adopted and a strategy for commencing work in this area would be discussed at the next Scientific Committee meeting. Initial work was likely to commence next year, and the Chair of the Scientific Committee hoped that relevant experts on the AFC Panel would contribute to the work. Copies of the DG Research presentation on the 7<sup>th</sup> Framework Programme were circulated and the Chair asked for any suggestions before the next Scientific Committee meeting. Members were surprised at the lack of enthusiasm from some Panel Chairs for the proposed role of EFSA's Scientific Expert Services in drafting documents for the Panels. It was noted that the Secretariat had produced several documents for AFC Working Groups and the Panel which had helped manage the workload and demands on Members. Members hoped that this support could be increased by greater input from EFSA's Scientific Expert Services. The Chair would continue to represent these views at forthcoming Scientific Committee meetings. Members also noted that they required more support with literature searches and supply of relevant papers, the Chair would raise the issue of additional library services at the next Scientific Committee meeting.

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

[http://www.efsa.eu.int/science/sc\\_committee/sc\\_meetings/517/sc\\_meet08\\_minutes\\_en1.pdf](http://www.efsa.eu.int/science/sc_committee/sc_meetings/517/sc_meet08_minutes_en1.pdf)

The Management Board had met in Parma in September. The Management Board had discussed quorum at their recent meeting, the Secretariat would inform Members of any relevant developments

[http://www.efsa.eu.int/mboard/mb\\_meetings/479\\_en.html](http://www.efsa.eu.int/mboard/mb_meetings/479_en.html)

The Advisory Forum had held a meeting, workshop and stakeholder colloquium in Berlin. A number of interesting issues had been raised including use of the benchmark dose, the challenges of risk communication to consumers especially when risk managers are still developing their proposals and examples of risk benefit evaluations for folic acid and fish. There had been criticism on EFSA from non-governmental organisations particularly over GMO issues and declarations of interest. EFSA had robustly supported the principle that having an interest did not necessarily mean there was a conflict of interest.

## **7. FOOD ADDITIVES**

### **7.1. Propan-2-ol.**

There was insufficient time to discuss the revised draft opinion and this item was deferred until the next meeting.

### **7.2. Neotame**

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. It was agreed that the rapporteur should revise the draft in line with these comments for discussion at the next Plenary.

### **7.3. Titanium dioxide**

The Secretariat introduced a draft opinion and there was extensive discussion and revision of this draft. The opinion was adopted subject to these revisions.

The Scientific Panel has been asked to evaluate the safety in use of rutile titanium dioxide in the platelet form as an alternative to the presently permitted anatase form.

Titanium dioxide is an approved food colour with an ADI “not specified” by JECFA. The 1969 JECFA assessment based this on the lack of significant absorption and tissue storage in several species including humans. In the European Union, Titanium Dioxide (E171) is listed in Annex I of Directive 94/36/EEC as a permitted colour in foodstuffs. Titanium dioxide can be manufactured to form two structures, anatase and rutile. The current specification for titanium dioxide in Directive 94/36 only permits the anatase form. The JECFA specification for titanium dioxide allows both forms.

The Panel considered that the rutile and anatase forms of titanium dioxide were similar chemically but differed in their crystalline structure and light reflectance. The Panel agreed that a new study showed that bioavailability of these forms was essentially the same and that therefore the toxicological database would be applicable to either form. The Panel noted that although estimated exposures were provided for the petitioner’s proposed uses of the platelet form of rutile titanium dioxide, the platelet form of rutile titanium dioxide could be used to replace anatase titanium dioxide in any of its current applications.

The full opinion can be found at

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

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

### **8.1. Boric acid and sodium borate**

The Chair indicated that she had an indirect interest in boric acid and sodium borate and would therefore vacate the Chair in favour of the 1<sup>st</sup> Vice Chair. Iona Pratt also declared an interest in boric acid and sodium borate having advised the Commission on the Classification and Labelling of boron. None of these were considered conflicts of interest by the 1<sup>st</sup> Vice Chair and both were invited to participate in the discussion.

The Secretariat introduced a draft statement on boric acid and sodium borate as nutrient sources, which was adopted following discussion and amendment of the draft (see Annex 1).

### **8.2. Magnesium aspartate**

The Secretariat introduced a draft opinion and there was extensive discussion and revision of this draft. It was agreed that this opinion should be adopted by the written procedure.

The Panel has been asked to advise on the safety and bioavailability of the substance magnesium-L-aspartate when used as a source of magnesium in dietary foods for special medical purposes.

The Panel concluded that magnesium L-aspartate showed similar bioavailability to other organic magnesium salts and the more soluble inorganic magnesium salts. The Panel concluded that the use of magnesium-L-aspartate as a source of magnesium in dietary foods for special medical purposes is not of safety concern at the proposed levels of usage. The Panel concluded that there would be no safety concern from aspartate at the proposed usage levels.

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

## **9. FLAVOURINGS**

### **9.1. Pulegone and menthofuran**

John Christian Larsen declared an interest as he had been involved in the JECFA evaluations of pulegone. This was not considered to be a conflict of interest and it was decided that this interest would not prevent him participating fully in the discussion.

Members were reminded that this opinion had previously been circulated for the written procedure during which new data on the metabolism of the compounds considered to require reconsideration of the draft opinion had been uncovered, the draft opinion had therefore been withdrawn and revised. The revised draft opinion was introduced and there was extensive discussion of this draft. A number of substantive changes to the text were agreed, together with a number of editorial changes. It was agreed to consider the draft with the agreed amendments at a later Plenary meeting.

## 9.2. Flavouring group evaluations

The opinions on the following flavouring group evaluations were introduced by the rapporteur. There was extensive discussion of these drafts. A number of substantive changes to the text were agreed, together with a number of editorial changes. The Chair of the Flavourings Working Group, the Flavis Secretariat and the Panel Secretariat would revise the documents and insert consequent changes into future flavouring group evaluations.

### 9.2.1. *FGE07 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 opinion was adopted.

Thirty-three of the flavouring substances in the present group of 35 flavouring substances have been reported to occur naturally in a wide range of food items.

On the basis of the default MSDI approach it was considered that these 35 flavouring substances would not give rise to safety concerns at the estimated levels of intake arising from their use as flavouring substances.

When the estimated intakes were based on the mTAMDI they range from 1563 to 3724 microgram/person/day for the 23 flavouring substances from structural class I, which are all above the threshold of concern for the structural class I of 1800 microgram/person/day except for two flavouring substances. For the 12 flavouring substances from structural class II the mTAMDI range from 1423 to 1563 microgram/person/day, which are all above the threshold of concern for structural class II of 540 microgram/person/day. The two substances, which have mTAMDI intake estimates below the threshold of concern for structural class I, are also expected to be metabolised to innocuous products.

Thus for 33 of the 35 flavouring substances considered in this opinion the intakes, estimated on the basis of the mTAMDI, exceed the relevant threshold for their structural class, to which the flavouring substance has been assigned. Therefore, for these 33 substances more reliable exposure data are required. On the basis of such additional data, these flavouring substances should be reconsidered along the steps of the Procedure. Following this procedure additional toxicological data might become necessary.

In order to determine whether this evaluation could be applied to the materials of commerce, it is necessary to consider the available specifications:

Adequate specifications including complete purity criteria and identity tests for the materials of commerce have been provided for the 35 flavouring substances, except that information on stereoisomerism is missing for nine of the substances. Thus, the final evaluation of the materials of commerce cannot be performed for these nine substances, pending further information.

The full opinion can be found at

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

9.2.2. *FGE.09 Secondary alicyclic saturated and unsaturated alcohols, ketones and esters containing secondary alicyclic alcohols from chemical groups 8*

The opinion was adopted.

The present Flavouring Group Evaluation deals with nine secondary alicyclic saturated and unsaturated alcohols, ketones and esters containing secondary alicyclic alcohols, and one ester of a phenol carboxylic acid and a secondary alicyclic alcohol.

It was considered that on the basis of the default MSDI approach nine of the ten candidate substances would not give rise to safety concerns at the estimated levels of intake arising from their use as flavouring substances. For cyclotetradecanone the evaluation has been deferred as additional data on toxicokinetics and/or toxicology are required.

When the estimated intakes were based on the mTAMDI they ranged from 405 to 3724 microgram/person/day for the eight flavouring substances from structural class I. Thus, the intakes were below the threshold of concern for structural class I of 1800 microgram/person/day, except for two candidate substances. The estimated intakes of the two flavouring substances assigned to structural class II, based on the mTAMDI are 1563 and 3724 microgram/person/day, which are above the threshold of concern for structural class II of 540 microgram/person/day. The six substances, which have mTAMDI intake estimates below the threshold of concern for structural class I, are also expected to be metabolised to innocuous products.

Thus for four of the ten flavouring substances considered in this opinion the intakes, estimated on the basis of the mTAMDI, exceed the relevant threshold for their structural class, to which the flavouring substance has been assigned. Therefore, for these four substances more reliable exposure data are required. On the basis of such additional data, these flavouring substances should be reconsidered along the steps of the Procedure. Following this procedure additional toxicological data might become necessary.

In order to determine whether this evaluation could be applied to the material of commerce, it is necessary to consider the available specifications.

Adequate specifications including complete purity criteria and identity tests for the materials of commerce have been provided for nine candidate flavouring substances, except that information on chirality is missing for five of the substances. The specification for menthyl salicylate is also deficient in one further parameter required. Thus, the final evaluation of the materials of commerce cannot be performed for five substances, pending further information.

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

### 9.2.3. FGE11 Aliphatic dialcohols, diketones, and hydroxyketones from chemical group 10

The opinion was adopted.

The present Flavouring Group Evaluation deals with six flavouring substances, alpha- and beta-diketones, one related ketal, hydroxyketones, and diols.

One flavouring substance, pentan-2,4-dione [FL-no: 07.191], is genotoxic *in vitro* and *in vivo*. Accordingly, its use as chemically defined flavouring substance is toxicologically not acceptable. Among the substances in this flavouring group, only pentan-2,4-dione [FL-no: 07.191] exhibits the structural feature of a methylene group which is activated due to its position between two carbonyl groups. Concerning the five other flavouring substances, the number of genotoxicity studies which can be considered as valid is very limited, however, the data which are available for some structurally related substances do not give rise to safety concern with respect to genotoxicity.

On the basis of the default MSDI approach it was considered that the five substances would not give rise to safety concerns at the estimated levels of intake arising from their use as flavouring substances.

When the estimated intakes were based on the mTAMDI they ranged from 1543 to 3724 microgram/person/day for the three flavouring substances from structural class I. Thus, the intake is above the threshold of concern for structural class I of 1800 microgram/person/day for one flavouring substance, and below for the two flavouring substances. For each of the three other flavouring substances assigned to structural class II, the estimated intake based on the mTAMDI is 1543 microgram/person/day, which is above the threshold of concern for structural class II of 540 microgram/person/day. The two substances, which have mTAMDI intake estimates below the threshold of concern for structural class I, are also expected to be metabolised to innocuous products.

Thus for three of the five flavouring substances considered in this opinion the intakes, estimated on the basis of the mTAMDI, exceed the relevant threshold for their structural class, to which the flavouring substance has been assigned. Therefore, for these three substances more reliable exposure data are required. On the basis of such additional data, these flavouring substances should be reconsidered along the steps of the Procedure. Following this procedure additional toxicological data might become necessary.

In order to determine whether this evaluation could be applied to the material of commerce for the flavouring substances, it is necessary to consider the available specifications. Adequate specifications including complete purity criteria and identity tests for the materials of commerce have been provided for all six flavouring substances.

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

#### 9.2.4. *FGE.19 Draft proposal for alpha,beta-unsaturated carbonyl substances and their precursors in the Register*

The candidate and supporting substances in this proposed flavouring group are proposed to be subdivided into the following structurally related groups;

Straight- and branched-chain aliphatic alpha,beta-unsaturated primary and secondary alcohols, aldehydes and ketones including hydrolysis products of acetals, esters and lactones of these

Alicyclic and heterocyclic alpha,beta-unsaturated substances with the alpha,beta-conjugation in the ring or in the side chain

Cinnamyl derivatives and other aromatic alkyl substituted substances with and without conjugation of the alpha,beta-unsaturation with the ring system

Furan derivatives with alpha,beta-unsaturation in the ring system or in side chains.

It was agreed that a strategy for addressing this diverse group be developed by the Flavourings Working Group, who were asked to consider commencing with a smaller representative selection from the group.

## **10. FOOD CONTACT MATERIALS**

### **10.1. Mineral oils in jute and sisal bags.**

The rapporteur introduced a draft opinion and there was extensive discussion of this draft. A large number of revisions were agreed to the text and subject to these revisions the opinion was adopted. The Secretariat produced a revised draft during the meeting

The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) has been asked to give an opinion on the use of mineral oils in jute bags. The Panel has chosen to include in its assessment the use of these oils in sisal bags as well.

Jute and sisal bags are used to transport raw materials, plants and fruit used for food production. In the manufacturing of jute and sisal bags, the use of batching oils is needed to soften the fibres before spinning. When semivolatile mineral hydrocarbons are present in batching oils, these may be transferred from the fibres to the food transported in the bags by evaporation and recondensation.

The International Jute Organisation (IJO) currently recommends that batching oil shall only contain non-toxic ingredients and it shall not contain compounds that produce off-flavours or off-tastes in food. The IJO also specifies limits for the presence of unsaponifiable material in the bags (less than 1250 mg/kg jute fibre). If these specifications for unsaponifiable residues in the bags are followed, the use of mineral oils as batching oils, and thus contamination of food, is effectively ruled out and the release of semivolatile mineral hydrocarbons from jute and sisal bags is expected to be significantly reduced. If the proposed specifications are followed, human exposure to semivolatile mineral hydrocarbons from jute and sisal bags is estimated to be well below the temporary Acceptable Daily Intake (ADI) for mineral hydrocarbons set by the Scientific Committee on Food in 1995. Adherence to the specifications can be monitored in the producing countries with simple laboratory equipment.

Adherence to the IJO specifications would result in a major reduction of human exposure to mineral hydrocarbons from food packaged in jute and sisal bags and in this aspect no further purity criteria are necessary.

The use of edible rice-bran oil or palm oil would not result in food contamination with semivolatile mineral hydrocarbons. However, more detailed specifications on batching oils said to be “based on” rice-bran oil or palm oil are needed for a full assessment of potential effects of such oils on human health.

The full opinion can be found at

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

#### 10.2. **Di-butyl phthalate (DBP) REF No 74880**

The Chair indicated that she had an indirect interest in phthalates and would therefore vacate the Chair in favour of the 1<sup>st</sup> Vice Chair. Following consultation with the Deputy Executive Director, it was decided that although this was not a conflict of interest the Chair should not participate in the discussion. Interests (advising national authorities or the Commission, or conducting studies on phthalates) were also declared by the following Members; Laurence Castle, Wim Mennes; Maria Rosaria Milana and Iona Pratt. None of these were considered conflicts of interest by the 1<sup>st</sup> Vice Chair and all were invited to participate in the discussion.

The rapporteur introduced the draft opinion and there was extensive discussion of this draft. A number of substantive changes to the text were requested, together with a number of significant editorial changes. It was agreed that a small group of Panel Members [Werner Grunow; John Christian Larsen; Catherine Leclercq; Wim Mennes; Iona Pratt; Ivonne Rietjens] would comment on the revised text by e-mail prior to reconsideration at the next Plenary. It was agreed that the other phthalate opinions should then be revised in line with these comments by the Working Group before being submitted to subsequent Plenaries.

#### 10.3. **Butylbenzyl phthalate (BBP) REF No 74560**

There was insufficient time to discuss the revised draft opinion and this item was deferred until after finalisation of the di-butyl phthalate at the next meeting.

#### 10.4. **Bis (2-ethylhexyl) phthalate (DEHP) REF No 74640**

There was insufficient time to discuss the revised draft opinion and this item was deferred until after finalisation of the di-butyl phthalate at the next meeting.

#### 10.5. **6<sup>th</sup> list of substances for food contact materials**

The draft opinion on the following substances was modified as follows and adopted.

##### 10.5.1. *Acrylic acid, methyl ester, telomer with 1-dodecanethiol, C16-C18 alkyl esters; REF No 31542*

This substance (CAS number 174254-23-0) was classified in SCF List 3 with the following restriction: 0.5% w/w in the final article.

10.5.2. *2,4-Bis(dodecylthiomethyl)-6-methylphenol; REF No 38940*

This substance (CAS number 116075-26-8) was classified in SCF List 3 with the following group restriction: 5mg/kg food as the sum of 2,4-bis(dodecylthiomethyl)-6-methylphenol and 2,4-bis(octylthiomethyl)-6-methylphenol.

10.5.3. *Iron Phosphide; REF No 62245*

This substance (CAS number 12751-22-3) was classified in SCF List 3 with no restriction as it is an inert insoluble material.

10.5.4. *Maleic anhydride-styrene, copolymer, sodium salt; REF No 64990*

This substance (CAS number 25736-61-2) was classified in SCF List 3 with no restriction.

10.5.5. *Mono-n-dodecyltin tris(isooctyl mercaptoacetate)/ Di-n-dodecyltin bis(isooctyl mercaptoacetate); REF No 67360/47600*

There was insufficient time to discuss this item and it was deferred until the next meeting.

10.5.6. *Petroleum hydrocarbon resins (hydrogenated); REF No 72081/10*

This substance (CAS number 088526-47-0) was discussed and a number of points regarding accumulation in the absence of toxicity identified which required further consideration. These should be considered at the FCM WG and revised text prepared for a subsequent Plenary.

10.5.7. *Polyester of adipic acid with glycerol or pentaerythritol, esters with even numbered unbranched C12-C22 fatty acids; REF No 76815*

This substance (CAS number not assigned for the group of substances) was classified in SCF List 3 with no restriction but with the following specification: Fraction with molecular weight below 1000D less than 5%.

10.5.8. *Polyethyleneglycol tridecyl ether phosphate; REF No 79600*

This substance (CAS number 9046-01-9) was classified in SCF List 3 with a restriction of 5 mg/kg food.

10.5.9. *Silver Zeolite A (Silver zinc sodium ammonium alumino silicate), silver content 2 – 5 %; REF No 86437*

There was insufficient time to discuss this item and it was deferred until the next meeting.

10.5.10. *Silver-zinc- aluminium – boron – phosphate glass, mixed with 5-20% barium sulphate, silver content 0.35 – 0.6 %; REF No 86437/50*

There was insufficient time to discuss this item and it was deferred until the next meeting.

## 11. SEMICARBAZIDE

The Chair of the Joint Working Group updated the Panel on progress and the anticipated timetable for completion of the draft. It was anticipated that the first draft of opinion would be discussed at the February Plenary meeting.

## **12. WORKING PROGRAMME**

Since the last meeting of the Panel the following questions have been received from the Commission. There had been 9 petitions for evaluation and re-evaluations of substances in FCM. A question has been received on nonivamide, a chemically defined flavouring substance which appears to be similar to the banned flavouring substance capsaicin.

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.

MINUTES OF THE 9<sup>TH</sup> PLENARY MEETING OF THE SCIENTIFIC PANEL ON  
FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS AND MATERIALS IN  
CONTACT WITH FOOD

Held in Brussels on 7-9 December 2004

Annex 1.

**Statement of the Scientific Panel on Food Additives, Flavourings, Processing  
Aids and Materials in Contact with Food on a request from the Commission  
related to**

**Boric Acid and Sodium borate as nutrient sources of boron**

Question number EFSA-2003-017

**(adopted on 8 December 2004)**

The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) has been asked to advise on the safety of boric acid and sodium borate as sources of boron in foods for particular nutritional uses (FPNUs), food supplements and foods intended for the general population.

The Scientific Panel on Nutrition, Dietetic Foods and Allergy (NDA) has recently issued an opinion on the tolerable upper intake level (UL) for boron (available at [http://www.efsa.eu.int/science/nda/nda\\_opinions/529\\_en.html](http://www.efsa.eu.int/science/nda/nda_opinions/529_en.html)). Since the NDA Panel opinion covers the two relevant forms of boron, the AFC Panel has based its advice on the NDA Panel opinion.

In nature boron is found only in compounds, for example with sodium and oxygen as sodium borate. In aqueous solution at near-neutral pH, monomeric boric acid is the most common species

present, regardless of whether the boron source is boric acid ( $\text{H}_3\text{BO}_3$ ) or borate ( $\text{B}_4\text{O}_7^{2-}$ ). Boron occurs in food as borate or boric acid.

The Panel noted the NDA Panel Opinion on the tolerable upper intake level (UL) of boron (sodium borate and boric acid). This opinion derived an UL of 10 mg/person/day for adults based on the most sensitive end-point detected in animal studies, i.e. the NOAEL for decreased fetal body weight in rats following maternal exposure during pregnancy.

This UL values applies to the intake of boron in the form of boric acid and borates. Based on its consideration of the safety of these substances, the Panel considers, on the basis of safety that boric acid and sodium borate are suitable for use in foods for particular nutritional uses (FPNUs), food supplements and foods intended for the general population providing the UL is not exceeded.

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