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MINUTES OF THE 22nd PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS AND MATERIALS IN CONTACT WITH FOOD

Held in Parma on 17-19 April 2007

Adopted on 16 May 2007 at 23rd Plenary meeting

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MINUTES OF THE 22nd PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS AND MATERIALS IN CONTACT WITH FOOD (AFC) Held in Parma on 17-19 April 2007

PARTICIPANTS

Panel Members:
Fernando Aguilar, Herman Autrup, Susan Barlow (Chair), Laurence Castle, Riccardo Crebelli; Wolfgang Dekant (2nd day), Karl-Heinz Engel (Vice Chair), David Gott, Sandro Grilli (1st and 2nd day), Rainer Gürtler (1st and 2nd day), John Christian Larsen (Vice Chair), Jean-Charles Leblanc, Catherine Leclercq (1st and 2nd day), F. Xavier Malcata, Wim C. Mennes, Maria Rosaria Milana, Ivonne Rietjens (1st and 3rd day).

Experts:
Jørn Gry (item 9.3).

Apologies
Nathalie Gontard, Iona Pratt, Paul Tobback, Fidel Toldrá.

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), Nicoletta Manghi (administrative secretary of AFC Panel), Maud Pâques (administrative secretary of AFC Panel).

Commission
Xavier Pavard (DG Health and Consumer Affairs), (videoconference), Wim Debeuckelaere (DG Health and Consumer Affairs), (item 9, video conference), Joana Antunes (DG Health and Consumer Affairs), (item 10, video conference).

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 (item 7.1) and flavouring group evaluation (item 9.3).

4. MATTERS ARISING FROM THE 21ST PLENARY MEETING HELD ON 6-8 FEBRUARY 2007

4.1. Adoption of the minutes

The minutes were adopted and can be seen on http://www.efsa.europa.eu/etc/medialib/efsa/science/afc/afc_meetings/afc_21st_meeting.Par.0002.File.dat/afc_minutes_21st_plenmeet_en.pdf

5. GENERAL INFORMATION FROM EFSA AND THE COMMISSION

None.

6. 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 15-16 February 2007.

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

At the Management Board meeting held in Berlin on 27 March the Panel Chair Sue Barlow gave a presentation on the work of the Panel and pointed out the large number of questions the Panel receives and offered some possible solutions which could ameliorate this backlog.

Minutes from the meetings of the Scientific Committee can be found on: http://www.efsa.europa.eu/science/sc_commitee/sc_meetings/catindex_en.html

Minutes from the Management Board meeting held on 27 March can be found on: http://www.efsa.europa.eu/en/mboard/mb_meetings/mb_30th_meeting.html

Minutes from the Advisory Forum meeting held on 8-9 February can be found on http://www.efsa.europa.eu/etc/medialib/efsa/advisory_forum/adv_meetings/af_21st_meeting.Par.0009.File.dat/af_minutes_%2020thmeet_en.pdf

7. FOOD ADDITIVES

7.1. Ethyl lauroyl arginate **(EFSA Q-2006-035)**

Sue Barlow declared an indirect interest in this substance and therefore the Vice Chair, Karl-Heinz Engel chaired this part of the meeting. She was not present during the discussions. It was also noted that she had not taken part in any discussions on this substance in the Additive's Working Group.

The draft opinion was discussed and several modifications were suggested. With these modifications the opinion was adopted subject to final confirmation by written procedure.

The Panel established an ADI of 0.5 mg/kg bw for ethyl lauroyl arginate conform to the proposed specifications. This ADI has been derived using a safety factor of 100 from a NOAEL of 3200 mg test formulation /kg diet amounting to 47 and 56 mg ethyl lauroyl

arginate /kg bw/day for males and females respectively in a 13-week rat study where effects on white blood cell counts and alopecia were observed.

Potential dietary exposure to ethyl lauroyl arginate was estimated based on UK food consumption data and on the assumption that it would be present in all food categories for which use levels are proposed.

Potential dietary exposure was found to be at or above the ADI in high consumers for both children aged 1.5 to 4.5 (580% of the ADI), children aged 4 to 18 (370% of the ADI) and adults (100% of the ADI). Potential mean dietary exposure to ethyl lauroyl arginate in consumers only was also at or above the ADI for both children aged 1.5 to 4.5 (170% of the ADI) and children aged 4 to 18 (106% of the ADI).

Therefore the Panel concluded that at the proposed uses and use levels, ethyl lauroyl arginate could be of safety concern.

The opinion will be published on
http://www.efsa.eu.int/science/afc/afc opinions/catindex_en.html

7.2. Guar gum, partially hydrolysed (EFSA Q-2006-122)

The draft opinion was discussed and was referred back to the Additives Working Group to address a new question that was raised.

7.3. Allura red AC (E 129) (Part of the re-evaluation process on food colours)

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

8. NUTRIENT SOURCES

8.1. D-alpha-tocopheryl polyethylene glycol 1000 succinate (TPGS) in use for food for particular nutritional purposes (EFSA-Q-2003-126)

The draft opinion was discussed and was adopted with some modifications.

TPGS is designed to provide tocopherol (vitamin E) in a water soluble form. It is only to be used for food for special medical purposes under medical supervision

From toxicology studies, an overall no-observed-adverse-effect level (NOAEL) of 1000 mg/kg bw/day can be derived.

The Panel concluded that in the absence of genotoxic effects the safety of TPGS can be assessed on the basis of the overall NOAEL equivalent to 1000 mg TPGS/kg body weight per day, established in a subchronic toxicity study in rats. Estimated intakes vary from 5 mg TPGS /kg bw in teenagers to 13 mg TPGS /kg bw in 1 month old infants. Potential intake would be lower in adults. This provides an adequate margin of safety (ratio between the NOAEL and the intake) of 80 to 200 for infants and young children. The Panel also noted that these estimated intakes of TPGS would correspond to intakes of polyethylene glycol-1000 at levels equivalent to 3.3 – 8.5 mg/kg bw/day. This is within the range of the group Acceptable Daily Intakes established by the EC Scientific Committee on Food (5 mg/kg bw for

polyethylene glycols 300 - 4000) and the Joint FAO/WHO Expert Committee on Food Additives (10 mg/kg bw for polyethylene glycols 200 - 10000).

The Panel therefore concluded that the use of TPGS in foods for special medical purposes is not of safety concern at the anticipated exposure level.

However, the Panel noted that others have advised that TPGS treatment should not be used for children with severe impairment of kidney function.

The Panel also noted that in studies in normal healthy humans, showed that the administration of TPGS, in contrast to fat-soluble vitamin E sources, only slightly elevated the plasma α-tocopherol level. Therefore, TPGS is not a useful source of vitamin E in healthy humans with a normal fat absorption.

8.2. Calcium ascorbate with a content of threonate for use as a nutritional substance as a source of vitamin C in food supplements (EFSA Q-2005-044)

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

The Panel noted that threonate is a normal metabolite in the body and concluded that the use of calcium ascorbate containing up to 2% threonate as a source of vitamin C in food supplements is not of safety concern.

The Panel noted that the bioavailability of vitamin C from calcium ascorbate with a content of threonate is comparable to that of ascorbic acid.

9. FLAVOURINGS

9.1. Camphor (EFSA-Q-2003-144)

Discussion deferred to next plenary on 15-16 May because of lack of time.

9.2. Smoke flavouring

The Panel discussed a draft opinion on a smoke flavouring primary product (PP) called FF-B.

This draft opinion was brought forward from 13 valid applications on smoke flavourings, currently under evaluation by the Panel, which have been submitted in accordance with the Regulation on smoke flavouring (regulation2065/2003 of 10 November 2003). In the draft opinion based on all available scientific evidence including *in vivo* (animal) genotoxicity studies, the Panel concluded that the product can be regarded as weakly genotoxic *in vivo* (that is, it can damage DNA, the genetic material in cells). Therefore the Panel considered that its safety in use when added to food cannot be established.

As the Panel was not quorate during the discussion it was not possible to formally adopt the opinion during the meeting and it was therefore designated to adopt it by written procedure.

Post meeting note:

On the 23 April EFSA was informed that the manufacturer had withdrawn the product from the EU market and therefore also withdrew its application.

Consequently EFSA no longer has as formal mandate to give an opinion according to the smoke flavour regulation.

9.3. Flavouring Group Evaluations (FGE)

I. Rietjens declared that she is a member of the FEMA (Flavour and Extract Manufacturers Association) Expert Panel. Although this was not considered a direct conflict of interest for the particular flavouring groups under evaluation at this meeting, it was decided that she should not participate in the discussion on flavouring group evaluations.

9.3.1. FGE.03-revised (EFSA-Q-2003-146 revised)

Acetals of branched- and straight-chain aliphatic saturated primary alcohols and branched- and straight-chain saturated or unsaturated aldehydes, and an orthoester of formic acid from chemical groups 1, 2 and 4

The draft opinion was presented by J. Gry. There were minor comments to the draft opinion, which was adopted.

The full opinion will be published on
http://www.efsa.eu.int/science/afc/afc opinions/catindex_en.html

9.3.2. FGE.11-revised (EFSA-Q-2003-154 revised)

Aliphatic dialcohols, diketones, and hydroxyketones from chemical group 10

The draft opinion was presented by J. Gry. There were comments to the draft opinion, which was adopted.

The full opinion will be published on
http://www.efsa.eu.int/science/afc/afc opinions/catindex_en.html as an update of the previously adopted opinions on the respective FGEs.

9.3.3. FGE.12 Revised (EFSA-Q-2003-155-revised)

Primary saturated or unsaturated alicyclic alcohols, aldehydes and esters from chemical group 7

J. Gry presented the draft opinion, which was adopted.

The full opinion will be published on
http://www.efsa.eu.int/science/afc/afc opinions/catindex_en.html as an update of the previously adopted opinions on the respective FGEs.

9.3.4. Review of JECFA evaluations of flavourings since 2000 (EFSA-Q-2004-049)

According to the provisions in Commission Regulation (EC) No 1565/2000 EFSA has been requested by the European Commission to consider JECFA's evaluations of flavourings substances assessed since 2000, and to decide whether further evaluation would be necessary. It has been decided to divide these evaluations into groups (FGE.50 and onwards), which can be compared to the Flavouring Group Evaluations (FGE), already adopted by the Plenary.

FGE.51: Consideration on 13 alicyclic ketones and secondary alcohols and related esters evaluated by JECFA (59th meeting)

The draft opinion was presented by J. Gry. There were comments to the draft opinion, which will be on the agenda for the next Plenary 15 – 16 May 2006.

FGE.52-56: JECFA (57th , 59th, 63rd meetingmeetings)

The draft opinions were not discussed due to lack of time. The draft opinions will be on the agenda for the next Plenary 15 – 16 May 2006.

10. FOOD CONTACT MATERIALS

10.1. 15th list of substances for food contact materials

The draft opinions on the following substances were discussed and referred back to the working group for further consideration:

REF No 31335	Acids, fatty (C8-C22) from animal or vegetable fats and oils, esters with branched alcohols, aliphatic, monohydric, saturated, primary (C3-C22)
REF No 31336	Acids, fatty (C8-C22) from animal or vegetable fats and oils, esters with alcohols, linear, aliphatic, monohydric, saturated, primary (C1-C22)
REF No 31348	Acids, fatty (C8-C22), esters with pentaerythritol

The draft opinions on the following substances were not discussed due to the lack of time and deferred to the Plenary of the 3-5 July:

REF No 15404	1,4:3,6-Dianhydrosorbitol
REF No 37520	1,2-Benzisothiazolin-3-one
REF No 66755	2-Methyl-4-isothiazolin-3-one
REF No 86430	20%w/w silver chloride coated onto 80% (w/w) titanium dioxide

11. ANY OTHER BUSINESS

None.