Parma, 27 May 2009

MINUTES OF THE 5th PLENARY MEETING

OF THE SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS AND PROCESSING AIDS (CEF)

Held in Parma on 24-26 March 2009

Adopted on 14 May 2009

AGENDA:

MINUTES OF THE 5th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS & PROCESSING AIDS (CEF)

PARTICIPANTS

Panel Members:

Arturo Anadón, David Bell (by teleconference on 2nd day afternoon), Mona-Lise Binderup (2nd and 3rd days), Wilfried Bursch, Laurence Castle, Riccardo Crebelli, Karl-Heinz Engel, Roland Franz, Nathalie Gontard, Thomas Haertlé, Trine Husøy, Klaus-Dieter Jany, Catherine Leclercq (1st and 2nd days), Jean-Claude Lhuguenot, Wim C. Mennes, Maria Rosaria Milana, Karla Pfaff, Kettil Svensson, Fidel Toldrá, Rosemary Waring, Detlef Wölfle.

External experts:

Jørn Gry, Vibe Beltoft (FLAVIS secretariat) and Ula Beckman-Sundh (for item 6); Ivonne Rietjens (for item 9).

Apologies:

None

EFSA:

Davide Arcella (Datex Unit) (for items 6, 7 and 9); Andrew Cutting (Communication) for items 7, 8 and 9).

CEF Unit:

Scientific staff: Alexandre Feigenbaum, Dimitrios Spyropoulos, Anne Theobald, Eric Barthélémy, Marika Collin, Cristina Croera, Kim Rygaard Nielsen;

Administrative staff: Hanne Pedersen, Eva-Maria Ferrari, Marco Lannutti.

1. WELCOME; APOLOGIES FOR ABSENCE

The Chair, Klaus-Dieter Jany asked the vice-chairs, Karl-Heinz Engel and Wim Mennes to chair the Panel discussions respectively on 2nd day afternoon (item 8, for which KD Jany is rapporteur) and on 3rd day morning (item 7, while KD Jany and KH Engel where involved in a meeting on Smoke Flavourings).

2. ADOPTION OF THE AGENDA

The agenda was adopted.

3. DECLARATIONS OF INTEREST

With regard to this meeting, the following interests were declared:

Enzymes (item 8)**:**

♦ C. Leclercq was the exposure assessment expert for the JECFA evaluations of enzymes

♦ M. L. Binderup was involved in the evaluation of enzymes for the Danish authorities.

Benzophenone and 4-methylbenzophenone (item 7.2)

♦ D. Wölfle, M.R. Milana, K. Pfaff and K. Svensson have advised their risk management Authorities on the issue.

♦ M.R. Milana declared that her Institute is conducting monitoring on benzophenone and 4-methylbenzophenone for the government.

♦ L. Castle declared that his laboratory had conducted the analytical work for the FSA survey report in 2000 and 2006 on benzophenone and 4-hydroxybenzophenone.

♦ R. Franz declared that his Institute has performed analytical measurements on benzophenone and 4-methylbenzophenone for industries to test compliance of articles with the regulation.

Smoke flavouring (item 9)**:**

♦ I. Rietjens declared that she is advising FEMA for flavourings and that she has never been involved in smoke flavourings evaluations there.

In accordance with EFSA's Policy on Declarations of Interests and implementing documents thereof, and taking into account the specific matters discussed at the meeting in question, the interests above were not deemed to represent a conflict of interest for the experts concerned.

4. MATTERS ARISING FROM THE 4TH PLENARY MEETING, 26-29 JANUARY 2009

The minutes of the 4th Plenary meeting were adopted with editorial changes. They can be seen on http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902275721.htm.

FGE.61Rev1 and FGE.89, which were discussed at the previous meeting but without quorum, were rescheduled for the current meeting.

5. GENERAL INFORMATION FROM THE EFSA, THE COMMISSION AND THE CHAIR

6. FLAVOURINGS

6.1. Flavouring group evaluations

According to Regulation 1565/2000 of 18 July 2000.

6.1.1. Flavouring Group Evaluation 07, Revision 2 (FGE.07Rev2): *Saturated and unsaturated aliphatic secondary alcohols, ketones and esters of secondary alcohols and saturated linear or branched-chain carboxylic acids from chemical group 5*

EFSA-Q-2009-00478

The FGE.07Rev2 includes the assessment of two additional flavouring substances [FL-no: 02.255 and 07.239] compared to FGE.07Rev1. Therefore, the present FGE.07Rev2 deals with 43 flavouring substances.

Information on stereoisomerism is required for eight substances [FL-no: 02.182, 02.190, 02.555, 07.156, 07.236, 09.676, 09.880 and 09.926].

The remaining 35 substances [FL-no: 02.077, 02.124, 02.142, 02.148, 02.177, 02.183, 07.072, 07.084, 07.150, 07.157, 07.158, 07.160, 07.162, 07.178, 07.181, 07.182, 07.185, 07.189, 07.199, 07.201, 07.205, 07.239, 09.304, 09.323, 09.325, 09.328, 09.332, 09.386, 09.388, 09.391, 09.604, 09.605, 09.606, 09.608 and 09.609] would present no safety concern at the levels of intake estimated on the basis of the MSDI approach.

Changes to the text of the draft opinion were noted. The opinion was adopted and will be published on http://www.efsa.europa.eu.

6.1.2. **Flavouring Group Evaluation 08, Revision 1 (FGE.08Rev1):** *Aliphatic and alicyclic mono-, di-, tri-, and polysulphides with or without additional oxygenated functional groups from chemical groups 20 and 30*

EFSA-Q-2009-00479

The FGE.08Rev1 includes the assessment of 14 additional candidate substances [FL-no: 12.093, 12.094, 12.182, 12.205, 12.266, 12.268, 12.269, 12.271, 12.277, 12.278, 12.282, 12.295, 12.298 and 15.125] compared to FGE.08. Therefore, the present FGE.08Rev1 deals with 66 flavouring substances in total.

Information on chirality is required for 20 substances [FL-no: 12.104, 12.106, 12.120, 12.135, 12.177, 12.178, 12.180, 12.182, 12.214, 12.266, 12.268, 12.269, 12.278, 12.295, 15.047, 15.048, 15.056, 15.083, 15.110 and 16.057] and information on geometric isomerism for three substances [FL-no: 12.098, 12.163 and 12.164]. An identity test is required for four substances [FL-no: 12.268, 12.269, 12.271 and 12.282]. EU production figures are required for four substances [FL-no: 12.268, 12.269, 12.271 and 12.295]. Additional toxicity data are required for 12 substances [FL-no: 12.093, 12.094, 12.097, 12.100, 12.112, 12.116, 12.164, 12.120, 12.167, 12.199, 15.102 and 15.125]. Additional *in vivo* data on genotoxicity are required for four substances [FL-no: 12.159, 12.172, 12.174 and 16.057].

The remaining 28 flavouring substances evaluated through the Procedure [FL-no: 12.096, 12.099, 12.103, 12.111, 12.117, 12.124, 12.125, 12.127, 12.129, 12.136, 12.151, 12.152, 12.158, 12.165, 12.166, 12.181, 12.183, 12.189, 12.191, 12.196, 12.200, 12.205, 12.221, 12.277, 12.298, 15.081, 15.103 and 15.111] would present no safety concern at the levels of intake estimated on the basis of the MSDI approach.

Changes to the text of the draft opinion were noted. The opinion was adopted and will be published on http://www.efsa.europa.eu.

6.1.3. **Flavouring Group Evaluation 16, Revision 2 (FGE.16Rev2):** *Aromatic ketones from chemical group 21*

EFSA-Q-2009-00480

The FGE.16Rev2 includes the assessment of one additional candidate substance [FL-no: 07.252] compared to FGE.16Rev1. Therefore, the present FGE.16Rev2 deals with seven flavouring substances in total.

Information on chirality is still required for one candidate substance [FL-no: 07.242].

The remaining six substances [FL-no: 07.193, 07.194, 07.195, 07.214, 07.254 and 07.259] would present no safety concern at the levels of intake estimated on the basis of the MSDI approach.

Changes to the text of the draft opinion were noted. The opinion was adopted and will be published on http://www.efsa.europa.eu .

6.1.4. **Flavouring Group Evaluation 21, Revision 1 (FGE.21Rev1):** *Thiazoles, thiophene, thiazoline and thienyl derivatives from chemical group 29. Miscellaneous substances from chemical group 30*

EFSA-Q-2009-00481

The FGE.21Rev1 includes the assessment of two additional candidate substances [FL-no: 15.129 and 15.133] compared to FGE.21. Therefore, the present FGE.21Rev1 deals with 56 flavouring substances.

It is concluded that the genotoxicity data are limited and that genotoxicity could not be assessed adequately for the flavouring substances in FGE.21, Revision 1. However, the genotoxicity data available do not preclude the evaluation of 49 of the 56 candidate substances using the Procedure.

The remaining seven substances [FL-no: 15.114, 15.133, 15.090, 15.099, 15.086, 15.060 and 15.119] cannot presently be evaluated through the Procedure. Additional genotoxicity data are requested for these substances.

Additional toxicity data are needed for 23 of the 49 flavouring substances evaluated through the Procedure [FL-no: 15.037, 15.040, 15.042, 15.043, 15.045, 15.054, 15.055, 15.064, 15.070, 15.072, 15.074, 15.076, 15.077, 15.088, 15.091, 15.092, 15.093, 15.094, 15.096, 15.097, 15.106, 15.107 and 15.129].

For nine substances [FL-no: 15.042, 15.054, 15.055, 15.060, 15.077, 15.090, 15.099, 15.119 and 15.129] in this evaluation, information on stereoisomerism is required and for two substances [FL-no: 15.129 and 15. 133] an identity test is required.

The remaining 26 flavouring substances [FL-no: 15.038, 15.039, 15.044, 15.050, 15.051, 15.052, 15.058, 15.061, 15.062, 15.063, 15.067, 15.068, 15.069, 15.071, 15.078, 15.080, 15.082, 15.084, 15.085, 15.087, 15.089, 15.098, 15.108, 15.115, 15.116 and 15.118] evaluated using the Procedure would present no safety concern at their estimated levels of intake estimated on the basis of the MSDI approach.

Changes to the text of the draft opinion were noted. The opinion was adopted and will be published on http://www.efsa.europa.eu .

6.1.5. **Flavouring Group Evaluation 43 (FGE.43):** *Thujyl alcohol from chemical group 8*

EFSA-Q-2008-047

The FGE.43 deals with thujyl alcohol [FL-no: 02.207].

The Panel concluded that thujyl alcohol [FL-no: 02.207] presents no safety concern at the levels of intake estimated on the basis of the Maximised Survey-derived Daily Intake (MSDI) approach. Additional information on stereoisomerism is required.

Changes to the text of the draft opinion were noted. The opinion was adopted and will be published on http://www.efsa.europa.eu .

6.1.6. **Flavouring Group Evaluation 53, Revision 1 (FGE.53Rev1):** *Consideration of phenethyl alcohol, aldehyde, acid and related acetals and esters evaluated by JECFA (59th meeting)*

EFSA-Q-2009-00482

The FGE.53Rev1 includes the assessment of one additional flavouring substance [FL-no: 09.704]. The genotoxicity of this alpha,beta-unsaturated substance, geranyl phenyl acetate [FL-no: 09.704] has been considered in FGE.202. The structural alert for genotoxicity is present in the metabolite, citral. The Panel concluded that the data available on citral ruled out the concern for genotoxicity and that geranyl phenyl acetate can be evaluated through the Procedure. The remaining 41 flavouring substances have originally been considered by EFSA in FGE.53. Therefore, the present FGE.53Rev1 deals with 42 flavouring substances.

For four substances [FL-no: 06.027, 09.702, 09.783 and 16.041] EU production figures are needed in order to finalise the evaluation of these substances.

For one substance [FL-no: 06.007] information on the stereoisomeric composition is required and for three substances [FL-no: 06.007, 06.027 and 09.805] further information on the composition of mixture is requested.

For the remaining 36 substances [FL-no: 02.019, 05.030, 05.042, 05.044, 06.006, 06.016, 06.024, 06.036, 08.038, 08.049, 09.031, 09.083, 09.137, 09.168, 09.261, 09.262, 09.407, 09.427, 09.466, 09.487, 09.496, 09.538, 09.703, 09.704, 09.707, 09.758, 09.772, 09.784, 09.785, 09.786, 09.787, 09.788, 09.789, 09.791, 09.797 and 09.804] the Panel agrees with the JECFA conclusion "No safety concern at estimated levels of intake as flavouring substances" based on the MSDI approach.

Changes to the text of the draft opinion were noted. The opinion was adopted and will be published on http://www.efsa.europa.eu

6.1.7. **Flavouring Group Evaluation 54, Revision 1 (FGE.54Rev1):** *Consideration of benzyl derivatives evaluated by JECFA (57th meeting)*

EFSA-Q-2009-00483

The FGE.54Rev1 includes the assessment of one additional flavouring substance: geranyl benzoate [FL-no: 09.767]. The genotoxicity of this alpha,beta-unsaturated substance has been considered in FGE.202. The structural alert for genotoxicity is present in the metabolite citral. The Panel concluded that the data available on citral ruled out the concern for genotoxicity and that geranyl benzoate can be evaluated through the Procedure. The remaining 36 flavouring substances have originally been considered by EFSA in FGE.54. Therefore, the present FGE.54Rev1 deals with 37 flavouring substances.

For four substances [FL-no: 06.019, 09.294, 09.803 and 09.812] EU production figures are needed in order to finalise the evaluation of these substances.

For seven substances [FL-no: 05.027, 06.002, 06.012, 06.019, 09.294, 09.755 and 09.806] further information on the composition of the mixture is requested.

For 28 of the 37 JECFA evaluated benzyl derivatives [FL-no: 02.010, 02.039, 05.013, 05.022, 05.068, 05.110, 06.003, 06.032, 08.021, 09.014, 09.051, 09.077, 09.132, 09.406, 09.426, 09.458, 09.494, 09.508, 09.705, 09.725, 09.726, 09.727, 09.757, 09.767, 09.768, 09.770, 09.771 and 09.776] the Panel agrees with the JECFA conclusion "No safety concern at estimated levels of intake as flavouring substances", based on the MSDI approach.

Changes to the text of the draft opinion were noted. The opinion was adopted and will be published on http://www.efsa.europa.eu .

6.1.8. Flavouring Group Evaluation 61, Revision 1 (FGE.61Rev1): Consideration of aliphatic acyclic acetals evaluated by JECFA (57th meeting)

EFSA-Q-2008-032M

The present Flavouring Group Evaluation 61, Revision 1 (FGE.61Rev1) deals with nine flavouring substances [FL-no: 06.001, 06.004, 06.005, 06.008, 06.009, 06.015, 06.028, 06.037 and 06.081].

For four substances [FL-no: 06.004, 06.005, 06.037 and 06.081] information on the stereoisomeric composition and/or composition of mixture is incomplete. For one substance [FL-no: 06.081] an EU production figure is needed in order to finalise the evaluation of this substance.

For the remaining five substances [FL-no: 06.001, 06.008, 06.009, 06.015 and 06.028] the Panel agrees with the JECFA conclusion "no safety concern at estimated levels of intake as flavouring substances" based on the MSDI approach.

The opinion has been discussed at the 4th meeting. Minor editorial changes were requested. However there was no quorum for adoption at the moment of the discussion. The opinion was adopted and will be published on http://www.efsa.europa.eu

6.1.9. Flavouring Group Evaluation 68 (FGE.68): *Consideration of cinnamyl alcohol and related substances evaluated by JECFA (55th meeting)*

EFSA-Q-2008-032T

This consideration deals with 54 JECFA evaluated substances.

For six substances [FL-no: 02.051, 05.094, 09.071, 09.084, 09.746 and 09.780] EU production figures are needed in order to finalise the evaluation of these substances.

Information on stereoisomerism is required for 41 substances [FL-no: 02.017, 02.030, 05.014, 05.039, 05.040, 05.041, 05.048, 05.050, 05.051, 05.103, 05.118, 05.122, 06.013, 06.014, 08.022, 09.018, 09.026, 09.053, 09.085, 09.090, 09.133, 09.459, 09.468, 09.470, 09.708, 09.730, 09.731, 09.732, 09.733, 09.734, 09.736, 09.737, 09.738, 09.739, 09.740, 09.742, 09.743, 09.744, 09.745, 09.780 and 09.782].

For eight substances in the group of JECFA evaluated cinnamyl alcohol and related substances [FL-no: 02.031, 05.080, 08.032, 09.032, 09.138, 09.428, 09.467 and 09.747] the Panel agrees with the JECFA conclusion "No safety concern at estimated levels of intake as flavouring substances" based on the MSDI approach.

Changes to the text of the draft opinion were noted. The opinion was adopted and will be published on http://www.efsa.europa.eu.

6.1.10. Flavouring Group Evaluation 89 (FGE.89): *Consideration of phenyl-substituted aliphatic tertiary alcohols and related aldehydes and esters evaluated by JECFA (63rd and 68th meetings)*

EFSA-Q-2008-309

The present Flavouring Group Evaluation 89 (FGE.89) deals with 10 substances [FL-no: 02.035, 02.037, 02.042, 02.108, 09.029, 09.086, 09.227, 09.232, 09.484 and 09.509]

For all these substances, the Panel agrees with the JECFA conclusion "No safety concern at estimated levels of intake as flavouring substances" based on the MSDI approach.

The opinion has been discussed at the 4th meeting. Minor editorial changes were requested. However there was no quorum for adoption at the moment of the discussion. The opinion was adopted and will be published on http://www.efsa.europa.eu

Proposal concerning the data required for the risk assessment of flavouring substances

EFSA-Q-2009-00004

The draft opinion on the data required for the risk assessment of chemically defined flavouring substances was discussed.

A new version will be available for the next Panel meeting, with the aim of adoption in the July Plenary.

6.2. Update of list of representative substances of FGE.19 subgroups to be tested

EFSA-Q-2008-709

The update of the List of Representative *alpha,beta*-Unsaturated Aldehydes and Ketones for Genotoxicity Testing was adopted. The List contains representatives from FGE.201, FGE.203, FGE.210, FGE.212, FGE.213, FGE.216, FGE.217 and FGE.220.

Original List adopted on 27 November 2007 will be replaced with the new version, containing the substances from the supplement list.

This new version of the list will be published in the week following the Panel meeting and be available on:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902211395.htm

7. FOOD CONTACT MATERIALS

7.1. Evaluation of substances of the 23rd list

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

EFSA Question Number:	**EFSA-Q2007-023**
Ref. No.:	38550
Name of the substance:	Bis(4-propylbenzylidene)propylsorbitol
CAS number:	882073-43-0
SCF_List:	3
Restriction:	5 mg/kg food including the sum of hydrolysis products, expressed as the parent substance
Remark for Commission:	The substance hydrolyses in the presence of acids. A conservative estimate of the migration can be received by the sum of the concentration of the parent substance plus three times the concentration of migrated 4-propylbenzaldehyde.

EFSA Question Number:	**EFSA-Q-2003-199**
Ref. No.:	80077
Name of the substance:	Polyethylene waxes, oxidised
CAS number:	068441-17-8
SCF_List:	2
Restriction:	TDI= 1 mg/kg bw
Remark for Commission:	None

EFSA Question Number:	**EFSA-Q-2008-678**
Ref. No. :	92475
Name of the substance:	3,3',5,5'-tetrakis(tert-butyl)-2,2'-dihydroxybiphenyl, cyclic ester with [3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propyl]oxyphosphonous acid
CAS number:	203255-81-6
SCF_List:	3
Restriction:	5 mg/kg food (expressed as the sum of phosphite and phosphate form of the substance and the hydrolysis products)
Remark for Commission:	FRF is applicable

The full opinions as adopted can be seen on the EFSA website at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902432546.htm

The draft opinion on the following substance was deferred to the next Plenary due to lack of time:

95500 N,N',N''-Tris(2-methylcyclohexyl)-1,2,3-propane-tricarboxamide

7.2. Opinion on Benzophenone, 4-hydroxybenzophenone and 4-methylbenzophenone

EFSA-Q-2009-00411

7.3.1 Preparation of the opinion

A first round of discussions on the draft opinion took place. A revised draft is expected to be adopted at the next Panel meeting.

7.3. Bisphenol A

A paper by Myers et al, published in March 2009 in Environmental Health Perspectives, was circulated to the Panel members.

8. ENZYMES:

Guidelines for evaluation of food enzymes

EFSA-Q-2007-080

The document was presented and discussed. After changes introduced, it was endorsed for public consultation, which starts in the first days of April.

9. SMOKE FLAVOURING

Smoke Flavouring Primary Product Scansmoke PB 1110 (SMK Nr 6)

EFSA-Q-2005-261

The Panel concluded that when assuming that the Primary Product Scansmoke PB 1110 is present at the normal or upper use levels provided by the applicant for the 18 food categories, the margin of safety as compared to the NOAEL of 700 mg/kg bw/day derived from the 90-day toxicity study with Scansmoke PB 1110 in rats amounts to 23 to 32 for the intake estimates based on the upper use levels and to 25-43 when normal use levels are considered.

When assuming the use of Primary Product Scansmoke PB 1110 in traditionally smoked products only, the margins of safety would amount to 48 to 84 for the intake estimates based on the upper use levels and to 58 to 104 when normal use levels are considered.

Given i) the fact that these margins of safety are based on a 90-day toxicity study, ii) the absence of data on reproduction and developmental toxicity and iii) the absence of long term studies, it is concluded that the uses and use levels of Primary Product Scansmoke PB 1110 would require a larger margin of safety. The Panel concludes that the margin of safety is insufficient and that the use of Primary Product Scansmoke PB 1110 at the proposed uses and use levels is of safety concern.

To decide whether despite the low margins of safety the use of Primary Product PB 1110 might be approved for traditionally smoked products, at use levels specified, to replace smoking, is outside the remit of the Panel.

10. ANY OTHER BUSINESS

No other business.