Parma, 11 June 2009

MINUTES OF THE 4th PLENARY MEETING

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

Held in Parma on 26-29 January 2009

Adopted on 24 March 2009

These minutes, published on 12 June 2009, replace the earlier version published on 06 April 2009[1].

AGENDA:

[1] Ivonne Rietjens declared in her ADoI that she is advising FEMA on flavourings. In January 2009 she informed the Secretariat that FEMA also assesses smoke flavourings but also that she has never been involved in smoke flavourings evaluations there. According to EFSA Policy on DoI, that activity does not represent a conflict of interest. Upon request from the Secretariat, she updated accordingly her ADoI in May 2009. Therefore, an *addendum* to the minutes of the 4th CEF Plenary meeting (26-29 January 2009) and to the scientific opinions was introduced *a posteriori* to clarify this issue.

MINUTES OF THE 4th PLENARY MEETING OF THE SCIENTIFIC PANEL ON CONTACT MATERIALS, ENZYMES, FLAVOURINGS AND PROCESSING AIDS (CEF)

Held in Parma on 26-29 January 2009

PARTICIPANTS

Panel Members:

Arturo Anadón (2nd , 3rd and 4th day), David Bell, Mona-Lise Binderup (2nd, 3rd and 4th day), Wilfried Bursch, Laurence Castle, Riccardo Crebelli (2nd, 3rd and 4th day), Karl-Heinz Engel (2nd and 3rd day), Roland Franz, Thomas Haertlé, Trine Husøy, Klaus-Dieter Jany (2nd, 3rd and 4th day), Catherine Leclercq (1st , 2nd and 3rd day), Jean-Claude Lhuguenot (2nd, 3rd and 4th day), Wim C. Mennes (2nd, 3rd and 4th day), Maria Rosaria Milana (1st , 2nd and 3rd day), Karla Pfaff (3rd and 4th day), Kettil Svensson, Fidel Toldrá (1st , 2nd and 3rd day), Detlef Wölfle.

Experts:

Jørn Gry (for item 6), Fernando Aguilar (for item 10), Ivonne Rietjens (for item 9)

Apologies:

Nathalie Gontard, Rosemary Waring

EFSA:

Davide Arcella (Datex Unit) (for items 8 and 9)

CEF Unit:

Alexandre Feigenbaum, Dimitrios Spyropoulos, Eric Barthélémy, Marika Collin, Cristina Croera, Kim Rygaard Nielsen(scientific staff); Hanne Pedersen, Marco Lannutti (administrative staff).

Commission:

Olga Solomon, Wim Debeuckelaere (2nd and 3rd day)

1. Welcome; apologies for absence

The Chair, Klaus-Dieter Jany and the Vice Chairs, Karl-Heinz Engel and Wim Mennes were not present on first day. The Panel Members present agreed with the proposal of Klaus-Dieter Jany that David Bell, chair of the "enzymes" Working Groups, would chair the first session.

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 items.

4. Matters arising from the 3rd Plenary Meeting, 25-27 November 2008

The minutes were adopted with editorial changes. They can be seen on http://www.efsa.europa.eu/cs/BlobServer/Event_Meeting/cef_minutes_plen3_en.pdf?ssbinary=true

5. General information from the EFSA, the Commission and the Chair

Dr. Toldrá (European Editor of Trends in Food Science and Technology, TIFS, very high scientific impact factor of 3.7), presented to the Panel the main outcomes of a meeting held on the 28 January between Elsevier representatives and EFSA. TIFS offers the possibility for EFSA and its Panels to publish articles review manuscripts Viewpoint articles.

These articles would be peer reviewed

5.1. Flavouring group evaluations

According to Regulation 1565/2000 of 18 July 2000

5.1.1. FGE.42

EFSA-Q-2008-046

Flavouring Group Evaluation 42 (FGE.42): Iron containing organic substances from chemical group 30

This Opinion was postponed.

5.1.2. FGE.57

EFSA-Q-2008-032H

Flavouring Group Evaluation 57 (FGE.57): Consideration of pulegone related substances evaluated by JECFA (55th meeting)

The present Flavouring Group Evaluation 57 (FGE.57) consists of isopulegol [FL-no: 02.067], isopulegone [FL-no: 07.067] and isopulegyl acetate [FL-no: 09.219].

For two substances [FL-no: 02.067 and 09.219], the composition of the mixture has to be specified and for all three substances additional toxicity data are required [FL-no: 02.067, 07.067 and 09.219].

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

5.1.3. FGE.61Rev1

EFSA-Q-2008-032M

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

Changes to the text of the draft opinion were noted. The opinion was discussed. Minor editorial changes were requested. However there was no quorum at the moment of the discussion and the adoption was postponed to the next meeting.

Note from the secretariat: Second revisions of FGEs adopted in 2009 will be presented in a shorter format, as an Addendum to the existing FGE. An Addendum will contain all new information and relevant background. In all cases, the FGEs will be updated after the end of the evaluation programme.

5.1.4. FGE.71

EFSA-Q-2008-055

Flavouring Group Evaluation 71 (FGE.71): Consideration of aliphatic, alpha,beta-unsaturated aldehydes, acids and related alcohols, acetals and esters evaluated by JECFA (63rd meeting)

This Opinion was postponed.

5.1.5. FGE.72

EFSA-Q-2008-056

Flavouring Group Evaluation 72 (FGE.72): Consideration of aliphatic branched-chain saturated and unsaturated alcohols, aldehydes, acids, and related esters evaluated by JECFA (61st meeting)

This Opinion was postponed

5.1.6. FGE.89

EFSA-Q-2008-309

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)

Changes to the text of the draft opinion were noted. The opinion was discussed. Minor editorial changes were requested. However there was no quorum at the moment of the discussion and the adoption was postponed to the next meeting.

5.1.7. FGE.210

EFSA-Q-2008-766

Flavouring Group Evaluation 210 (FGE.210): alpha,beta-Unsaturated alicyclic ketones and precursors from chemical subgroup 2.4 of FGE.19.

The present Flavouring Group Evaluation 210 (FGE.210) consists of 12 *alpha,beta*-unsaturated alicyclic ketones [FL-no: 07.007, 07.009, 07.011, 07.036, 07.061, 07.088, 07.091, 07.130, 07.134, 07.170, 07.226 and 07.231] and one precursor [FL-no: 02.105] from chemical group 2.4 of FGE.19. For explanation of the subgroup classification, please consult Minutes from the 26th AFC Panel meeting November 2007:
http://www.efsa.europa.eu/EFSA/Event_Meeting/afc_minutes_26thplen_en.pdf.

The Panel concluded that a genotoxic potential of the 13 *alpha,beta*-unsaturated alicyclic ketones and precursors in the FGE.210 could not be ruled out based on the data available. Accordingly these 13 substances cannot be evaluated through the Procedure. Additional data on genotoxicity for representative substances of this subgroup should be provided, according to the test strategy which can be seen on:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902211354.htm

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

5.1.8. FGE.217

EFSA-Q-2008-762

Flavouring Group Evaluation 217 (FGE.217): alpha,beta-Unsaturated ketones and precursors from chemical subgroup 4.1 of FGE.19: Lactones

The present Flavouring Group Evaluation 217 (FGE.217) consists of 14 *alpha,beta*-unsaturated lactones [FL-no: 10.023, 10.030, 10.031, 10.034, 10.036, 10.037, 10.042, 10.044, 10.046, 10.054, 10.060, 10.066, 10.169 and 13.012] and two lactones [FL-no: 10.043 and 10.057] which are precursors for alpha,beta-unsaturated ketones from chemical group 4.1 of FGE.19.

For explanation of the subgroup classification, please consult Minutes from the 26th AFC Panel meeting November 2007,

http://www.efsa.europa.eu/EFSA/Event_Meeting/afc_minutes_26thplen_en.pdf

6-Methylcoumarin [FL-no: 13.012] is not considered to be genotoxic, and therefore can be evaluated through the Procedure. It will be allocated to FGE.80Rev1 for full evaluation.

Based on the data available, a genotoxic potential of the remaining 15 substances [FL-no: 10.023, 10.030, 10.031, 10.034, 10.036, 10.037, 10.042, 10.043, 10.044, 10.046, 10.054, 10.057, 10.060, 10.066 and 10.169] cannot be excluded. Therefore, the Panel concluded that they cannot be evaluated through the Procedure. Additional data on genotoxicity for representative substances of this subgroup should be provided, according to the test strategy which can be seen on:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902211354.htm

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

5.1.9. FGE.220

EFSA-Q-2008-763

Flavouring Group Evaluation 220 (FGE.220): alpha,beta-Unsaturated ketones [and precursors] from chemical subgroup 4.4 of FGE.19: 3(2H)-Furanones

The present Flavouring Group Evaluation 220 (FGE.220), corresponding to subgroup 4.4 of FGE.19, concerns 10 alpha,beta-unsaturated, 3(2H)-furanones [FL-no: 13.010, 13.084, 13.085, 13.089, 13.099, 13.117, 13.119, 13.157, 13.175 and 13.176]. Five of the 10 substances are non-enolisable ketones [FL-no: 13.089, 13.117, 13.119, 13.157 and 13.175] (subgroub 4.4a). Of the remaining five substances, three can exist under ketonic or enolic tautomeric forms [FL-no: 13.010, 13.084 and 13.085] and two are esters which give a enolisable ketone after hydrolysis [13.099 and 13.176] (subgroup 4.4b). For explanation of the subgroup classification, please consult Minutes from the 26th AFC Panel meeting November 2007,

http://www.efsa.europa.eu/EFSA/Event_Meeting/afc_minutes_26thplen_en.pdf

For the substances in subgroup 4.4a [FL-no: 13.089, 13.117, 13.119, 13.157 and 13.175] the Panel considered that presently the available data on genotoxicity are too limited to evaluate these substances through the Procedure. Additional data on genotoxicity for representative substances of this subgroup 4.4a should be provided.

For the substances in subgroup 4.4b [FL-no: 13.010, 13.084, 13.085, 13.099 and 13.176], evidence for genotoxicity was obtained *in vitro* and *in vivo*. Evidence is available from *in vitro* studies that the genotoxicity of the candidate substances in this subgroup may be caused by indirect (thresholded) mechanisms of action (in particular generation of reactive oxygen species). However, the concern for carcinogenicity is alleviated since one of the substances, for which positive genotoxicity data in mice were obtained, was not carcinogenic in a valid chronic assay in rats. Therefore, no further genotoxicity tests in somatic cells are required. However, some evidence was also available that this substance might elicit genotoxic effects in germ cells, which theoretically may result in reduced reproductive capacity or in inheritable genetic damage. Reproductive capacity and inheritable genetic damage are

toxicological endpoints which differ from carcinogenicity and therefore, the negative results for the carcinogenicity study cannot be used to overrule this concern. Also it is not clear if (and if so to what extent) the thresholded mechanism mentioned above would be relevant for genotoxic effects in the germ cells. Therefore, the Panel concluded that presently these five substances cannot be evaluated through the Procedure.

The Panel recognised that the studies which provided indications for germ cell genotoxicity are of limited validity. For that reason a robust GLP-controlled cytogenetic investigation in mouse spermatocytes according to the OECD guideline 483 is requested for subgroup 4.4b.

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

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

Taking into account the evaluation of the subgroups for which additional data have been requested, representative substances should be defined for:
CEF Plen 2: FGE.201
CEF Plen 3: FGE.203, 212, 213 and 216
CEF Plen 4: FGE 210, 217 and 220

The updated list will be prepared by the next Plenary meeting

6. Food contact materials

6.1. Evaluation of substances of the 22nd list

M.-L. Binderup declared an interest for the substances REF. No. 14876, 49080 and 92460, as her Institute had prepared the evaluation report of the substances under contract with EFSA. This was considered as a conflict of interest because she could not act at the same time as a representative of the contractor and a member of the Panel with voting rights. She was allowed to stay in the room to answer to specific technical questions but did not participate in the discussion of the opinions. Another Panel member presented the draft opinions.

K. Pfaff and D. Woefle declared an interest for the substance Ref. No. 92460 as they were involved in the risk assessment of the substance in their Institute. This was not considered as a conflict of interest and they were invited to participate in the discussion.

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

EFSA Question Number:	EFSA-Q-2008-298
Ref. No.:	14876
Name of the substance:	1,4-Cyclohexanedicarboxylic acid
CAS number:	001076-97-7
SCF_List:	3
Restriction:	5 mg/kg food Only to be used for manufacture of polyesters
Remark for Commission:	None

EFSA Question Number:	EFSA-Q-2007-182
Ref. No.:	19965
Name of the substance:	Malic acid
CAS number:	6915-15-7
SCF_List:	1
Restriction:	ADI “not specified” Only to be used as a comonomer in aliphatic polyesters up to the level of 1 % on a molar basis
Remark for Commission:	None

EFSA Question Number:	EFSA-Q-2007-199
Ref. No. :	49080
Name of the substance :	N-(2,6-Diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-benzo[de]isoquinolin-1,3(2H)-dione
CAS number:	852282-89-4
SCF_List:	3
Restriction:	0.05 mg/kg food
Remark for Commission:	The migration limit may be exceeded at elevated temperature and/or from plastics containing the substance at the maximum intended level and/or in contact with high alcoholic foods. The FRF is applicable.

EFSA Question Number:	EFSA-Q-2008-001
Ref. No.:	55610
Name of the substance:	Glass powder, ground, made from post consumer recycled glass (up to 100%)
CAS number :	65997-17-3
SCF_List:	5
Restriction:	The recycled glass powder produced by this process should not be used in materials in contact with food.
Remark for Commission:	None

EFSA Question Number:	EFSA-Q-2007-006
Ref. No.:	68119
Name of the substance:	Neopentyl glycol, diesters and monoesters with benzoic acid and 2-ethylhexanoic acid
CAS number:	-
SCF_List:	3
Restriction:	5 mg/kg food
Remark for Commission:	Migration could be exceeded. The data provided cover only foods simulated by water, 3% acetic acid and 10% ethanol.

EFSA Question Number:	EFSA-Q-2008-295
Ref. No.:	80350

Name of the substance:	Poly(12-hydroxystearic acid)-polyethyleneimine copolymer
CAS number:	124578-12-7
SCF_List:	3
Restriction:	Only to be used in PET, PS, HIPS and PA up to 0.1% w/w. Prepared by the reaction of poly(12-hydroxystearic acid) with polyethyleneimine.
Remark for Commission:	None

EFSA Question Number:	EFSA-Q-2006-315
Ref. No.:	92460
Name of the substance:	Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo-[4,5-d]imidazol-2,5(1H,3H)-dione as non defined process mixture with tri-, di-, mono- and non-hydroxymethylated derivatives
CAS number:	-
SCF_List:	3
Restriction:	Less than 0.07% in the paper-making process water or less than 0.14% when used as a preservative in water-based emulsion coatings The use of the substance must not result in an anti-microbial effect at the surface of the polymer nor on the food itself.
Remark for Commission:	Only a valid analytical method for the determination of the substance in the final product is available.

EFSA Question Number:	EFSA-Q-2007-007
Ref. No.:	94985
Name of the substance:	Trimethylolpropane, mixed triesters and diesters with benzoic acid and 2-ethylhexanoic acid
CAS number:	-
SCF_List:	3
Restriction:	5 mg/kg food
Remark for Commission:	The data provided cover only foods simulated by water, 3% acetic acid and 10% ethanol.

The full opinions as adopted can be seen on the EFSA website at:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902327822.htm

The draft opinions on the following substances were deferred to the next Plenary due to lack of time:

38550	Bis(4-propylbenzylidene)propylsorbitol
80077	Polyethylene waxes, oxidised

6.2. Update from CASCADE meeting on endocrine disruptors

D. Woelfle informed the members of the outcome of the CASCADE forum on endocrine disrupters held on 2 October 2008 in Brussels. The issue of endocrine disruption was primarily discussed in the forum with a view to identify the major data gaps and plan future actions taken into account the current status of research in this area.

For more details check the CASCADE website at: www.cascadenet.org

7. Enzymes: Guidelines for evaluation of food enzymes

The draft guidelines were discussed. An improved version will be presented to the next Plenary in view of adoption for public consultation.

8. Smoke flavourings:

- Karl-Heinz Engel has declared an interest for 8.4, as a student in his laboratory is paid with a grant of Symrise. As the funding is going to the University and as the subject of the work is not related to Smoke Flavourings, this is not a conflict.

Ivonne Rietjens declared in her ADoI that she is advising FEMA on flavourings. In January 2009 she informed the Secretariat that FEMA also assesses smoke flavourings but also that she has never been involved in smoke flavourings evaluations there. According to EFSA Policy on DoI, that activity does not represent a conflict of interest. Upon request from the Secretariat, she updated accordingly her ADoI in May 2009. Therefore, an *addendum* to the minutes of the 4th CEF Plenary meeting (26-29 January 2009) and to the scientific opinions is introduced *a posteriori* to clarify this issue.

8.1. Dietary exposure assessment methods for smoke flavouring Primary Products

EFSA-Q-2008-402

The CEF Panel concludes that the specially designed SMK-TAMDI and SMK-EPIC methods are suitable for assessing the dietary exposure to smoke flavourings used or intended for use in or on foods. The SMK-TAMDI method, due to its calculation principles, will always yield exposure values equal to or higher than the SPET method. Due to the different scenarios taken into account by each of these methodologies, the CEF Panel suggests to estimate dietary exposure to smoke flavourings by means of Upper use Levels, using the SMK-TAMDI and SMK-EPIC methods and to always use the highest value among these estimates when carrying out risk assessments for these substances.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902429516.htm

8.2. Smoke Flavouring Primary product Unismoke (SMK application. 13)

EFSA-Q-2005-267

The Panel concluded that when assuming that the Primary Product Unismoke is present at the normal or upper use levels provided by the petitioner for the 18 food categories, the margin of safety as compared to the NOAEL derived from the 90-day toxicity study in rats amounts to 14 to 24 for the intake estimates based on the upper use levels and to 18 to 30 when normal use levels are considered.

When assuming the use of Primary Product Unismoke in traditionally smoked products only the margins of safety would amount to 28 to 36 for the intake estimates based on the upper use levels and to 34 to 45 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 Unismoke would

require a larger margin of safety. The Panel concludes that the margin of safety is insufficient and that the use of Primary Product Unismoke 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 Unismoke might be approved for traditionally smoked products, at use levels specified, to replace smoking, is outside the remit of the Panel.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902433663.htm

8.3. Smoke Flavouring Primary Product Zesti Smoke Code 10 (SMK application 14)

EFSA-Q-2005-268

The Panel concluded that when assuming that the Primary Product Zesti Smoke Code 10 is present at the normal or upper use levels provided by the petitioner for the 18 food categories, the margins of safety as compared to the NOAEL derived from the 90-day toxicity study in rats amount to 5 to 6 for the intake estimates based on the upper use levels and to 11 to 14 when normal use levels are considered.
When assuming the use of Primary Product Zesti Smoke Code 10 in traditionally smoked products only the margins of safety would amount to 10 to 16 for the intake estimates based on the upper use levels and to 21 to 32 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 Zesti Smoke Code 10 would require a larger margin of safety. The Panel concludes that the margin of safety is insufficient and that the use of Primary Product Zesti Smoke Code 10 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 Zesti Smoke Code 10 might be approved for traditionally smoked products, at use levels specified, to replace smoking, is outside the remit of the Panel.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902433675.htm

8.4. Smoke Flavouring Primary Product Smoke Concentrate 809045 (SMK application 16)

EFSA-Q-2005-270

The Panel concluded that the technical description of the manufacturing process is sufficient, and that the analytical methods used for the chemical characterisation of Smoke Concentrate 809045, and the content of PAHs are in compliance with legislation. Smoke Condensate 809045 is genotoxic *in vitro*, but not *in vivo*. The NOAEL is derived from a 90-day study and amounts to 1000 mg/kg bw/day the highest dose level tested. Given the margin of safety of at least 2000 and the fact that this margin of safety is based on a conservative exposure estimate and a NOAEL that is the highest dose level tested, the Panel concludes that the use of Smoke Condensate 809045 at the proposed uses and use levels is not of safety concern.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902433705.htm

9. Processing aids: dimethyl ether as extraction solvent

EFSA-Q-2007-186

The Panel considered the intended use of dimethyl ether as an extraction solvent to remove fat from animal protein raw materials. Considering (i) that the defatted animal protein is submitted to vacuum to remove the residual volatile dimethyl ether, (ii) that the maximum residual limit of dimethyl ether is of 9 µg /kg of extracted animal proteins and (iii) that these proteins are used at a level of up to 2 % in the final food, the Panel considered that there is no safety concern.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902387011.htm

10. Any other business

None