Parma, 3 February 2009

MINUTES OF THE 3rd PLENARY MEETING

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

Held in Parma on 25-27 November 2008

Adopted on 29 January 2009

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MINUTES OF THE 3rd PLENARY MEETING OF THE SCIENTIFIC PANEL ON CONTACT MATERIALS, ENZYMES, FLAVOURINGS AND PROCESSING AIDS (CEF)

Held in Parma on 25-27 November 2008

PARTICIPANTS

Panel Members:
David Bell (2nd and 3rd day), Mona-Lise Binderup, Wilfried Bursch, 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 (3rd day), Karla Pfaff (2nd and 3rd day), Kettil Svensson, Fidel Toldrá, Rosemary Waring, Detlef Wölfle (2nd and 3rd day).

Experts:
Jørn Gry (for items 6.1, 6.2 and 6.3) (2nd and 3rd day) and Rainer Gürtler (for item 6.2) (2nd day), John C. Larsen (2nd day).

Apologies:
Arturo Anadón, Laurence Castle.

EFSA:
Davide Arcella (Datex Unit) (item 8), David Carlander (Scientific Committee) (item 7.2.3) and Andrew Cutting (Press office) (for items 6.1 and 7.2.3).

CEF Unit:
Alexandre Feigenbaum, Dimitrios Spyropoulos, Anne Theobald, Kim Rygaard Nielsen, Eric Barthélémy, Marika Collin (scientific staff).
Hanne Pedersen, Marco Lannutti (administrative staff).

Commission:
Xavier Pavard, Anette Schaefer (1st day)

1. WELCOME; APOLOGIES FOR ABSENCE

The Chair, Klaus-Dieter Jany, welcomed the participants.
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 items.

4. MATTERS ARISING FROM THE 2ND PLENARY MEETING HELD ON 23-25 SEPTEMBER 2008

The minutes of the previous meeting have been adopted by written procedure on 31 October 2008. They can be seen on:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902091633.htm

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

- The FIAP Regulation has been adopted and will enter in force on 20 January.

- Definitions of EFSA's scientific outputs

EFSA has released a document defining its scientific outputs from the Scientific Panels/Scientific Committee and from EFSA.
The document can be found on:
http://www.efsa.europa.eu/EFSA/ScientificOpinionPublicationReport/efsa_locale-1178620753812_1211902186929.htm

- Chair's meeting

The Chair informed the Panel members about the 4th meeting of Chairs and secretariats of Commission and agency SCs/Panels involved in RA - Parma - 4-5/11/2008.
More details about this meeting can be found on: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902156310.htm

- Extranet

The new extranet for the CEF Panel members was presented.

6. FLAVOURINGS

6.1. Flavouring Group Evaluations (FGE)

On proposal of the secretariat, the Panel decided to evaluate in priority the FGEs derived from FGE.19 gathering α,β-unsaturated carbonyl compounds, a structure which is an alert for possible genotoxicity. Only such FGEs were evaluated in this meeting. Other FGEs are postponed for the January and the March Plenary meetings.

6.1.1. *FGE.203 (EFSA-Q-2008-765)*

Flavouring Group Evaluation 203 (FGE.203): alpha,beta-Unsaturated aliphatic aldehydes and precursors from chemical subgroup 1.1.4 of FGE.19 with two or more conjugated double bonds and with or without additional non-conjugated double bonds
The Flavouring Group Evaluation 203 (FGE.203) consists of 12 alpha,beta-unsaturated aldehydes with two or more conjugated double bonds with and without additional non-conjugated double bonds [FL-no: 05.057, 05.064, 05.071, 05.084, 05.101, 05.108, 05.125,

05.127, 05.140, 05.141, 05.173 and 05.196] and five precursors for such aldehydes [FL-no: 02.139, 02.153, 02.162, 02.188 and 09.573] from chemical subgroup 1.1.4 of FGE.19.
For explanation of 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 draft Opinion was discussed.

Based on the available data on carcinogenicity and genotoxicity, there is a safety concern for hexa-2(trans),4(trans)-dienal [FL-no: 05.057] since a non-threshold mechanism cannot be excluded. Therefore, due to the structural similarities and to the lack of data, the substances of this FGE cannot be evaluated through the Procedure. The Panel requests data which clarify whether the carcinogenic effects were based on a thresholded mechanism.

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. ***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 for such ketones [FL-no: 02.105] from chemical group 2.4 of FGE.19.

This issue was deferred to the next Plenary meeting due to lack of time.

6.1.3. ***FGE.212 (EFSA-Q-2008-767)***

Flavouring Group Evaluation 212 (FGE.212): alpha,beta-Unsaturated alicyclic ketones and precursors from chemical subgroup 2.6 of FGE.19.
The present Flavouring Group Evaluation 212 (FGE.212) consists of 15 alpha,beta-unsaturated alicyclic ketones [FL-no: 07.033, 07.035, 07.094, 07.098, 07.112, 07.126, 07.129, 07.140, 07.146, 07.147, 07.172, 07.175, 07.196, 07.202 and 07.255] and eight precursors for such [FL-no: 02.062, 02.083, 02.101, 02.214, 09.143, 09.215, 09.821 and 09.870] from the chemical subgroup 2.6 of FGE.19.
For explanation of 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.

d-Carvone [FL-no: 07.146] was found genotoxic *in vitro*. However, d-carvone was not carcinogenic in mice. Therefore, the Panel concluded that this substance together with the structurally related l-carvone as well as carveol and the carvyl derivatives [FL-no: 02.062, 07.147, 09.143, 09.215 and 09.870] could be evaluated through the Procedure. These six substances [FL-no: 02.062, 07.146, 07.147, 09.143, 09.215 and 09.870] will be allocated to existing FGEs for final evaluation.

Since isophorone [FL-no: 07.126] is genotoxic *in vitro* and since there is some evidence of carcinogenicity in male rats and equivocal evidence of carcinogenicity in male mice and since a non-threshold mechanism could not be excluded based on the data currently available, the Panel concluded that additional data are required for isophorone in order to clarify whether genotoxicity occurs *in vivo* and whether there is a threshold for the effects observed in the target organs in the long-term bioassays. Therefore, for isophorone, an *in vivo* Comet assay in F344/N rats covering these target organs is required in addition to an *in vivo* bone marrow assay with oral application.

Due to the structural similarities and to the lack of data, the remaining substances cannot be evaluated through the usual Procedure [FL-no: 02.083, 02.101, 02.214, 07.033, 07.035, 07.094, 07.098, 07.112, 07.129, 07.140, 07.172, 07.175, 07.196, 07.202, 07.255 and 09.821]. Additional data on genotoxicity are requested for representative substances of this subgroup. according to the document
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

6.1.4. ***FGE.213 (EFSA-Q-2008-768)***

Flavouring Group Evaluation 213 (FGE.213): alpha,beta-Unsaturated alicyclic ketones and precursors from chemical subgroup 2.7 of FGE.19.
The present Flavouring Group Evaluation 213 (FGE.213) consists of 23 alpha,beta-unsaturated alicyclic ketones [FL-no: 07.008, 07.010, 07.014, 07.041, 07.047, 07.056, 07.057, 07.075, 07.076, 07.080, 07.083, 07.089, 07.108, 07.109, 07.117, 07.118, 07.119, 07.120, 07.127, 07.136, 07.168, 07.200 and 16.044] and three precursors for such ketones [FL-no: 02.106, 09.305 and 09.525] from subgroup 2.7 of FGE.19.
For explanation of 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 considered that ethyl maltol [FL-no: 07.047] can be evaluated through the Procedure. It will be allocated to FGE.83Rev1 for final evaluation.

A micronucleus assay after oral application is required in addition to an *in vivo* Comet assay in order to clarify the genotoxic potential of maltol [FL-no: 07.014]. A combination of the micronucleus assay and the Comet assay in a single study would also be acceptable. The outcome would also be applicable to maltyl isobutyrate [FL-no: 09.525].

3-Ethyl-2-hydroxy-2-cyclopenten-1-one [FL-no: 07.057] and the nine structurally related substances [FL-no: 07.056, 07.075, 07.076, 07.080, 07.117, 07.118, 07.119, 07.120 and 07.168] could be evaluated through the Procedure.
Of these ten substances, nine [FL-no: 07.056, 07.057, 07.075, 07.076, 07.080, 07.117, 07.118, 07.119 and 07.120] were evaluated by JECFA before 2000; therefore they will not be considered further within the current evaluation programme. The remaining substance [FL-no: 07.168] will be allocated to FGE.11Rev2 for final evaluation.

The remaining 13 substances (including two precursors of a ketone) [FL-no: 02.106, 07.008, 07.010, 07.041, 07.083, 07.089, 07.108, 07.109, 07.127, 07.136, 07.200, 09.305 and 16.044]

cannot be evaluated through the Procedure. Accordingly, additional data on genotoxicity are required for representatives of these 13 substances, according to the document 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

6.1.5. ***FGE.214 (EFSA-Q-2008-760)***

Flavouring Group Evaluation 214 (FGE.214): alpha,beta-Unsaturated aldehydes and precursors from chemical subgroup 3.1 of FGE.19: Cinnamyl derivatives
The present Flavouring Group Evaluation 214 (FGE.214) consists of 11 alpha,beta-unsaturated cinnamyl aldehydes [FL-no: 05.014, 05.039, 05.040, 05.041, 05.048, 05.050, 05.051, 05.118, 05.122, 05.154 and 05.155] and 18 precursors for these aldehydes [FL-no: 02.017, 02.030, 06.013, 06.014, 09.018, 09.026, 09.053, 09.085, 09.090, 09.133, 09.306, 09.339, 09.459, 09.468, 09.470, 09.708, 09.739 and 09.780] from subgroup 3.1 of FGE.19.
For explanation of 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 the data available do not preclude an evaluation of the alpha,beta-unsaturated cinnamaldehyde-derivatives in FGE.214 (subgroup 3.1 of FGE.19) using the Procedure.

Four of the substances [FL-no: 05.154, 05.155, 09.306 and 09.339] will be evaluated in FGE.15Rev2 and the other 25 substances will be allocated to FGE.68 for final evaluation.

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. ***FGE.216 (EFSA-Q-2008-761)***

Flavouring Group Evaluation 216 (FGE.216): alpha,beta-Unsaturated aldehydes from chemical subgroup 3.3 of FGE.19: 2-Phenyl-2-alkenals
The present Flavouring Group Evaluation 216 (FGE.216) consists of five alpha,beta-unsaturated, 2-phenyl-substituted aldehydes [FL-no: 05.062, 05.099, 05.100, 05.175 and 05.222] from subgroup 3.3 of FGE.19.
For explanation of 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 five 2-phenyl-substituted aldehydes in the present FGE.216 could not be ruled out. Accordingly, these five substances cannot be evaluated through the Procedure. Additional data on genotoxicity for representative substances of this subgroup should be provided, according to the document:
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

6.1.7. ***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 which are precursors for alpha,beta-unsaturated ketones [FL-no: 10.043 and 10.057] from chemical group 4.1 of FGE.19.

This issue was deferred to the next Plenary meeting due to lack of time.

6.1.8. ***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) consists of 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] from chemical subgroup 4.4 of FGE.19.

This issue was deferred to the next Plenary meeting due to lack of time.

6.2. **List of representative α,β-unsaturated aldehydes and ketones for genotoxicity testing (EFSA-Q-2008-709) -** (Statement of the CEF Panel)

α,β-unsaturated aldehyde and ketone subgroups of FGE.19 compounds are considered by the Panel as structural alerts for genotoxicity ((EFSA, 2007), see http://www.efsa.europa.eu/EFSA/Event_Meeting/afc_minutes_26thplen_en.pdf.)

It is believed that nucleophilic sites in DNA react through a nucleophilic addition with α,β-unsaturated carbonyl compounds. For those subgroups of FGE.19 which could not be evaluated through the Procedure, since additional data were needed, the Panel decided that genotoxicity data should be requested for substances considered as representative for the subgroup.

In each subgroup, representative substances were selected taking into account chain length, branching, lipophilicity and possible additional functional groups. The anticipated influence of substituents on the nucleophilic addition, as well as results of (Q)SAR predictions were also considered. The list will be updated regularly.

The full statement can be seen on
http://www.efsa.europa.eu/EFSA/ScientificPanels/efsa_locale-1178620753812_CEF.htm

6.3. **Status of the guidelines for evaluation of new flavouring substances**

Since the Regulation will enter in force in January, the adoption of guidelines after public consultation should take place by July 2009.

7. FOOD CONTACT MATERIALS

7.1. Guidelines for active and intelligent packaging

The draft guidelines were discussed and amended. The new text agreed by the Panel is scheduled for public consultation after the adoption of the corresponding Regulation which is expected to be in February 2009.

7.2. Evaluation of FCM substances for the 21st list

R. Franz declared an interest for the substances REF. No. 91530, sulphosuccinic acid, alkyl (C4-C20) or cyclohexyl diesters, sodium salts, REF. No. 91815, sulphosuccinic acid mono-alkyl (C10-C16) polyethyleneglycol esters, sodium salts and REF. No. 93485, titanium nitride, nanoparticles as his Institute had performed some of experimental work for the first two dossiers and had submitted the last dossier on behalf of industry. This was considered as a conflict of interest. Thus, he left the room during the discussions on these dossiers.

M.-L. Binderup declared an interest for the substance REF. No. 92460, Tetrahydro-1,3,4,6-tetrakis (hydroxymethyl)imidazo-[4,5-d]imidazol-2,5(1H,3H)-dione, as her Institute had prepared the evaluation report of the substance 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 questions specifically addressed to her but did not participate to the discussion of the Opinion. Another Panel member presented the draft Opinion.

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

EFSA Question Number:	EFSA-Q-2005-151
Ref. No.:	91530
Name of the substance:	Sulphosuccinic acid alkyl (C4-C20) or cyclohexyl diesters, sodium salts
CAS number:	-
SCF_List:	3
Restriction:	5mg/kg food
Remark for Commission:	This evaluation covers also the relevant salts

EFSA Question Number:	EFSA-Q-2006-324
Ref. No.:	91815
Name of the substance:	Sulphosuccinic acid mono-alkyl (C10-C16) polyethyleneglycol esters, sodium salts
CAS number:	-
SCF_List:	3
Restriction:	2 mg/kg food
Remark for Commission:	This evaluation covers also the relevant salts

EFSA Question Number:	EFSA-Q-2006-323
Ref. No.:	93485
Name of the substance:	Titanium nitride, nanoparticles
CAS number:	25583-20-4
SCF_List:	Only to be used in PET bottles up to 20 mg/kg PET
Restriction:	None
Remark for Commission:	25583-20-4

The full Opinions as adopted can be seen on the EFSA website at:
http://www.efsa.europa.eu/EFSA

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

49080	N-(2,6-Diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-benzo[de]isoquinoline-1,3(2H)-dione
18444	Hexahydroterephthalic acid
55610	Glass powder, ground, made from post consumer recycled glass (up to 100%)
94985	Trimethylolpropane, mixed triesters and diesters with benzoic acid and 2-ethylhexanoic acid
68119	Neopentyl glycol, mixed diesters with benzoic acid and 2-ethylhexanoic acid

8. SMOKE FLAVOURINGS

A general presentation of the Smoke Flavourings, their preparation and their composition was given.

16 dossiers were received in 2005, of which 2 dossiers were found not valid and 3 were withdrawn by their applicant. Currently 11 dossiers are under evaluation.
The draft Opinion on the evaluation of the exposure to smoke flavouring substances (self mandate EFSA-Q-2008-402) was presented. In overall the Panel welcomed the approach. Editorial changes were made and the revised Opinion will be on the agenda of the next Plenary.

9. ANY OTHER BUSINESS

None.