Parma, 02 February 2010

MINUTES OF THE 10th PLENARY MEETING

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

Held in Parma on 24-26 November 2009

Adopted on 28th January 2010

AGENDA:

Table of Contents

MINUTES OF THE 10th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS & PROCESSING AIDS (CEF)

PARTICIPANTS

Panel Members:

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

Invited Experts, hearing experts:

Rainer Gürtler (for item 8.1 and 8.2), Ron Walker (for item 8.3 and 8.4), Jörn Gry (for item 6.1)

Apologies: Nathalie Gontard,

European Commission: Sirkku Heinimaa

EFSA:

CEF Unit Scientific staff: Alexandre Feigenbaum, Dimitrios Spyropoulos, Anne Theobald, Eric Barthélémy, Cristina Croera, Kim Rygaard Nielsen; Anna Castoldi, Alina Lupi

Administrative staff: Hanne Pedersen, Marco Lannutti.

1. WELCOME, APOLOGIES FOR ABSENCE

2. ADOPTION OF THE AGENDA

The agenda was adopted.

3. DECLARATIONS OF INTEREST

In accordance with EFSA's Policy on Declarations of Interests, the EFSA secretariat screened the Specific Declarations of Interests (SdoIs) completed by the scientific experts invited to this meeting. For further details on the outcome of this screening please refer to Annex I of these minutes.

4. MATTERS ARISING FROM THE 9TH PLENARY MEETING, 22-24 SEPTEMBER 2009

The minutes of the 9th Plenary meeting were adopted. They can be seen on http://www.efsa.europa.eu/en/events/event/cef090922.htm

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

Launching of an ESCO WG on "Non Plastics Food Contact Materials**"**

6. FLAVOURINGS

According to Regulation 1565/2000 of 18 July 2000

6.1. Flavouring group evaluations

6.1.1. Flavouring Group Evaluation 05Rev2 (FGE.05Rev2):

Branched- and straight-chain unsaturated carboxylic acids and esters acids with straight-chain aliphatic saturated alcohols from chemical groups 1, 2, 3 and 5.

EFSA-Q-2009-00904

The present Flavouring Group Evaluation 05, Revision 2 (FGE.05Rev2), includes the assessment of eight additional candidate substances [FL-no: 08.072, 08.083, 08.101, 08.119, 08.120, 09.181, 09.287 and 09.578], compared to FGE.05Rev1. So, the present FGE.05Rev2 deals in total with 37 candidate substances which are branched- and straight-chain unsaturated carboxylic acids and esters of these acids with straight-chain aliphatic saturated alcohols. The present FGE supersedes FGE.05 and FGE.05Rev1.

This Revision further includes the reconsideration of a neurotoxicity study on ethyl methacrylate [FL-no: 09.375], due to recent concerns expressed by the Committee of Toxicology on the quality and interpretation of data from other similar neurotoxicity studies performed by the same author.

There are three methacrylate candidate substances in this group (ethyl methacrylate [FL-no: 09.375], methyl methacrylate [FL-no: 09.647] and isobutyl 2-methylprop-2-enoate [FL-no: 09.586]). It has been suggested in FGE.05 that these substances might cause neurotoxicity after oral exposure. However, after re-evaluation of the data available and following the comments of COT, the Panel concluded that the indications for this effect were not sufficiently underpinned. Thus, the Panel concluded that these substances should be evaluated via the A-side of the Procedure-scheme.

On the basis of the default MSDI approach, it is considered that all the 37 candidate substances would not give rise to safety concerns at the estimated levels of intake arising from their use as flavouring substances.

In order to determine whether the conclusions for the candidate substances can be applied to the materials of commerce, it is necessary to consider the available specifications. Information on geometrical isomerism/chirality has not been specified for 13 of the substances ([FL-no: 08.083, 08.101, 08.119, 08.120, 09.181, 09.266, 09.287, 09.326, 09.329, 09.335, 09.379, 09.637 and 09.942]). For five of the flavouring substances [FL-no: 08.072, 09.329, 09.335, 09.379 and 09.637], Industry has informed that they exist as a "mixture of isomers". However, the Panel does not consider this information sufficient and requests data on the actual ratios. In addition, for the substance [FL-no: 09.326], an identity test is missing and for two substances [FL-no: 09.287 and 09.578] no specifications including complete purity criteria and identity tests have been provided. Thus, the final evaluation of the materials of commerce cannot be performed for 15 of the substances ([FL-no: 08.072, 08.083, 08.101, 08.119, 08.120, 09.181, 09.266, 09.287, 09.326, 09.329, 09.335, 09.379, 09.578, 09.637 and 09.942]), pending further information on geometrical isomerism/chirality and specifications.

The remaining 22 substances [FL-no: 09.248, 09.321, 09.324, 09.330, 09.365, 09.370, 09.372, 09.374, 09.375, 09.586, 09.596, 09.603, 09.624, 09.625, 09.636, 09.641, 09.647, 09.652, 09.680, 09.699, 09.865 and 09.934] 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 71 (FGE.71):

Consideration of aliphatic, linear, alpha,beta-unsaturated aldehydes, acids and related alcohols, acetals and esters evaluated by JECFA (63rd meeting).

EFSA-Q-2008-055

The current FGE.71 is a consideration of nine flavouring substances [FL-no: 08.054, 08.073, 08.123, 09.156, 09.157, 09.158, 09.235, 09.037 and 09.239] evaluated by the JECFA in its 63rd meeting as the flavouring group of aliphatic, linear, alpha,beta-unsaturated carboxylic acids and related esters. The Panel concluded that these substances are structurally related to the group of branched- and straight-chain unsaturated carboxylic acids and esters of these acids with straight-chain aliphatic saturated alcohols evaluated by EFSA in the Flavouring Group Evaluation 05, Revision 2 (FGE.05Rev2).

The Panel agrees with the way the Procedure has been applied by the JECFA for all nine substances in the group. However, for four substances [FL-no: 08.073, 08.123, 09.157 and 09.239] the evaluation of JECFA is only based on MSDI values derived from production figures from the USA. EU production figures are needed in order to finalise the evaluation of these substances.

In order to determine whether the conclusion for the JECFA evaluated substances can be applied to the materials of commerce, it is necessary to consider the available specifications. Adequate specifications including complete purity criteria and identity are available for seven of the nine JECFA evaluated substances. For two substances [FL-no: 08.073 and 09.235] information on stereoisomerism has not been specified.

In conclusion, for five substances [FL-no: 08.073, 08.123, 09.157, 09.235 and 09.239] the Panel has reservations (no European production volumes available, preventing them to be evaluated using the Procedure and missing information on stereoisomerism).

For the remaining four substances [FL-no: 08.054, 09.037, 09.156 and 09.158] the Panel agrees with the conclusion of JECFA that there is no safety concern for their use as flavouring substances, based on levels of intake estimated using 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 72 (FGE.72):

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

EFSA-Q-2008-056

This FGE.72 is a consideration of 22 flavouring substances evaluated by the JECFA. in the JECFA flavouring group of aliphatic branched-chain saturated and unsaturated alcohols, aldehydes, acids and related esters. The Panel concluded that these 22 substances are structurally related to the group of branched- and straight-chain unsaturated carboxylic acids and esters of these acids with straight-chain aliphatic saturated alcohols evaluated by EFSA in the Flavouring Group Evaluation 05, Revision 2 (FGE.05Rev2).

The Panel agrees with the way the Procedure has been applied by the JECFA for 20 of the 22 substances considered in this FGE. For two substances [FL-no: 05.148 and 08.079] the evaluation of JECFA is only based on MSDI values derived from production figures from the USA. EU production figures are needed in order to finalise the evaluation of these substances.

In order to determine whether the conclusions can be applied to the materials of commerce, it is necessary to consider the available specifications. Adequate specifications including complete purity criteria and identity are available for ten of the 22 substances. For six substances [FL-no: 02.029, 05.020, 05.148, 08.055, 08.079 and 09.273] information on stereoisomerism has not been specified and for six substances [FL-no: 02.011, 02.012, 02.027, 05.021, 08.036 and 08.044] further information on the composition is requested. Thus, for 12 substances [FL-no: 02.011, 02.012, 02.027, 02.029, 05.020, 05.021, 05.148, 08.036, 08.044, 08.055, 08.079 and 09.273] the Panel has reservations (no European

production volumes available, preventing them to be evaluated using the Procedure, and/or missing data on composition and/or isomerism).

For the remaining 10 of the 22 substances [FL-no: 02.058, 02.076, 02.109, 05.124, 05.169, 08.047, 08.064, 08.070, 09.408 and 16.001] the Panel agrees with the conclusion of JECFA, that there is no safety concern for their use as flavouring substances, based on levels of intake estimated using 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 13Rev1 (FGE.13Rev1):

Furfuryl and furan derivatives with and without additional side-chain substituents and heteroatoms from chemical group 14.

EFSA-Q-2009-00905

The present Revision of FGE.13, FGE.13Rev1, includes the assessment of seven additional candidate substances [FL-no: 13.125, 13.135, 13.141, 13.143, 13.162, 13.185 and 13.199], in addition to the 18 candidate substances in FGE.13. So, the present FGE.13Rev1 deals in total with 25 furfuryl and furan derivatives with and without additional side-chain substituents and heteroatoms.

Data on *in vitro* genotoxicity were provided for two candidate substances: 5-hydroxymethylfurfuraldehyde (5HMF) [FL-no: 13.139] and 2-furoic acid [FL-no: 13.136] as well as for nine supporting substances. Data on *in vivo* genotoxicity were only provided on four of the supporting substances. Based on data on the genotoxic activity of 5HMF [FL-no: 13.139] mediated by its sulphate conjugation to its 5-hydroxymethyl group, there is sufficient evidence for a genotoxic potential *in vitro*. However, the lack of *in vivo* data does not allow a final evaluation and the substance FL-no: 13.139] cannot be taken through the Procedure.

For the two candidate substances [FL-no: 13.125 and 13.162], metabolism studies on closely related substances indicate a potential for DNA-binding of metabolites. In addition, in several *in vitro* studies with related substances there were indications for genotoxic activity. These data preclude the evaluation of the two candidate flavouring substances [FL-no: 13.125 and 13.162] through the Procedure.

In total, the substances [FL-no: 13.125, 13.139 and 13.162] could not be evaluated through the Procedure due to concern of genotoxicity *in vitro*.

The remaining 22 candidate substances (including [FL-no: 13.136]) were evaluated through the Procedure. The Panel considered that they would not give rise to safety concerns as flavouring substances, at the estimated levels of intake estimated using the MSDI default approach.

In order to determine whether the conclusion for the 22 candidate substances evaluated through the Procedure can be applied to the material of commerce, it is necessary to consider the available specifications. Adequate specifications including complete purity criteria and identity for the materials of commerce have been provided for 20 of the 22 flavouring substances evaluated through the procedure. For two substances [FL-no: 13.185 and 13.199] information on the isomeric composition has not been specified. Therefore the final

evaluation of the material of commerce cannot be performed for these substances, pending further information.

In total, three substances [FL-no: 13.125, 13.139 and 13.162] could not be evaluated through the Procedure due to concern of genotoxicity *in vitro*. The Panel has reservations for [FL-no: 13.185 and 13.199] (missing data on stereo-isomerism). For these five substances additional date are required.

For the remaining 20 flavouring substances [FL-no: 13.011, 13.102, 13.108, 13.113, 13.114, 13.122, 13.124, 13.127, 13.129 13.132, 13.133, 13.135, 13.136, 13.141, 13.143, 13.144, 13.145, 13.146, 13.149 and 13.178], the Panel concluded that they would be of no safety concern at the levels of intake estimated using 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 67 (FGE.67):

Consideration of 40 furan-substituted aliphatic hydrocarbons, alcohols, aldehydes, ketones, carboxylic acids and related esters, sulfides, disulfides and ethers evaluated by JECFA (65th meeting).

EFSA-Q-2008-032S

This FGE.67 is a consideration of 26 flavouring substances evaluated by the JECFA. The 26 substances belong to the JECFA flavouring group of 40 furan-substituted aliphatic hydrocarbons, alcohols, aldehydes, ketones, carboxylic acids and related esters, sulfides, disulfides and ethers. In this group, 14 substances are alpha,beta-unsaturated aldehydes or ketones which have been considered in FGE.19 with respect to their genotoxic potential. This concern for genotoxicity could not be clarified by the time of the current evaluation. Therefore, these substances are not considered here.

The Panel concluded that the 26 substances in FGE.67 are structurally related to the group of 25 furfuryl and furan derivatives evaluated by EFSA in the Flavouring Group Evaluation 13, Revision 1 (FGE.13Rev1). The substances are also structurally related to a group of 33 sulfur-substituted furan derivatives used as flavouring agents, evaluated by EFSA in the FGE.65 and to 14 furfuryl derivatives evaluated in FGE.66.

For 13 of the 26 substances [FL-no: 13.029, 13.030, 13.052, 13.059, 13.061, 13.069, 13.092, 13.103, 13.106, 13.107, 13.123, 13.148 and 13.191] there are concerns with respect to genotoxicity and carcinogenicity. The Panel therefore agrees with the JECFA that these 13 substances cannot be evaluated through the Procedure.

In line with the approaches taken in previous FGEs with structurally related compounds (FGE.13.Rev1, FGE.65 and FGE.66), the Panel considers that the remaining 13 substances [FL-no: 13.006, 13.021, 13.022, 13.023, 13.024, 13.045, 13.047, 13.058, 13.074, 13.116, 13.138, 13.190 and 13.192] could be evaluated using the Procedure.

After application of the Procedure it was concluded that ten substances [FL-no: FL-no: 13.006, 13.021, 13.022, 13.023, 13.024, 13.047, 13.074, 13.116, 13.190 and 13.192] would be of no safety concern at levels of intake estimated based on the MSDI approach. For the

remaining three substances [FL-no: 13.045, 13.058 and 13.138] this conclusion could not be drawn due to lack of an adequate No Observed Adverse Effect Level (NOAEL).

In order to determine whether the conclusion for the evaluated substances can be applied to the materials of commerce, it is necessary to consider the available specifications. Adequate specifications including complete purity criteria and identity are available for 22 of the 26 substances. Information on isomerism has not been specified for two substances [FL-no: 13.058 and 13.190], the composition of steroisomer mixture has not been specified for [FL-no: 13.192] and information on solubility in water is missing for [FL-no: 13.045].

In conclusion, thirteen [FL-no: 13.029, 13.030, 13.052, 13.059, 13.061, 13.069, 13.092, 13.103, 13.106, 13.107, 13.123, 13.148 and 13.191] of the 26 substances cannot be evaluated through the Procedure, based on concerns with respect to genotoxicity and carcinogenicity. For three substances [FL-no: 13.045, 13.058 and 13.138] additional toxicity data are required. For four substances data on isomerism and purity criterion are missing.

For the remaining eight substances [FL-no: 13.006, 13.021, 13.022, 13.023, 13.024, 13.047, 13.074 and 13.116] of the 26 furan derivatives, the Panel concluded that they would be of no safety concern as flavouring substances at levels of intake estimated using 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*.

6.1.6. Flavouring Group Evaluation 32 (FGE.32):

Phenol derivatives containing ring-alkyl, ring-alkoxy, and side-chains with an oxygenated functional group (Flavonoids).

EFSA-Q-2008-036

The Rapporteur presented the Draft Opinion, which was discussed. It was sent back to the Flavouring Working Group and will be on the Agenda of the additional meeting on 17 December. It is expected to be evaluated at the next plenary meeting January 2010.

6.1.7. Flavouring Group Evaluation 20Rev2 (FGE.20Rev2):

Benzyl alcohols, benzaldehydes, related acetals, benzoic acids and related esters from chemical groups 23 and 30.

EFSA-Q-2009-00906

The present Flavouring Group Evaluation 20, Revision 2 (FGE.20Rev2) includes the assessment of 5 additional candidate substances [FL-no: 05.221, 08.132, 08.133, 09.693 and 09.696], compared to FGE.20Rev1, which included 36 candidate substances. Therefore the present FGE.20Rev2 deals in total with 41 benzyl alcohols, benzaldehydes, related acetals, benzoic acids and related esters and a hydroxy- and alkoxy-substituted biphenyl derivative.

The Panel considered that the use of the 41 candidate substances as flavouring substances would not give rise to safety concerns at the levels of intake estimated on the basis of the default MSDI approach.

In order to determine whether the conclusion for the 41 candidate substances can be applied to the materials of commerce, it is necessary to consider the available specifications. Adequate specifications including complete purity criteria and identity for the materials of commerce have been provided for the 41 flavouring substances. Information on stereoisomerism has not been specified for two of the substances [FL-no: 06.104 and 09.570]. Thus, the final evaluation of the materials of commerce cannot be performed for these two substances, pending further information.

The remaining 39 substances esters [FL-no: 02.205, 02.164, 05.066, 05.129, 05.142, 05.153, 05.158, 05.221, 06.017, 08.080, 08.087, 08.132, 08.133, 09.152, 09.313, 09.314, 09.315, 09.316, 09.317, 09.318, 09.362, 09.363, 09.367, 09.560, 09.581, 09.611, 09.623, 09.631, 09.656, 09.693, 09.779, 09.825, 09.835, 09.696, 09.762, 09.798, 09.799, 09.852 and 09.895] 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.

6.1.8. Flavouring Group Evaluation 65 (FGE.65):

Consideration of sulfur-substituted furan derivatives used as flavouring agents evaluated by JECFA (59th meeting).

EFSA-Q-2008-032Q

This FGE.65 is a consideration of 33 flavouring substances evaluated by the JECFA in the JECFA flavouring group of sulfur-substituted furan derivatives. The 33 substances are structurally related to the group of sulfur-substituted furans evaluated in the group of furfuryl and furan derivatives with and without additional side-chain substituents and heteroatoms evaluated by EFSA in FGE.13Rev1.

The Panel agrees with the way the Procedure has been applied by the JECFA for all 33 candidate substances included in this FGE. For 29 substances the Panel reached the same conclusion as the JECFA with respect to their use as chemically defined flavouring substances in food. For the four remaining substances [FL-no: 13.056, 13.160, 13.193 and 13.194] no adequate NOAEL could be identified by the Panel and subsequently, no conclusion as to their safety could be reached.

In order to determine whether the conclusion for the 33 substances can be applied to the materials of commerce, it is necessary to consider the available specifications. For eight substances [FL-no: 13.075, 13.077, 13.078, 13.153, 13.160, 13.193, 13.194 and 13.196] information on the isomeric composition/ composition of mixture is missing. For the remaining 25 substances, adequate specifications are available.

In total, the Panel has reservations for nine substances [FL-no: 13.056, 13.075, 13.077, 13.078, 13.153, 13.160, 13.193, 13.194 and 13.196]. Data on stereoisomerism/composition of mixture are needed for [FL-no: 13.075, 13.077, 13.078, 13.153, 13.160, 13.193, 13.194 and 13.196] and additional toxicity data are requested for [FL-no: 13.056, 13.160, 13.193 and 13.194].

For the remaining 24 [FL-no:13.015, 13.016, 13.017, 13.026, 13.032, 13.033, 13.040, 13.041, 13.050, 13.051, 13.053, 13.055, 13.063, 13.064, 13.065, 13.071, 13.079, 13.082, 13.086,

13.093, 13.142, 13.151, 13.152, 13.197] of the 33 substances, the Panel agrees with the conclusion of JECFA, that there is no safety concern for their use as flavouring substances at the levels of intake estimated using 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.

6.1.9. Flavouring Group Evaluation 62Rev1 (FGE.62Rev1):

Consideration of linear and branched-chain aliphatic unsaturated, non conjugated alcohols, aldehydes, acids, and related esters evaluated by JECFA (61st meeting).

EFSA-Q-2009-00907

Compared to FGE.62, which deals with 19 substances, the present Revision 1 (FGE.62Rev1) includes the assessment of three additional substances [FL-no: 09.540, 05.224 and 05.208], which have been evaluated by the JECFA at the 68th meeting. So, the present FGE.62Rev1 deals in total with 22 substances in the JECFA flavouring group of linear and branched-chain aliphatic unsaturated, non conjugated alcohols, aldehydes, acids, and related esters. The 22 substances are structurally related to the group of branched- and straight-chain unsaturated carboxylic acids and esters of these and straight-chain aliphatic saturated alcohols evaluated by EFSA in the Flavouring Group Evaluation 05, Revision 2 (FGE.05Rev2) and related to straight- and branched-chain aliphatic unsaturated primary alcohols, aldehydes, carboxylic acids, and esters evaluated by EFSA in FGE.06Rev1.

The Panel agrees with the way the Procedure has been applied by the JECFA for the 22 substances considered in this FGE. However, for two substances [FL-no: 02.189 and 02.243] the evaluation of the JECFA is based on MSDI values derived from production figures from the USA only. EU production figures are needed in order to finalise the evaluation of these substances.

In order to determine whether the conclusion for the 22 JECFA evaluated substances can be applied to the materials of commerce, it is necessary to consider the available specifications. For four substances [FL-no: 05.192, 08.075, 09.846 and 09.540] information of the isomeric composition is lacking and for four substances additional information on the composition is requested [FL-no: 02.243, 05.192, 09.568 and 09.932].

Thus, for eight substances [FL-no: 02.189, 02.243, 05.192, 08.075, 09.568, 09.846, 09.932 and 09.540] the Panel has reservations (no European production volumes available, preventing them to be evaluated using the Procedure, and/or missing data on isomerism/composition of isomers).

For the remaining 14 substances [FL-no: 02.249, 05.139, 05.208, 05.224, 09.559, 09.563, 09.564, 09.566, 09.571, 09.655, 09.917, 09.918, 09.921 and 09.922] the Panel agrees with the conclusion of JECFA that there is no safety concern for their use as flavouring substances at the levels of intake estimated 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 08Rev2 (FGE.08Rev2), in Addendum:

Aliphatic and alicyclic mono-, di-, tri-, and polysulphides with or without additional oxygenated functional groups from chemical groups 20 and 30.

EFSA-Q-2009-00908

The present Revision of FGE.08, FGE.08Rev2, includes the assessment of one additional candidate substance [FL-no: 12.250] compared to FGE.08Rev1. So in total the current FGE.08Rev2 67 substances.

No toxicity and/or metabolism data were provided for [FL-no: 12.250]. However, adequate repeated-dose toxicity studies are available for supporting substances from the subgroup of monothiols in FGE.08Rev1, allowing derivation of adequate margins of safety by comparing the NOAEL values with the MSDI.

In conclusion, based on this structural similarity and on the levels of intake estimated based on the MSDI approach. the Panel evaluated the candidate substance as to be of no safety concern when used as a flavouring substance.

However, information on stereoisomerism has not been specified for the substance [FL-no: 12.250]. Thus, the final evaluation of the material of commerce cannot be performed for this substance, pending further information.

FGE.08Rev2 is an addendum [FGE.08 Rev2 (Addendum)]. As there is no safety concern expressed, it will be published after the end of the evaluation programme, as decided in the 4th CEF Plenary meeting. See:
http://www.efsa.europa.eu/cs/BlobServer/Event_Meeting/cef_minutes_plen4_en_rev.pdf?ssbinary=true

6.1.11. Flavouring Group Evaluation 83Rev1 (FGE.83Rev1):

Consideration of ethyl maltol and two 6-keto-1,4-dioxane derivatives substances evaluated by JECFA (65th meeting).

EFSA-Q-2008-00909

Compared to FGE.83, which deals with 2 substances, FGE.83Rev1, includes the assessment of one additional substance, ethylmaltol, [FL-no: 07.047]. Ethylmaltol was originally considered in FGE.213 with respect to genotoxicity. The Panel concluded that the genotoxicity data available do not preclude its evaluation through the Procedure. So, the present FGE.83Rev1 deals in total with three substances in the JECFA flavouring group of ethylmaltol and 6-keto-1,4-dioxane derivatives. The Panel concluded that no corresponding FGE is available.

The Panel agrees with the way the Procedure has been applied by the JECFA for the three substances considered in this FGE. However, for two of them [FL-no: 13.027 and 13.028] the MSDI values are derived from USA production figures only. EU production figures are needed in order to finalise their evaluation.

In order to determine whether the conclusion for the three substances can be applied to the materials of commerce, it is necessary to consider the available specifications. For two of these substances [FL-no: 13.027 and 13.028] information on the stereoisomeric composition has not been provided.

In overall, for two substances [FL-no: 13.027 and 13.028] the Panel has reservations (no European production volumes available, preventing them from being evaluated using the Procedure, and missing information on stereoisomerism).

For the remaining substance [FL-no: 07.047] the Panel agrees with the conclusion of JECFA, that there is no safety concern for its use as flavouring substance at the levels of intake estimated 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.

6.1.2 Flavouring guidelines

Guideline stepwise approach

Legal deadline for "Opinion on data needed for the evaluation of Flavourings" is July 2009.

Proposal for a stepwise approach:

- July 2009: Adoption of an Opinion on data for evaluation of Flavouring substances.
- October-November: Public consultation, deadline 8 December 2009.
- January 2010: Plenary discussion of outcome of Public consultation.
- 4 and 5 March 2010: Workshop on flavourings w. stakeholders.
- March 2010: adoption of guidelines

Workshop

The planned workshop 4-5 March 2010 on flavourings was shortly presented and discussed.

- Regulation requests EFSA to specify data needed for evaluation of
  - flavouring substances
  - preparations,
  - thermal process flavourings,
  - flavour precursors,
  - other flavourings,
  - sources.
- Purpose of the workshop (consultation of stakeholders):
  - Industry is expected to clarify the type of flavourings for each of the above mentioned flavouring areas,
  - Clarification of the issues relevant for risk assessment of the different flavouring areas.

7. FOOD CONTACT MATERIALS

7.1. Evaluation of substances for use in plastics

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

PM Ref	Name
46330	**2,4-Diamino-6-hydroxypyrimidine**
	EFSA-Q-2009-00681
34240	**Alkyl (C10-C21)sulphonic acid, ester with phenol**
	EFSA-Q-2009-00733
45676	**Cyclic oligomers of (1,4-butylene terephthalate)**
	EFSA-Q-2007-096

- The draft opinions on the following substances were deferred to the next meeting due to lack of time.

80345	**Poly(12-dihydroxystearic acid) stearate**
	EFSA-Q-2004-040
43730	**5-Chloro-2-methyl-2H-isothiazol-3-one, mixture with 2-methyl-2H-isothiazol-3-one**
	EFSA-Q-2009-00515

8. SMOKE FLAVOURINGS

8.1. Draft opinion on Smoke Flavouring Primary Product TRADISMOKE™ A MAX

EFSA-Q-2005-257

The opinion was adopted and published on:
http://www.efsa.europa.eu/en/scdocs/scdoc/1394.htm

8.2. Draft opinion on Smoke Flavouring Primary Product Scansmoke R909

EFSA-Q-2005-259

The opinion was adopted and published on:
http://www.efsa.europa.eu/en/scdocs/scdoc/1395.htm

8.3. Draft opinion on Smoke Flavouring Primary Product AM 01

EFSA-Q-2005-269

The opinion was adopted and published on:
http://www.efsa.europa.eu/en/scdocs/scdoc/1396.htm

8.4. Draft opinion on Interpretation of the Margin of Safety

EFSA-Q-2009-00764

The opinion was adopted and published on:
http://www.efsa.europa.eu/en/scdocs/scdoc/1325.htm

9. AOB

No other business.

10. ANNEX 1: INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF SPECIFIC DECLARATION OF INTERESTS

In her Specific Declaration of Interests, Dr. M.-L. Binderup declared an interest for the substance 2,4-diamino-6-hydroxypyrimidine (REF. No. 43330), 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 to specific technical questions but did not participate in the discussion of the opinion. Another Panel member presented the draft opinion.