Parma, 08 April 2011

MINUTES OF THE 18th PLENARY MEETING

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

Held in Parma on 2-4 February 2011

Adopted on 24 March 2011

AGENDA:

Table of Contents

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

PARTICIPANTS

Panel Members:

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

Invited Experts, hearing experts:

Apologies: Nathalie Gontard, Rosemary Waring, Maria Rosaria Milana

European Commission: Jiri Sochor, Josiane Houins-Roulet

EFSA:

CEF Unit:

Scientific staff: Alexandre Feigenbaum, Dimitrios Spyropoulos, Anne Theobald, Eric Barthélémy, Cristina Croera, Kim Rygaard Nielsen; Anna Castoldi, Alina Lupu, Maria Carfi

Administrative staff: Hanne Pedersen, Marco Lannutti.

Library: Lara Congiu

1. WELCOME, APOLOGIES FOR ABSENCE

2. ADOPTION OF THE AGENDA

The agenda was adopted.

3. DECLARATIONS OF INTEREST

Declarations of interest were recorded and evaluated in compliance with EFSA's policy on declarations of interest:
http://www.efsa.europa.eu/en/efsawho/doi.htm
See Annex I

4. MATTERS ARISING FROM THE 15TH (22-23 SEPTEMBER 2010) AND 17TH (23-25 NOVEMBER 2010) PLENARY MEETINGS.

The minutes of the 15th Plenary meeting were adopted after revision.
The minutes of the 17th Plenary meeting were adopted.

They can be seen on http://www.efsa.europa.eu/en/panels/cef.htm

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

5.1. Implementing measures

The corresponding regulation is about to be published.

6. FLAVOURINGS

According to Regulation 1565/2000 of 18 July 2000

6.1. FLAVOURING GROUP EVALUATIONS

6.1.1. Flavouring Group Evaluation 08, Revision 3 (FGE.08Rev3)

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

(EFSA-Q-2011-0039 & EFSA-Q-2011-0040)

The present Revision of FGE.08, FGE.08Rev3, includes the assessment of three additional candidate substances [FL-no: 15.007, 15.134 and 16.114]. No metabolism data were provided for these three substances. Two substances [FL-no: 15.134 and 16.114] were allocated to subgroup VII, for which adequate 90-day subchronic studies are available for supporting substances.

Based on the corresponding NOAEL, the candidate substances are not expected to be of safety concern at the estimated levels of intake, when evaluated through the Procedure. However, the final evaluation of the materials of commerce cannot be performed for [FL-no: 15.134 and 16.114] as the stereoisomeric composition has to be specified.

The third new substance [FL-no: 15.007] was allocated to a new subgroup XI. The Panel noted that the JECFA has evaluated a 90-day toxicity study (Wheldon et al., 1970) and derived a NOAEL. However, some of the study details that are described in the JECFA report are not in accordance with the data in the original publication. Furthermore since there were dose-dependent signs of toxicity even at the lowest dose, the Panel considered that this study was not appropriate for derivation of a NOAEL. Consequently, additional toxicity data are requested for [FL-no: 15.007].

New toxicity data provided:

In FGE.08, the Panel considered that no adequate toxicity study was available for subgroup II to establish a NOAEL, neither on the candidate substances nor on supporting substances. Therefore, the Panel had concluded that additional data are required for the three cyclic sulphides [FL-no: 12.120, 15.102 and 15.125].

Additional toxicity data have been submitted by industry for the supporting substance [FL-no: 12.120] and the present FGE.08Rev3 includes the evaluation of these toxicity data. A 28-day oral study in rats has been made available since the publication of FGE.08Rev2. According to the practice of the Panel, a minimum requirement to derive adequately a NOAEL for flavourings is a 90-day study (the Panel reiterates that 90 days studies are already surrogates for chronic studies. The Panel will not take into account shorter studies).
The 28 day oral study is an unpublished and incomplete report in which histopathology results are not available. The Panel confirmed the overall conclusion from previous versions of FGE.08.Rev2, that for the 3 flavouring substances of subgroup II [FL-no: 12.120, 15.102 and 15.125] additional adequate toxicity data are needed.

New data on isomerim provided:

New information on optical isomers has been provided by Industry on 14 substances [FL-no: 12.104, 12.106, 12.120, 12.135, 12.177, 12.178, 12.180, 12.182, 12.214, 12.295, 15.047, 15.048, 15.083 and 16.057], and for five geometrical isomeric substances [FL-no: 12.098, 12.163, 12.164, 15.056 and 15.110]. For six of these substances [FL-no: 12.098, 12.120, 12.163, 12.164, 15.056 and 15.110], the stereoisomeric composition has not been specified sufficiently and the ratios of the isomers are needed.

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 13, Revision 2 (FGE.13Rev2)

Furfuryl and furan derivatives with and without additional side-chain substituents and heteroatoms.

(EFSA-Q-2011-0041)

Postponed. It will be on the agenda of a further meeting.

6.1.3. Flavouring Group Evaluation 21, Revision 2 (FGE.21Rev2)

Thiazoles, thiophene, thiazoline and thienyl derivatives.

(*EFSA-Q-2011-0042*)

Additional toxicity data

In the FGE.21 and FGE.21Rev1, the Panel considered that additional toxicity data were needed for 23 of the substances to be evaluated through the Procedure. Additional toxicity data and metabolism data have now become available for two of the 23 substances: [FL-no: 15.106] in subgroup A-Ia and [FL-no: 15.096] in subgroup A-Ib.

For thiophene [FL-no: 15.106], a combined repeated dose/reproductive and developmental toxicity study was submitted, in which males were dosed for 42 days and females from 14 days before mating.

For 2-pentylthiophene [FL-no: 15.096], a 28-day gavage study was available.

The Panel considered that both studies are inadequate for deriving an appropriate NOAEL (the Panel reiterates that 90 days studies are already surrogates for chronic studies. The Panel will not take into account shorter studies).

So, the overall conclusion from previous version of FGE.21 remains: for the 23 flavouring substances to be 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] additional toxicity data are needed.

Data on isomerism

Information on stereoisomeric composition has been provided by Industry on nine substances, [FL-no: 15.042, 15.054, 15.055, 15.060, 15.077, 15.090, 15.099, 15.119 and 15.129], for which a clarification of the stereoisomeric composition was requested. For four substances [FL-no: 15.042, 15.054, 15.119 and 15.129], the ratios of the diastereoisomers are still needed.

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 22, Revision 1 (FGE.22Rev1)

Ring-substituted phenolic substances.

(EFSA-Q-2011-0045, EFSA-Q-2011-0046, EFSA-Q-2011-0047, EFSA-Q-2011-0048, EFSA-Q-2011-0049)

The present revision of FGE.22, FGE.22Rev1, includes the assessment of five newly notified candidate substances [FL-no: 08.134, 09.943, 09.944, 09.945 and 09.946]. FGE.22 dealt with 23 substances, so the present revision, FGE.21Rev1 deals in total with 28 substances.

As concluded in FGE.21, one of the candidate substances, 3,4-methylenedioxyphenol [FL-no: 04.080] cannot be evaluated through the Procedure until adequate genotoxicity data become available.

The available genotoxicity data on the other 27 candidate and supporting substances would not preclude their evaluation through the Procedure. These substances, evaluated through the Procedure, are not expected to be of safety concern when used as flavouring substances at their estimated levels of intake, based on the MSDI approach.

Adequate specifications for the materials of commerce have been provided for all these 27 flavouring substances.

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 30, Revision 1 (FGE.30Rev1)

Two hydroxypropenylbenzenes, 4-prop-1-enylphenol and 2-methoxy-4-(prop-1-enyl)phenyl 3-methylbutyrate.

(*EFSA-Q-2011-0050*)

The present revision of FGE.30, includes the assessment of one additional candidate substance [FL-no: 04.097].

4-Prop-1-enylphenol [FL-no: 04.097] and 2-methoxy-4-(prop-1-enyl)phenyl 3-methylbutyrate [FL-no: 09.894] are not expected to be of safety concern when used as flavouring substances at their estimated levels of intake, 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.

6.1.6. Flavouring Group Evaluation 48 (FGE.48)

Evaluation of additional data submitted by industry in response to genotoxicity data requested in FGE.48 on 2-aminoacetophenone.
(EFSA-Q-2010-01100)

The former EFSA AFC Panel, in the opinion "Flavouring Group Evaluation 48: Aminoacetophenone from chemical group 33" of 9 July 2008, had expressed concern for a possible genotoxic potential of the candidate substance, 2-aminoacetophenone [FL-no: 11.008] due to structural alert.

On 8 April 2010 new information and data on 2-aminoacetophenone had been submitted to EFSA.

The CEF Panel concluded that the new information and data provided by Industry do not challenge the previous conclusion of the AFC Panel and are not sufficient to alleviate the concern for the genotoxic potential of 2-aminoacetophenone. The Panel re-confirmed the need for additional genotoxicity studies. In particular, two in vitro tests (a bacterial gene mutation and a micronucleus test) are considered adequate for purpose.

6.1.7. Flavouring Group Evaluation 59, Revision 1 (FGE.59Rev1)

Consideration of aliphatic and aromatic ethers evaluated by JECFA (61st meeting and 63rd meeting).

(*EFSA-Q-2011-0051*)

Postponed. It will be on the agenda of a further meeting.

6.1.8. Flavouring Group Evaluation 209 (FGE.209)

Consideration of genotoxiciy data on one α,β-unsaturated aldehyde from chemical subgroup 2.3 of FGE.19.
(*EFSA-Q-2011-01249*)

The present Flavouring Group Evaluation 209 (FGE.209), corresponding to subgroup 2.3 of FGE.19, concerns one cyclic aldehyde with the alpha,beta-unsaturations in the ring system, 2,6,6-trimethylcyclohexa-1,3-diene-1-carbaldehyde [FL-no: 05.104] (safranal).

After evaluation of new data, the Panel concluded that [FL-no: 05.104] is not of safety concern with respect to genotoxicity and it will be evaluated through the Procedure for a final safety assessment.

Changes to the text of the draft Opinion were noted. The Opinion was adopted and is published on http://www.efsa.europa.eu/en/efsajournal/pub/1992.htm.

6.1.9. Flavouring Group Evaluation 211 (FGE.211)

Consideration of genotoxiciy data on representatives for one α,β-unsaturated ketone and three precursors from chemical subgroup 2.5 of FGE.19.
(*EFSA-Q-2011-01250*)

The present Flavouring Group Evaluation 211 (FGE.211), corresponding to subgroup 2.5 of FGE.19, concerns one alicyclic ketone [FL-no: 07.034] and three precursors [FL-no: 02.100, 09.119 and 09.930].

After evaluation of new data, the Panel concluded that, the four substances [FL-no: 02.100, 07.034, 09.119 and 09.930] in subgroup 2.5 of FGE.19 would be of no safety concern with respect to genotoxicity and will be evaluated through the Procedure for a final safety assessment.

Changes to the text of the draft Opinion were noted. The Opinion was adopted and is published on http://www.efsa.europa.eu/en/efsajournal/pub/1993.htm.

6.1.10. Flavouring Group Evaluation 300 (FGE.300)

One cycloaliphatic amide.
(*EFSA-Q-EFSA-Q-2009-00579*)

Postponed. It will be on the agenda of a further meeting.

6.1.11. Flavouring Group Evaluation 301 (FGE.301)

A Sulphur substituted pyrimidin-derivative and its hydrochloride salt.
(*EFSA-Q-2009-0058*)

The present FGE consists of 4-amino-5,6-dimethylthieno[2,3-d]pyrimidin-2(1H)-one [FL-no: 16.116] and its hydrochloride salt [FL-no: 16.120]. The Panel decided to evaluate it as the same substance. The available 90 day study will be re-examined in order to evaluate whether the NOAEL was the lowest dose.

The FGE was deferred back to the Flavouring WG for revision. It will be on the agenda of the 20th Plenary in May.

6.1.12. Flavouring Group Evaluation 303 (FGE.303)

Spilanthol.
(EFSA-Q-2010-00006)

The candidate substance in FGE.303 is spilanthol [FL-no: 16.121].

No *in vitro* or *in vivo* data are available for the candidate substance spilanthol. However, for two of the supporting substances [FL-no: 16.091 and 16.093] negative genotoxicity studies are available. The Panel therefore considers that the candidate substance spilanthol [FL-no: 16.121] can be evaluated through the Procedure.

Spilanthol [FL-no: 16.121] cannot be anticipated to be metabolised to innocuous products.

No relevant data on toxicity are available for the candidate substance or for the supporting substances. The only toxicity data available is a 28-day study which is not adequate for evaluations of chronic

effects. Accordingly, additional data are required for the candidate substance in order to derive a NOAEL.

Changes to the text of the draft Opinion were noted. The Opinion was adopted and is published on http://www.efsa.europa.eu/en/efsajournal/pub/1995.htm.

6.1.13. Flavouring Group Evaluation 308 (FGE.308)

Sodium Diacetate, Glucose Pentaacetate and Sucrose Octaacetate.
(*EFSA-Q-2010-01504 & EFSA-Q-2010-01505*)

The present FGE308 deals with three substances: sodium diacetate [FL-no: 16.073], glucose pentaacetate [FL-no: 09.258] and sucrose octaacetate [FL-16.081]. However, it was agreed that sodium diacetate was not sufficient structurally related to the two other substances, so sodium diacetate will be evaluated separately.

For sodium glucose pentaacetate [FL-no: 09.258] and sucrose octaacetate [FL-16.081] the Panel considered that there were valid toxicological data providing adequate margins of safety compared to the intakes from use as flavouring substances. Therefore, these flavouring substances 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 is published on http://www.efsa.europa.eu/en/efsajournal/pub/2014.htm.

6.2. SELECTION OF REPRESENTATIVE SUBSTANCES FOR TOXICITY TESTING

(EFSA-Q-2010-01492)

An Opinion laying down a list of 85 substances in sub-groups with representatives for which additional data are required prior to their group evaluation through the evaluation Procedure was presented and adopted.
It has been published on http://www.efsa.europa.eu/en/efsajournal/doc/1985.pdf

6.3. OPINION ON DATA NEEDED FOR THE EVALUATION OF FLAVOURINGS

(EFSA-Q-2009-00004)

The secretariat informed the Panel that the report on the public consultation on the Guidance document on the data required for the risk assessment of flavourings has been published in December 2010 (http://www.efsa.europa.eu/en/efsajournal/pub/1957.htm).

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:

Ref No 25885
Trimethyl trimellitate
(EFSA-Q-2010-00838)

The draft opinion was discussed, modified and adopted. The full opinion is available through: http://www.efsa.europa.eu/en/efsajournal/pub/1997.htm

Ref No 47060
3-(3,5-Di-tert-butyl-4-hydroxyphenyl)propanoic acid, esters with C13-C15 branched and linear alcohols
(EFSA-Q-2010-00934)

The draft opinion was discussed, modified and adopted. The full opinion is available through: http://www.efsa.europa.eu/en/efsajournal/pub/1998.htm

Ref No 86437
Silver Zeolite A (Silver zinc sodium ammonium alumino silicate)
(EFSA-Q-2009-00708)

The draft opinion was discussed, modified and adopted. The full opinion is available through: http://www.efsa.europa.eu/en/efsajournal/pub/1999.htm

Ref No 22931
(Perfluorobutyl)ethylene
(EFSA-Q-2010-01039)

The draft opinion was discussed, modified and adopted. The full opinion is available through: http://www.efsa.europa.eu/en/efsajournal/pub/2000.htm

Ref No 38885
2,4-Bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine
(EFSA-Q-2009-00768)

The draft opinion was discussed, modified and adopted. The full opinion is available through: http://www.efsa.europa.eu/en/efsajournal/pub/2001.htm

Ref No 15260
1,10-Decanediamine
(EFSA-Q-2009-00674)

The draft opinion was discussed, modified and adopted. The full opinion is available through: http://www.efsa.europa.eu/en/efsajournal/pub/2002.htm

Ref No 93460
Titanium dioxide, reacted with octyltriethoxysilane
(EFSA-Q-2009-00917)

The draft opinion was discussed, modified and adopted. The full opinion is available through: http://www.efsa.europa.eu/en/efsajournal/pub/2003.htm

7.2. DRAFT OPINION ON PHENOL

(EFSA-Q-2010-00177)

The draft opinion was discussed and changes were proposed. It was decided that the opinion should be re-discussed in the working group to address the proposed changes.

7.3. UPDATE FROM RECYCLING WORKING GROUP

It was deferred to the 19th Plenary meeting in March.

8. A.O.B.

8.1. Update from the Mineral hydrocarbons Working Group

The Panel members were informed that the EFSA has received a mandate concerning the contamination of food with mineral oils. The CONTAM Panel has the lead in preparing a scientific opinion and the CEF Panel is expected to prepare a section on the contamination of food with mineral oils migrating from food contact materials.

8.2. Request for a scientific opinion on the evaluation of the safety and efficacy of lactic acid for the removal of microbial surface contamination of beef carcasses, cuts and trimmings.

EFSA has been requested to evaluate the safety and efficacy of lactic acid for the removal of microbial surface contamination of beef carcasses, cuts and trimmings.
The submitted dossier will be evaluated by CEF Panel for the toxicological safety of the substance. The BIOHAZ Panel will evaluate the dossier for the efficacy of the treatment.

8.3. Need for a Revision of the guidance document on the submission of a dossier on a substance to be used in Food Contact Materials.

The mandate for a self-tasking scientific opinion on “Guidelines for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation”, has been signed by the Executive Director.

9. ANNEX I: INTERESTS & ACTIONS RESULTING FROM THE SCREENING OF SPECIFIC DECLARATION OF INTERESTS

Both R. Crebelli and T. Husoy declared interest in FGE.13Rev2 (Furfuryl and furan derivatives with and without additional side-chain substituents and heteroatoms), due to their involvement in research projects on furan and derivatives. As these projects are funded exclusively by public research authorities and as no financial benefit has been received by these experts in their personal capacity, these interests are not conflicts (level A), according to EFSA policy on declarations of interest.

M. Binderup declared interest in Ref No 15260 (1,10-Decanediamine), as her Institute (DTU Copenhagen) 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.

D. Wolfle and K. Pfaff, in the meeting, declared interest for phenol, as they work for BfR, the requestor for the re-evaluation of the substance. However, they are not involved at all in this matter in their organisation. According to EFSA policy on declarations of interest, these interests are not conflicts (level A).