Parma, 15 December 2010

MINUTES OF THE 16th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS AND PROCESSING AIDS (CEF)

Held in Parma on 28-30 September 2010

Adopted on 25 November 2010

AGENDA:

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MINUTES OF THE 16th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS & PROCESSING AIDS (CEF)

PARTICIPANTS

Panel Members:

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

Invited Experts, hearing experts:

Vibe Meister Beltoft and Angelo Carere (item 6.1)

Apologies: Arturo Anadón, Mona-Lise Binderup, Maria Rosaria Milana, Karla Pfaff

European Commission: Joaquim Ordeig-Vila (for item 8), Sirkku Heinima (for item 6)

EFSA:

CEF Unit:

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

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 14TH PLENARY MEETING, 6-8 JULY 2010

The minutes of the 14th Plenary meeting were adopted. They can be seen on (http://www.efsa.europa.eu/en/events/event/cef100706.htm).

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

6. FLAVOURINGS

According to Regulation 1565/2000 of 18 July 2000

6.1. Flavouring group evaluations (according to Regulations 1565/2000 and 1834/2008)

FGE.218Rev1

α,β-Unsaturated aldehydes and precursors from subgroup 4.2 of FGE.19: Furfural derivatives.

EFSA-Q-2009-01083

In FGE.218 there was a request for data on 5-methylfurfural [FL-no: 13.001]. New genotoxicity data have been submitted on the related substance 5-hydroxymethylfurfural [FL-no: 13.139] (evaluated in FGE.13).

It is anticipated that 5-methylfurfural [FL-no: 13.001] can be oxidised to the primary alcohol 5-hydroxymethylfurfural [FL-no: 13.139], which was evaluated by EFSA in FGE.13, dealing with furfuryl and furan derivatives. As 5-hydroxymethylfurfural may be metabolised to 5-[(sulphoxy)methyl]furfural, which shows genotoxic potential *in vitro*, it was concluded in FGE.13 that 5-hydroxymethylfurfural could not be evaluated through the Procedure. Accordingly, 5-methylfurfural could not be evaluated through the Procedure either.

The rapporteur presented the new data on carcinogenicity and metabolism of 5-hydroxymethylfurfural [FL-no: 13.139], which were discussed. The essentially negative results of the carcinogenicity study in rats and mice indicate that 5-hydroxymethylfurfural [FL-no: 13.139] and 5-methylfurfural [FL-no: 13.001] are of no concern under the conditions of intended use. Accordingly, it was concluded that 5-methylfurfural [FL-no: 13.001], as well as 5-hydroxymethylfurfural [FL-no: 13.139] can be evaluated through the Procedure.

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

FGE.220Rev1

α,β-Unsaturated ketones and precursors from chemical subgroup 4.4 of FGE.19: 3(2H)-Furanones.

EFSA-Q-2009-00568

EFSA considered in FGE.220 the subgroup 4.4 of FGE.19, consisting of 10 α,β-unsaturated 3(2H)-furanones. The subgroup had been subdivided further into two subgroups 4.4a and 4.4b. For both subgroups the outcome were that the genotoxic alert could not be ruled out based on data available at that time, and accordingly representative substances were selected for both groups.

The present revision of FGE.220, FGE.220Rev1, concerns the evaluation of additional data submitted by Industry in response to the requested genotoxicity data in FGE.220 on the representative substance for subgroup 4.4b, 4-hydroxy-2,5-dimethylfuran-3(2H)-one [FL-no: 13.010].

The rapporteur presented the new data on 4-hydroxy-2,5-dimethylfuran-3(2H)-one [FL-no: 13.010], which were discussed. Overall, taking into account all the presently available data it was concluded that there is no concern for the reproductive capacity and for the possible heritable genetic damage at the current use levels of 4-hydroxy-2,5-dimethylfuran-3(2H)-one [FL-no: 13.010] as flavour ingredient. Accordingly, it was concluded that 4-hydroxy-2,5-dimethylfuran-3(2H)-one [FL-no: 13.010] as well as the four other substances [FL-no: 13.084, 13.085, 13.099 and 13.176] in subgroup 4.4.b of FGE.220 can be evaluated through the Procedure.

For subgroup 4.4a, no data have been submitted so far.

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

FGE.17Rev2

Pyrazine derivatives.

EFSA-Q-2010-00006

In the previous FGE.17Rev1, it had been found that two of the candidate substances, quinoxaline [FL-no: 14.147] and 2-methylquinoxaline [FL-no: 14.139] showed possible genotoxic potential *in vitro*. Therefore, the Panel had decided that the Procedure could not be applied to these two substances nor to the structurally related 2,3-dimethylquinoxaline [FL-no: 14.108] until adequate genotoxicity data become available. This conclusion did also have implications for the structurally related 5-methylquinoxaline [FL-no: 14.028] (considered in FGE.50), and the Panel considered that the Procedure should not be applied until adequate genotoxicity data become available for this substance either.

Additional genotoxicity data have now become available for the substance [FL-no: 14.028] from FGE.50 and the present revision of FGE.17Rev1, FGE.17Rev2 includes the evaluation of these genotoxicity data submitted by the Industry.

Besides, the present FGE.17Rev2 also includes the evaluation of one new substance [FL-no: 14.051]. No metabolism or toxicity data were submitted for this new substance. Furthermore, [FL-no: 14.051] no intake data were available. Therefore the substance cannot be evaluated through the Procedure.

The rapporteur presented the new genotoxicity data on 5-methylquinoxaline [FL-no: 14.028], which were discussed. During the discussion, the issue was raised whether the genotoxicity data on this substance also can cover the evaluation of 2-methyl- and 2,3-dimethylquinoxaline [FL-no: 14.139 and 14.108]. It was decided to scrutinise again these genotoxicity data in the Working Group for a final decision at the Plenary in November.

FGE.50Rev1

Consideration of pyrazine derivatives evaluated by JECFA (57th meeting).

EFSA-Q-2010-00007

In FGE.50 the Panel concluded that for one of the substances, 5-methylquinoxaline [FL-no: 14.028], the Procedure should not be applied until adequate genotoxicity data become available. This conclusion was in line with the Panel conclusion for three other quinoxalines evaluated in FGE.17Rev1.

Additional genotoxicity data have now been submitted by the Industry for [FL-no: 14.028] and the present revision of FGE.50 and FGE.50Rev1 includes the evaluation of these genotoxicity data.

Based on the re-evaluation of all available data (*in vitro and in vivo*) it was agreed that there is no more genotoxic concern for 5-methylquinoxaline [FL-no: 14.028].

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

FGE.74Rev1

Consideration of simple aliphatic sulphides and thiols evaluated by JECFA (61st meeting).

EFSA-Q-2009-00954

The rapporteur presented the FGE. In connection with the evaluation of the candidate substances in FGE.08Rev1, it was recognized that tri-and polysulphides (subgroup VI of FGE.08Rev1) may form reactive metabolites through reaction with endogenous thiols forming a thiol and a hydropersulphide or perthiol. Compared to thiols, perthiols may be strong reducing agents, forming reactive products when exposed to oxidants. Thus, it was concluded that tri- and polysulphides could not be covered by No Observed Adverse Effect Level (NOAEL) for disulphides, due to the formation of more reactive metabolites. No NOAEL was available for subgroup VI, and additional toxicity data was required for the substances in this subgroup. This decision had also an impact on the tri- and polysulphides in FGE.74 (one substance [FL-no: 12.280]) as well as those evaluated by JECFA at its 53rd meeting, before 2000 (seven substances [FL-no: 12.009, 12.013, 12.020, 12.023, 12.045, 12.074 and 12.155]), which are therefore included in this Revision.

Therefore, the present evaluation deals with 18 substances evaluated by JECFA: the 11 substances considered in the previous version of FGE.74 and the additional 7 supporting substances in FGE.08 (evaluated by JECFA before 2000).

The Panel agrees with the application of the Procedure as performed by the JECFA for eight of the 18 aliphatic sulphides and thiols [FL-no: 12.179, 12.198, 12.212, 12.238, 12.239, 12.255, 12.257 and 12.291]. The Panel concluded that 2-methyl-4-oxopentane-2-thiol [FL-no: 12.169] and 2-mercapto-2-methylpentan-1-ol [FL-no: 12.241] should not be evaluated through the Procedure, as they are structurally related to 2-methylpropane-2-thiol [FL-no: 12.174], 2-methylbutane-2-thiol [FL-no: 12.172] and 2,4,4-trimethyl-1,3-oxathiane [FL-no: 16.057] in FGE.08Rev1 for which the Panel has previously concluded that they could not be evaluated through the Procedure due to concerns with respect to genotoxicity *in vitro.*

For the eight tri- and polysulphides [FL-no: FL-no: 12.009, 12.013, 12.020, 12.023, 12.045, 12.074, 12.155 and 12.280], the Panel did not agree with the JECFA that appropriate studies were available for deriving NOAELs, and accordingly the Panel concluded that additional data are needed for these eight substances.

For two substances [FL-no: 12.045 and 12.155] the JECFA evaluation is only based on MSDI values derived from production figures from the USA. EU production figures are needed in order to finalize the evaluation of these substances.

In order to determine whether the conclusion for the 18 substances can be applied to the materials of commerce, it was necessary to consider the available specifications. For four substances [FL-no: 12.009, 12.020, 12.045 and 12.169] information on the composition is requested.

Thus, for five substances [FL-no: 12.009, 12.020, 12.045, 12.155, 12.169] the Panel has reservations: (missing European production volumes and/or compositional information of

mixture). For two substances [FL-no: 12.169 and 12.241] the Procedure should not be applied until adequate genotoxicity data become available and for eight substances [FL-no: 12.009, 12.013, 12.020, 12.023, 12.045, 12.074, 12.155 and 12.280] additional toxicity data are required.

For the remaining eight of the 18 JECFA evaluated simple aliphatic sulphides and thiols [FL-no: 12.179, 12.198, 12.212, 12.238, 12.239, 12.255, 12.257, and 12.291] the Panel agrees with JECFA conclusion "No safety concern at estimated levels of intake as flavouring substances" based on the MSDI approach.

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

FGE.01Rev2

Branched-chain aliphatic saturated aldehydes, carboxylic acids and related esters of primary alcohols and branched chain carboxylic acids.

EFSA-Q-2009-00566

The rapporteur presented the FGE. The present revision 2 of FGE.01 includes the assessment of one additional candidate substance, 6-methylheptanal [FL-no: 05.225]. The substance was concluded to be of no safety concern.

In addition, requested data in the previous version, FGE.01Rev1, on stereoisomeric composition for three candidate substances [FL-no: 05.160, 05.211 and 05.219] have now been forwarded by Industry and are included in the present revision.

In total FGE.01Rev2 contain 22 substances, for which it were concluded that no safety concern exist at the levels of intake estimated on 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.

FGE.06 Rev2

Straight- and branched-chain aliphatic unsaturated primary alcohols, aldehydes, carboxylic acids, and esters.

EFSA-Q-2010-01131

The rapporteur presented the FGE. The present revision of FGE.06 includes the assessment of one additional candidate substance, nona-3,6-dienyl acetate [FL-no: 09.674]. The substance was evaluated at step A3 to be of no safety concern.

In addition, requested data in the previous version of FGE.06, FGE.06Rev1, on stereoisomeric composition have now been forwarded by Industry and included in the present revision.

In order to determine whether the conclusion for the total 48 candidate substances can be applied to the material of commerce, it is necessary to consider the available specifications. Adequate specifications including complete purity criteria and identity tests for the materials of commerce have been provided for 47 of the 48 flavouring candidate substances. However sufficient information on geometrical isomerism/chirality is still missing for 13 of the substances [FL-no: 02.152, 02.222, 05.061, 05.203, 05.218, 08.074, 08.102, 09.377, 09.640, 09.674, 09.831, 09.884 and 09.885]. For one substance [FL-no: 09.938], an identity tests is missing. Thus, the final evaluation of the materials of commerce cannot be performed for 17 substances [FL-no: 02.152, 02.222, 02.234, 05.061, 05.082, 05.203, 05.217, 05.218, 08.074, 08.102, 09.377, 09.640, 09.674, 09.831, 09.884, 09.885 and 09.938], pending further information.

The remaining 34 substances [FL-no: 02.125, 02.138, 02.170, 02.175, 02.176, 02.195, 02.201, 02.234, 05.082, 05.143, 05.174, 05.217, 05.220, 08.100, 09.341, 09.368, 09.567, 09.569, 09.572, 09.575, 09.612, 09.638, 09.643, 09.672, 09.673, 09.838, 09.855, 09.871, 09.872, 09.897, 09.898, 09.928, 09.937 and 09.939] 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

FGE.07Rev3

Saturated and unsaturated aliphatic secondary alcohols, ketones and esters of secondary alcohols and saturated linear or branched-chain carboxylic acids.

EFSA-Q-2009-00570

The rapporteur presented the FGE. The present revision of FGE.07 includes the assessment of one additional candidate substance, 9-Decen-2-one [FL-no: 07.262] and the inclusion of submitted additional information on isomerism in response to requests in FGE.07Rev2.

The substance 9-Decen-2-one [FL-no: 07.262] was evaluated at step A3 to be of no safety concern.

So, in total, specifications including purity and identity for the materials of commerce have been provided for all 44 candidate substances. Sufficient information on the composition of the stereoisomeric mixture is still lacking for the substance [FL-no: 07.156].

Thus, the final evaluation of the materials of commerce cannot be performed for one substance [FL-no: 07.156], pending further information on the stereoisomeric composition. The remaining 43 substances [FL-no: 02.077, 02.124, 02.142, 02.148, 02.177, 02.182, 02.183, 02.190, 02.255, 07.072, 07.084, 07.150, 07.157, 07.158, 07.160, 07.162, 07.178, 07.181, 07.182, 07.185, 07.189, 07.199, 07.201, 07.205, 07.236, 07.239, 07.262, 09.304, 09.323, 09.325, 09.328, 09.332, 09.386, 09.388, 09.391, 09.604, 09.605, 09.606, 09.608, 09.609, 09.676, 09.880 and 09.926] 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.

FGE.08Rev3

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

EFSA-Q-2009-00576

The opinion was postponed due to lack of time. It will be on the agenda of a future Plenary.

FGE.12Rev2

Primary saturated or unsaturated alicyclic alcohol, aldehyde, acid, and esters.

EFSA-Q-2009-00578

The rapporteur presented the FGE. The present revision of FGE.12 includes the assessment of two additional candidate substances 4-(2,2,3-trimethylcyclopentyl)butanoic acid [FL-no: 08.135] and ethyl cyclohexylacetate [FL-no: 09.829]. The two substances were evaluated at step A3 to be of no safety concern.

In addition, requested data in the previous versions of FGE.12, on stereoisomers and specifications have now been forwarded by Industry and they are included in the present revision. Adequate specifications including complete purity criteria and identity tests for the materials of commerce have been provided for all nine substances. However sufficient information on stereoisomeric composition is still missing for four of the substances [FL-no: 02.186, 05.157, 05.198 and 09.670].

Thus, the final evaluation of the materials of commerce cannot be performed for these four substances, pending further information on the stereoisomeric composition. The five remaining substances [FL-no: 02.134, 05.183, 08.135, 09.342 and 09.829] would present no safety concern at the 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.

FGE.18Rev2

Aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols, aromatic tertiary alcohols and their esters.

EFSA-Q-2010-01132

The rapporteur presented the FGE. The present revision of FGE.18 includes the assessment of two additional candidate substances, bisabola-1,12-dien-8-ol [FL-no: 02.129] and 3,7-dimethylocta-1,5,7-trien-3-ol [FL-no: 02.146]. Since the publication of FGE.18Rev1 additional specification information has become available and is included in this revision.

In connection with the re-evaluation of the candidate substances for which Industry has submitted further data since the publication of FGE.18Rev1, two metabolism studies on cedrol [FL-no: 02.120] indicate that the candidate substances cedrol [FL-no: 02.120], cedryl

acetate [FL-no: 09.171] guaiyl acetate [FL-no: 09.808] and 1,2,3,4,4a,5,6,7-octahydro-2,5,5-trimethylnaphthalen-2-ol [FL-no: 02.197] will be further hydroxylated and excreted in urine as such or as conjugates; hence they are anticipated to be metabolised to innocuous products. The Panel noted that in FGE.07, Revision 2 (adopted 26 march 2009), two substances, hex-5-en-2-one [FL-no: 07.162] and tridec-12-en-2-one [FL-no: 07.201] with terminal double bond and an additional functional group distant from the terminal double bond were evaluated via the A-side of the Procedure scheme; any risk from epoxide formation of those substances had been considered to be low since the substances can be directly conjugated with glucuronic acid. Furthermore, any epoxides formed are anticipated to be metabolised by conjugation with glutathione or by epoxide-hydrolase mediated hydrolysis. Therefore, in this present revision of FGE.18, it was concluded that the five substances [FL-no: 02.120, 02.144, 02.197, 09.171 and 09.808] are anticipated to be metabolised to innocuous products and thereby they can be evaluated via the A-side of the Procedure scheme and not, as in the previous version of FGE.18, via B-side.

Twenty-nine of the total number of 32 candidate substances are anticipated to be metabolised to innocuous products and would not give rise to safety concerns at the estimated levels of intakes. For the remaining three candidate substances [FL-no: 02.185, 02.191 and 09.669] no metabolism data are available and therefore they cannot be predicted to be metabolised to innocuous products. No appropriate NOAEL was available for these three candidate substances. Therefore, additional data are required for these three candidate substances.

In conclusion, for three flavouring substances [FL-no: 02.185, 02.191 and 09.669] the Panel considered that additional toxicity data are needed. For seven substances [FL-no: 02.146, 02.147, 02.168, 02.191, 02.197 and 02.230], information on the stereoisomeric composition/composition of mixture is missing. For the 24 flavouring substances [FL-no: 02.041, 02.052, 02.054, 02.120, 02.123, 02.129, 02.140, 02.144, 02.149, 02.150, 02.171, 02.181, 02.184, 02.203, 02.206, 02.219, 02.226, 02.253, 09.171, 09.356, 09.614, 09.617, 09.671 and 09.808] the Panel considered that they would present no safety concern at their estimated levels of intake estimated on the basis of the MSDI approach.

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

FGE.23Rev2

Aliphatic, alicyclic and aromatic ethers including anisole derivatives.

EFSA-Q-2009-00580

The rapporteur presented the FGE. The present revision of FGE.23 includes the assessment of one additional candidate substance, digeranyl ether [FL-no: 03.024]. The substance was evaluated at step A3 to be of no safety concern.

In addition, since the publication of FGE.23Rev1 additional specification information has become available and is included. However, for the substance [FL-no: 03.022] sufficient information on stereoisomeric composition is still missing. Thus, the final evaluation of these materials of commerce cannot be performed, pending further information on stereoisomeric composition.

The remaining 18 substances [FL-no: 02.247, 02.248, 03.008, 03.011, 03.012, 03.015, 03.016, 03.020, 03.024, 04.059, 04.067, 04.068, 04.069, 04.075, 04.079, 04.084, 08.127 and 09.687] would present no safety concern at the estimated levels of intake based on the MSDI approach.

FGE.46Rev1

Ammonia and two ammonium salts.

EFSA-Q-2010-01133

The opinion was postponed due to lack of time. It will be on the agenda of a future Plenary.

FGE.301

A sulphur substituted pyrimidin derivative and its hydrochloride salt.

EFSA-Q-2009-00581

The rapporteur presented the FGE. A concern was raised whether the data present were sufficient for establishing a NOAEL and hence for evaluation of the substance as a flavouring.

The draft Opinion was send back to the Working Group in order to check the available 90 days study.

FGE.302

N-(2-Methylcyclohexyl)-2,3,4,5,6-pentafluoro-benzamide.

EFSA-Q-2009-01084

The rapporteur presented the FGE. The evaluation was put on hold as the data available were not considered to be sufficient for an evaluation.

The Panel conducted a stepwise evaluation of N-(2-methylcyclohexyl)-2,3,4,5,6-pentafluorobenzamide [FL-no: 16.119]. The substance is classified into the Cramer structural class III (TTC threshold is 90 µg/person/day). Since the substance cannot be anticipated to be metabolised to innocuous products, the evaluation proceeds via the B-side of the Procedure scheme.

However, no adequate toxicity study is available, from which a NOAEL could be established, neither for the substance itself nor for any structurally related substance. The safety of the substance when used as a flavouring can therefore not be assessed.

Therefore, the Panel concluded that additional data are required for the substance. These data would include ADME data and an extended 90-day study, including endpoints on reprotoxicity.

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. The full opinions are available through: www.efsa.europa.eu.

PM Ref Name

39150 N,N-Bis(2-hydroxyethyl)dodecanamide

EFSA-Q-2009-00591

The CEF Panel concluded that the substance N,N-bis(2-hydroxyethyl)dodecanamide be classified in the SCF_List 3, with a restriction of 5 mg/kg food. The residual amount of diethanolamine into plastics should not be more than 0.3 mg/6dm².

45197 Copper hydroxide phosphate

EFSA-Q-2010-00708

The CEF Panel concluded that the substance copper hydroxide phosphate be classified in the SCF_List 3. The general restriction for copper of 5mg/kg food, as laid down in Directive 2002/72/EC, applies.

94987 Trimethylolpropane, mixed triester and diesters with n-octanoic and n-decanoic acid

EFSA-Q-2010-00045

The CEF Panel concluded that the substance trimethylolpropane, mixed triesters and diesters with n-octanoic and n-decanoic acids be classified in the SCF_List 3, with a restriction of 0.05 mg/kg food and only to be used for PET in contact with all types foods other than fatty, high-alcoholic and dairy products.

86437 Silver Zeolite A (Silver zinc sodium ammonium alumino silicate)

EFSA-Q-2009-00708

Due to lack of time, the draft opinion on the substance was postponed at the next Panel meeting in November.

7.2. Update from recycling Working Group

The issue was postponed due to lack of time.

7.3. Revision of FCM Guidance document

The need to update this document was emphasized. Further discussions will take place in 2011.

8. OPINION ON CHEMICAL SAFETY OF IRRADIATION

EFSA-Q-2006-034

Since the previous discussion of the draft opinion, changes were introduced in the text. They were presented by the rapporteur and discussed.

The Panel noted publications on case reports and an experimental study on leukoencephalo-myelopathy in cats fed with pet food irradiated at relatively high doses. The Panel agreed that cats are a sensitive species, but wished to have further information in order to evaluate the possible relevance for humans. A revised version will be presented in the November Plenary and is foreseen for adoption.

9. PREPARATION OF NOTE FOR GUIDANCE FOR ENZYMES

EFSA-Q-2010-01152

The CEF unit has received an internal mandate to prepare a note for guidance for enzymes.

10. ANY OTHER BUSINESS

- Definition of EFSA outputs (www.efsa.europa.eu)
- Nano, opinion of the Scientific Committee: the 2nd opinion on the safety of nanotechnologies is in preparation.
- Endocrine disruptors, document from Scientific Committee

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

No interest was declared for the issues on the agenda.