Parma, 22 February 2011

MINUTES OF THE 17th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS AND PROCESSING AIDS (CEF)

Held in Parma on 23-25 November 2010

Adopted by written procedure on 21 February 2011

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MINUTES OF THE 17th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS & PROCESSING AIDS (CEF)

PARTICIPANTS

Panel Members:

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

Apologies: Roland Franz

Invited Experts, hearing experts:

Karin Nørby (2nd and 3rd days), Angelo Carere (2nd and 3rd days).

European Commission: Josiane Houins-Roulet, Jiri Sochor.

EFSA:

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

CEF Unit Administrative staff: Hanne Pedersen, Marco Lannutti

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 1)

4. MATTERS ARISING FROM THE 16TH PLENARY MEETING, 28-30 SEPTEMBER 2010

The minutes of the 16th Plenary meeting were adopted. They can be seen on http://www.efsa.europa.eu/en/events/event/cef100928-m.pdf

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

5.1. Deadlines and workflow for flavouring substances in 2010-2011

Substances of the evaluation programme: the evaluation programme was completed by the Panel on 31 December 2009.
For re-evaluation of the genotoxicity data of FGE.19 substances, EFSA has proposed a deadline of 6 month (letter of ED to SANCO of 23/1/2010).
For other toxicity data and for evaluation of substances through the procedure (e.g. Footnote 10 substances, for which there are some differences between EFSA and JECFA early evaluations), the proposed deadline is 31/12/2014. Given that only few data have been submitted by industry yet, this deadline may even need to be postponed.

Substances submitted in 2008-2011, between the evaluation programme and the entry in force of the new Regulation on implementing measures, EFSA has no legal deadline for the evaluation. All deadlines are resulting from an agreement with Commission services, depending on the Panel's work load.

Substances submitted after entry in force of the implementing measures, the deadline will be 1 month for checking the suitability of the data for Risk Assessment followed by 9 months for the evaluation of the data.

5.2. ESCO working group on non-plastics FCM

The ESCO WG has collected the lists of substances evaluated by MS. It is now discussing criteria for prioritisation of evaluations and establishing a list of knowledgeable experts who can be contacted in case of new crisis with the non plastic parts of FCM.
A meeting with stakeholders will be held on 9-10 March 2011 in Milan. Panel members wishing to participate to that event are invited to register.
Interested stakeholders should apply and send their CV by 20 January 2011 (announcement will be made on EFSA web site).

5.3. Draft opinion on nanomaterials

The secretariat informed the Panel that the Scientific Committee has finalised its draft opinion on nanomaterials.

5.4. Update from WHO expert meeting on BPA

A summary report of the meeting is being prepared and expected to be published in 2010. The full report of the meeting is planned for mid 2011.

6. FLAVOURINGS

According to Regulation 1565/2000 of 18 July 2000 and regulatory context presented in item 5.1

6.1. Flavouring group evaluations

6.1.1. Flavouring Group Evaluation 17, Revision 2 (FGE.17Rev2):

Pyrazine derivatives from chemical group 24 (*EFSA-Q-2010-00006*).

The current FGE deals with re-evaluation of substances of the evaluation programme and with one new substance. In the previous version of FGE.17 (FGE.17Rev1), the Panel had considered 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 Procedure could not be applied to these two substances nor to the structurally related 2,3-dimethylquinoxaline [FL-no: 14.108] and 5-methylquinoxaline [FL-no: 14.028] (considered in FGE.50 (Item 6.1.2)) until adequate genotoxicity data become available.

Industry has now provided additional genotoxicity data for the substance [FL-no: 14.028] from FGE.50.

Based on these new data, the Panel considered that there is no genotoxicity concern for the substance.

During the discussion, the issue was raised whether the genotoxicity data on this substance also cover 2-methyl- and 2,3-dimethylquinoxaline [FL-no: 14.139 and 14.108] in the present FGE.17. There is evidence, both from data submitted and from the scientific literature indicating that read-across among the methylquinoxalines is not possible in view of the absence of an apparent structure-activity relationship *in vitro* and the different profile of genotoxicity *in vitro* displayed by quinoxaline, 2-methylquinoxaline and 5-methylquinoxaline. The activity profiles of 5-methylquinoxaline [FL-no: 14.028] (Ames negative but clastogenic *in vitro*) and of 2-methylquinoxaline [FL-no: 14.139] (one Ames negative and one showing some activity) are different. *In vitro* data indicate a genotoxic potential for quinoxaline [FL-no: 14.147] and 2-methylquinoxaline [FL-no: 14.139], for which no *in vivo* data are available. Consequently the methylquinoxaline derivatives in this opinion will be evaluated individually and not as a group.
For 2,3-dimethylquinoxaline [FL-no: 14.108], there are three negative Ames tests which, although limited, consistently indicate lack of genotoxicity. Thus, no further genotoxicity data are required for this substance, which will be evaluated through the Procedure.

For 2-methylquinoxaline [FL-no: 14.139], two Ames tests are available, one negative and one suggesting some activity. No *in vivo* data are available. Thus, this substance cannot be evaluated through the Procedure until new data become available to clear the genotoxicity concern. These data should be provided within 1 year following the publication of the opinion. If the requested studies are not provided, the CEF Panel will not be able to establish the absence of safety concern.

The present FGE.17Rev2 also includes the evaluation of one new substance 2-,5- or 6-methoxy-3-ethylpyrazine [FL-no: 14.051]. No metabolism, no toxicity data and no intake data were available for this new substance. Therefore this substance cannot be evaluated through the Procedure.

Changes to the text of the draft Opinion were noted. The Opinion was adopted, the final version was send for written procedure for acceptance of the changes introduced during the meeting. The opinion will be published on http://www.efsa.europa.eu.

6.1.2. Flavouring Group Evaluation 50, Revision 1 (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. Additional genotoxicity data have now been submitted by the Industry for [FL-no: 14.028] and the present FGE.50Rev1 includes their evaluation. Based on the re-evaluation of all available data (*in vitro and in vivo*), the Panel concluded 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, the final version was send for written procedure for acceptance of the changes introduced during the meeting. The Opinion will be published on http://www.efsa.europa.eu.

6.1.3. Statement of the Panel on data provided for subgroup 1.1.1. (Flavouring Group Evaluation 200 - FGE.200)

Statement of the CEF Panel on genotoxicity data on representatives for 70 α,β-unsaturated aldehydes and precursors for such from chemical subgroup 1.1.1 of FGE.19
(*EFSA-Q-2010-01247*).

Having evaluated the data provided on representatives for chemical subgroup 1.1.1 of FGE.19, the Panel decided not to publish a full opinion and agreed on the following statement.

"The α,β-unsaturated aldehyde and ketone structures are alerts for genotoxicity and the data on genotoxicity previously available did not rule out the concern for genotoxicity.

Thus FGE deals with the re-evaluation of flavouring substances of the evaluation programme. The Panel had identified four substances in subgroup 1.1.1 as representatives for the 70 substances in this subgroup, for which genotoxicity data should be provided according to the "Genotoxicity Test Strategy for Substances in Subgroups of FGE.19" (The EFSA Journal (2008) 854, 1-5).

Supplementary information now provided includes both new data and arguments, which have been discussed by the Panel. Overall, the supplementary information provided by EFFA is not considered sufficient.

- Although some of arguments provided by EFFA (e.g. those on metabolism and GSH-depletion and those on the role of DNA damage) are plausible, they are not sufficient to alleviate concerns for the genotoxic and carcinogenic potential of the substances belonging to subgroup 1.1.1.
- The data provided are not compliant with the "Genotoxicity Test Strategy for Substances in Subgroups of FGE.19".

Therefore, the need for additional genotoxicity data has not been alleviated and genotoxicity studies should be carried out for the representative substances of subgroup 1.1.1. In line with the Genotoxicity Test Strategy, the Panel recommended to perform *in vivo* dietary COMET assays (in drinking water or in feed, not by gavage) for the three linear representatives of subgroup 1.1.1 (FL. no: 05.073, 05.058 and 05.060). The results may allow to identify whether there is a critical chain length for DNA damage.

Last, the Panel agreed with the proposal of industry that the fourth substance (Fl. no: 15071, epoxide structure) is not sufficiently related to the subgroup and takes note that data will be submitted separately.

The results should be provided within 9 months. If the requested studies are not provided, the CEF Panel will communicate that it cannot establish the absence of safety concern for the flavouring substances in subgroup 1.1.1."

6.1.4. Flavouring Group Evaluation 206 (FGE.206):

Consideration of genotoxicity data on representatives for 12 α,β-unsaturated ketones and precursors from chemical subgroup 1.2.3 of FGE.19.
(*EFSA-Q-2010-01248*)

The present Flavouring Group Evaluation 206 (FGE.206), corresponding to subgroup 1.2.3 of FGE.19, concerns seven aliphatic ketones [FL-no: 07.099, 07.190, 07.198, 07.204, 07.247, 07.253 and 07.256] and their five precursors [FL-no: 02.145, 02.194, 02.211, 02.252 and 09.936].

The α,β-unsaturated aldehyde and ketone structures are structural alerts for genotoxicity and the data on genotoxicity previously available did not rule out the concern for genotoxicity. The Panel had identified two substances: 6-methylhepta-3,5-dien-2-one [FL-no: 07.099] and pseudo-ionone [FL-no: 07.198] in subgroup 1.2.3 as representatives for the other 10 substances, for genotoxicity testing.

In vitro genotoxicity data have now been submitted on [FL-no: 07.099] and [FL-no: 07.198]. The Panel concluded that the *in vitro* genotoxicity data on these two representative substances [FL-no: 07.099 and 07.198] do not indicate genotoxic potential. Accordingly, all 12 substances [FL-no: 02.145, 02.194, 02.211, 02.252, 07.099, 07.190, 07.198, 07.204, 07.247, 07.253, 07.256 and 09.936] in FGE.19 subgroup 1.2.3 will not be of concern with respect to genotoxicity and can be evaluated through the Procedure.

Changes to the text of the draft Opinion were noted. The Opinion was adopted, the final version was send for written procedure for acceptance of the changes introduced during the meeting. The Opinion will be published on http://www.efsa.europa.eu.

6.1.5. Flavouring Group Evaluation 209 (FGE.209):

Consideration of genotoxicity data on one α,β-unsaturated aldehyde from chemical subgroup 2.3 of FGE.19
(*EFSA-Q-2010-01249*).

Postponed due to lack of time. Will be on the Agenda for the next Plenary, February 2011.

6.1.6. Flavouring Group Evaluation 211 (FGE.211):

Consideration of genotoxicity data on four α,β-unsaturated aldehydes from chemical subgroup 2.5 of FGE.19
(*EFSA-Q-2010-01250*).

Postponed due to ongoing evaluation of the received genotoxicity data. Will be on the Agenda for the next Plenary, February 2011.

6.1.7. Flavouring Group Evaluation 212, Revision 1 (FGE.212Rev1):

α,β-Unsaturated alicyclic ketones and precursors from chemical subgroup 2.6 of FGE.19 (*EFSA-Q-2010-01251*).

The present first revision of FGE.212, FGE.212Rev1, includes the evaluation of additional information and genotoxicity data submitted by Industry following a request presented in FGE.212 for 3,5,5-trimethylcyclohex-2-en-1-one [FL-no: 07.126] (isophorone) and structurally related substances.

In FGE.212, it was explained that isophorone is genotoxic *in vitro* and that there was some evidence of carcinogenicity in male rats and equivocal evidence of carcinogenicity in male mice; a non-threshold mechanism could not be excluded based on the data then available. The Panel had then concluded that additional data were required for isophorone. Due to structural similarities and given a lack of other data, the substances [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] in FGE.212 could not be evaluated through the Procedure either. Therefore additional data on genotoxicity had been requested for the three representative substances [FL-no: 02.214, 07.112 and 07.126] of this subgroup according to the "Genotoxicity Test Strategy for Substances Belonging to Subgroups of FGE.19".

These data have now been submitted and are evaluated in the present FGE.212Rev1.

Based on these new data, the Panel concluded that there is no more concern with respect to genotoxicity of isophorone and that isophorone [FL-no: 07.126] and the structurally related substances with 6-membered ring systems, [FL-no: 02.083, 02.101, 07.035, 07.098, 07.129, 07.172, 07.175, 07.196, 07.202 and 07.255] can be evaluated through the Procedure.

For the evaluation of the genotoxicity of the remaining substances in FGE.212Rev1 [FL-no: 02.214, 07.033, 07.094, 07.112, 07.140 and 09.821], additional data on genotoxicity are still requested for the two representative substances [FL-no: 02.214 and 07.112], which should be tested according to the "Genotoxicity Test Strategy for Substances Belonging to Subgroups of FGE.19"; alternatively, a good modelling study showing whether the data on the six-membered ring substances could cover the 5- and 7-membered ring substances as well, could be provided.

Changes to the text of the draft Opinion were noted. The Opinion was adopted, the final version was send for written procedure for acceptance of the changes introduced during the meeting. The Opinion will be published on http://www.efsa.europa.eu.

6.1.8. Flavouring Group Evaluation 96 (FGE.96):

Scientific Opinion on Flavouring Group Evaluation 96 (FGE.96), addendum to FGE. 50, 51, 52, 53, 54, 56, 58, 59, 61, 62, 63, 64, 66, 68, 69, 70, 71, 73, 76, 77, 79, 80, 83, 84, 85, 86 and 87: Consideration of 107 flavouring substances considered by EFSA for which EU production volumes / anticipated production volumes have been submitted on request by DG SANCO). (*EFSA-Q-2010-01246*).

The present FGE.96 concerns 107 substances evaluated by JECFA in different groups and which have formerly been considered by EFSA in FGE.50, 51, 52, 53, 54, 56, 58, 59, 61, 62, 63, 64, 66, 68, 69, 70, 71, 73, 76, 77, 79, 80, 83, 84, 85, 86 and 87.

In these FGEs, genotoxicity of these substances had been addressed. For none of these substances were concerns for genotoxicity identified.

For all 107 substances, no European production volumes were available at the time of the first consideration of the different FGEs. Therefore no MSDI could be calculated and accordingly the substances could not be considered by EFSA using the usual Procedure. EU Production volume / anticipated production volumes have now been provided for the 107 substances, which are evaluated through the Procedure. The outcome of this evaluation is presented in the Opinion (FGE.96).
The Opinion was adopted and will be published on http://www.efsa.europa.eu.

6.1.9. Flavouring Group Evaluation 46, Revision 1 (FGE.46Rev1):

Ammonia and three ammonium salts.
(*EFSA-Q-2010-01133).*

The present FGE.46Rev1 includes ammonia [FL-no: 16.009] and three ammonia salts, ammonium chloride [FL-no: 16.048], ammonium hydrogen sulphide [FL-no: 16.059] and the new candidate substance diammonium sulphide [FL-no: 16.002].

For diammonium sulfide [FL-no: 16.002], no toxicity and/or metabolism data were available from industry nor from the scientific literature.

All four candidate substances are predicted to be metabolised to innocuous products at the estimated levels of exposure and have, according to the default "Maximised Survey-derived Daily Intake" (MSDI) approach, estimated intakes in Europe below the threshold of concern for their structural classes. These four candidate substances were evaluated via the A-side of the Procedure scheme and do not pose a safety concern when used as flavouring substances, based on the MSDI approach.

In order to determine whether this evaluation could be applied to the materials of commerce, it is necessary to consider the available specifications. Information requested in FGE.46 on specifications has now been supplied by Industry and is included in the present FGE.46Rev1. An identity test is still missing for one of the flavouring substances, ammonium hydrogen sulphide [FL-no: 16.059]. Thus, the final evaluation of the materials of commerce cannot be performed for this substance, pending further information. The remaining three flavouring

substances, ammonia [FL-no: 16.009], ammonium chloride [FL-no: 16.048] and diammoniun sulfide [FL-no: 16.002] would present no safety concern at the levels of intakes 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.

6.1.10. Flavouring Group Evaluation 86, Revision 1 (FGE.86Rev1):

Consideration of Consideration of aliphatic and aromatic amines and amides evaluated by JECFA (65th meeting) (*EFSA-Q-2010-01261).*

The present FGE.86, Revision 1 (FGE86Rev1) concerns the re-consideration of three substances evaluated by JECFA [FL-no: 16.091, 16.093 and 16.094] for which additional toxicity data had been requested by EFSA in FGE.86.
Additional data (acute toxicity data and mutagenicity data) have been submitted by Industry on [FL-no: 16.093]. The Industry suggests that these data can support the evaluation of [FL-no: 16.091 and 16.094] as well.

Industry also submitted a 28 day study and mutagenicity data on substance [FL-no: 16.095] (evaluated in FGE.94) to support the evaluation of [FL-no: 16.091, 16.093 and 16.094]. However, for the present evaluation the Panel consider the substance [FL no: 16.095] not to be sufficiently structurally related to candidate substances [FL-no: 16.091, 16.093 and 16.094] owing to the configuration of the amide bond and the different structures of possible hydrolysis products: cyclopropyl amine and unsaturated carboxylic acid for [FL-no: 16.093] vs. cyclopropyl carboxylic acid and unsaturated amine for [FL no: 16.095]; no cyclopropyl group in [FL-no: 16.091 and 16.094]. Given these structural differences, different routes of metabolism and differences in toxicity have to be anticipated.
In conclusion, the acute toxicity data on [FL-no: 16.093] and the 28-days study on [FL-no: 16.095] could not be used to establish a NOAEL for [FL-no: 16.091, 16.093 and 16.094] and a 90 day study is requested. The supporting substance [FL-no: 16.095] should be deleted from this FGE as it is not supporting the evaluation of the three substances [FL-no: 16.091, 16.093, 16.094].
Changes to the text of the draft Opinion were noted. The Opinion was adopted and will be published on http://www.efsa.europa.eu.

A 90 day study on a representative substance should be submitted within 18 months following the date of the publication of this opinion, otherwise EFSA will not be able to assess the safety of the candidate substances.

6.2. Proposal for selection of representative substances for testing of Footnote-10 substances

(*EFSA-Q-2010-01492)*

Within the evaluation programme, further genotoxicity data have been requested for 265 α,β-unsaturated carbonyl compounds ("FGE.19" substances) and for 165 other substances for which additional toxicity data (other than genotoxicity) has been requested ("Footnote 10" substances), as a No Observed Adverse Effect Level (NOAEL) could not be established.

A list of substances representative of FGE.19 subgroups had been adopted by the CEF Panel. The current Opinion lays down a list of 85 substances representative of the Footnote 10

substances for which additional data are required prior to their group evaluation through the evaluation Procedure (Regulation (EC) No 2232/96).

7. FOOD CONTACT MATERIALS

7.1. Substances for use in plastics

Ref. No. 18117 Glycolic acid

(EFSA-Q-2010-01090)

The draft opinion was discussed, modified and adopted. The full opinion is available through: www.efsa.europa.eu.

Ref. No. 13303 Bis(2,6-diisopropylphenyl)carbodiimide

(EFSA-Q-2010-00813)

The draft opinion was discussed, modified and adopted. The full opinion is available through: www.efsa.europa.eu.

Ref. No. 86437 Silver Zeolite A (Silver zinc sodium ammonium aluminosilicate)

(EFSA-Q-2009-00708)

The draft opinion was discussed and changes were proposed. Subject to these changes a new draft opinion will be scheduled for the next Panel meeting in February 2011.

Ref. No. 25885 Trimethyl trimellitate

(EFSA-Q-2010-00838)

Due to lack of time, the draft opinion was deferred to the next Panel meeting in February 2011.

7.2. Processes for manufacturing recycled plastics

13303 Recycling process "PP crates CHEP"
(EFSA-Q-2009-00682)

The draft opinion was discussed, modified and adopted. The full opinion is available through: www.efsa.europa.eu.

7.3. Criteria for safety evaluation for PET recycling

The CEF Working Group on "Recycling" of plastics informed the Panel that approximately 90% of the dossiers received for evaluation of recycling processes concern PET recycling.

On the basis of the dossiers examined up to now and the scientific literature reviewed, the WG has established evaluation criteria specific to PET recycling.

On a proposal of the WG and the secretariat, the Panel agreed on the need of a self-mandate for the preparation of a draft opinion on the criteria to be used for safety evaluation of a recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food.

8. CHEMICAL SAFETY OF IRRADIATION

Opinion on Chemical safety of irradiation (EFSA-Q-2006-0034)

Since the previous discussion of the draft opinion, changes had been introduced in the text. They were presented by the rapporteur and discussed. The Panel has wished to have further information on case reports and experimental studies on leukoencephalomyelopathy in cats fed with pet food irradiated at relatively high doses, in order to evaluate the possible relevance for humans. The secretariat gave a summary of the information collected from literature and from contacts with researchers and with other risk assessment bodies. None of these sources provided a clear mechanistic explanation in terms of risk assessment.

The Panel therefore highlighted in the opinion that the relevance of these cats case studies for human health should be clarified, as in absence of this understanding, the relevance for humans cannot be ruled out.
Both BIOHAZ and CEF panels have adopted respectively their opinion on the safety of irradiation.

9. A.O.B

The secretariat informed the Panel on a self mandate to prepare a technical report of EFSA as a "Note for Guidance on the Guidance on the submission of a dossier on Food Enzymes". This 'Note for Guidance' shall give assistance to applicants with practical examples and explanations for data needed for risk assessment established in the EFSA guidance. It will be elaborated by the CEF secretariat with the assistance of the Enzyme WG.
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ANNEX 1: INTERESTS & ACTIONS RESULTING FROM THE SCREENING OF SPECIFIC DECLARATION OF INTERESTS

M.R. Milana had declared interest in Silver Zeolite, and D. Wölfle in trimethyl trimellitate, as they have been advising their national authorities on these topics. According to EFSA policy on declarations of interest, these interests are not conflicts (level A).