Parma, 08 June 2011

MINUTES OF THE 19th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS AND PROCESSING AIDS (CEF)

Held in Parma on 22-24 March 2011

Adopted by written procedure on 06 June 2011

AGENDA:

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MINUTES OF THE 19th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS & PROCESSING AIDS (CEF)

PARTICIPANTS

Panel Members:

Arturo Anadón, Mona-Lise Binderup, Wilfried Bursch (1st and 2nd days), Laurence Castle, Riccardo Crebelli, Karl-Heinz Engel (1st and 2nd days), Roland Franz, Nathalie Gontard, 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 (2nd and 3rd days), Kettil Svensson, Fidel Toldrá, Rosemary Waring, Detlef Wölfle.

Invited Experts, hearing experts:

Karin Noerby (1st and 2nd days)

Apologies: Thomas Haertlé

European Commission: Josiane Houins-Roulet

EFSA: Davide Arcella (for item 5)

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: Eva Maria Ferrari, Marco Lannutti.

1. WELCOME, APOLOGIES FOR ABSENCE

2. ADOPTION OF THE AGENDA

The agenda was adopted with the addition of the following item under point 7.1:

REF. No. 93360, thiodipropionic acid, ditetradecyl ester

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 18TH (2-4 FEBRUARY 2011) PLENARY MEETING.

The minutes of the 18th Plenary meeting were adopted after revision.
They can be seen on:
http://www.efsa.europa.eu/en/events/event/cef110202.htm

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

5.1. e3

Panel members were informed that the organisation chart of EFSA is being changed.

5.2. Exposure assessment in EFSA

A review on methods used in EFSA to assess human exposure is in preparation.

5.3. Opinion on irradiation

The opinion on irradiation will be published together with the opinion of the BIOHAZ Panel and the statement summarising the conclusion of the two opinions.

6. FLAVOURINGS

According to Regulation 1565/2000 of 18 July 2000 and to recent requests from Commission

6.1. FLAVOURING GROUP EVALUATIONS

FGE.10Rev2
Aliphatic primary and secondary saturated and unsaturated alcohols, aldehydes, acetals, carboxylic acids and esters containing an additional oxygenated functional group and lactones.
(EFSA-Q-2011-00128)

The present revision of FGE.10, FGE.10Rev2, includes the assessment of three substances [FL-no: 08.113, 10.059 and 10.063].

The panel agreed that these three new candidate substances [FL-no: 08.113, 10.059 and 10.063] do not pose a safety concern when used at estimated levels of intake as flavouring substances, based on the MSDI approach.

Editorial 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 from chemical group 24.
(EFSA-Q-2010-00006)

The Opinion was adopted at the 17th Plenary. After the meeting it turned out that some editorial improvement was still needed. Therefore the draft Opinion was sent for written procedure for acceptance of some changes. The final version has now been accepted. The conclusion, as published in the minutes of the 17th Plenary is not changed. The Opinion will be published on http://www.efsa.europa.eu.

FGE.50Rev1
Consideration of pyrazine derivatives evaluated by JECFA.
(EFSA-Q-2010-00007)

The Opinion was adopted at the 17th Plenary. After the meeting it turned out that some editorial improvement was still needed. Therefore the draft Opinion was sent for written procedure for acceptance of some changes. The final version has now been accepted. The conclusion, as published in the minutes of the 17th Plenary is not changed. The Opinion will be published on http://www.efsa.europa.eu.

FGE.59Rev1
Consideration of aliphatic and aromatic ethers evaluated by JECFA (61st and 63rd meeting).
(*EFSA-Q-2011-0051*)

Revision based on new data.
At its 61st meeting the JECFA evaluated a group of 29 flavouring substances consisting of aliphatic and aromatic ethers. These 29 substances have been considered by EFSA in FGE.59.

FGE.59Rev1 includes a new aliphatic ether, l-menthyl methyl ether [FL-no: 16.088], which had been evaluated by the JECFA in its 63rd meeting.

In addition, since the publication of FGE.59, Industry has submitted additional information on specifications and EU production figures. These data have been taken into consideration in the present revision of FGE.59 (FGE.59Rev1).

The Panel agreed with the 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.97
Scientific Opinion on Flavouring Group Evaluation 97 (FGE.97), addendum to FGE.51, 52, 53, 54, 55, 56, 58, 59, 60, 61, 62, 63, 64, 66, 68, 69, 70, 71, 72, 73, 75, 77, 79, 80, 81, 82, 83, 84, 85, 86, 87, 90, 91 and 94: Consideration of additional information on specifications submitted by EFFA in response to requests in published FGEs.
(EFSA-Q-2011-00130)

The rapporteur presented the FGE and the background for this FGE only considering requested specifications. Some revisions were requested and the opinion will be presented at the next plenary.

FGE.98
Consideration of three ring-unsaturated delta-lactones.
(EFSA-Q-2011-00131)

The FGE will be on the Agenda of the 20th Plenary in May.

FGE.306
Scientific Opinion on Flavouring Group Evaluation 306 (FGE.306), addendum to FGE.07, 09, 15 and 21: Consideration of additional information on specifications submitted by EFFA in response to requests in published FGEs.
(EFSA-Q-2011-00129)

The rapporteur presented the FGE and the background for this FGE only considering requested specifications. Some revisions were requested and the opinion will be presented at the next plenary.

6.2. Flavourings workflow (general information by the secretariat)

6.2.1. Re-evaluation of substances of the flavourings evaluation programme

In a meeting with the flavourings industry (Parma, 21-22 March 2011), representatives from the flavourings industry have presented to EFSA a plan for submission of the data requested for re-evaluation of the substances of the flavourings evaluation programme.

6.2.2. Re-evaluation of sub-group 1.1.1 of FGE.19

The CEF Panel had requested in its Scientific Opinion "***Statement on data provided for subgroup 1.1.1 of FGE.19***" (EFSA Journal (2011) 9(2):2086) (see also the minutes of the 18th Plenary) an *in vivo* comet assay for three linear representatives of subgroup 1.1.1 of Flavouring Group Evaluation 19 (FGE.19) using dietary administration, in order to alleviate any genotoxicity concern for this subgroup. The Panel considered comments from the flavouring industry about technical difficulties encountered in designing the Comet assay by dietary administration and discussed alternative approaches. The Panel concluded that a Comet assay by gavage, or alternatively a dietary transgenic mouse mutation assay complemented by a micronucleus test, using the most potent representative of subgroup 1.1.1 (trans-2-hexenal), would comply with the "***Genotoxicity Test Strategy for Substances belonging to Subgroups of FGE.19***" (EFSA Journal (2008), 854, 1-5). The Panel also concluded that comparative *in vitro* studies to support possible read-across from trans-2-hexenal to the longer homologues in subgroup 1.1.1 may provide a sound basis to possibly waive a need for additional *in vivo* genotoxicity testing with these longer homologues.

7. FOOD CONTACT MATERIALS

7.1. Substances for use in plastics

Ref No 40560, (Butadiene, styrene, methyl methacrylate) copolymer cross-linked with 1,3-butanediol dimethacrylate
(EFSA-Q-2009-00807)

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

Ref No 40563, (Butadiene, styrene, methyl methacrylate, butyl acrylate) copolymer cross-linked with divinylbenzene or 1,3-butanediol dimethacrylate
(EFSA-Q-2009-00805)

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

Ref No 66765, (Methyl methacrylate, butyl acrylate, styrene, glycidyl methacrylate) copolymer
(EFSA-Q-2009-00806)

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

Ref No 80350, Poly(12-hydroxystearic acid)-polyethyleneimine
(EFSA-Q-2010-01244)

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

Ref. No. 93360, thiodipropionic acid, ditetradecyl ester
(EFSA-Q-2010-00935)

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

7.2. Opinion on Phenol
(EFSA-Q-2010-00177)

The draft opinion on phenol was presented by the rapporteur. Strengths and limitations of the reviewed studies were discussed. The Panel was informed that an extensive investigation on phenol immunotoxicity in mice has been performed under the National Toxicology Program (NTP) of the USA. A report presenting the new data on phenol immunotoxicity in mice is currently under review by NTP and is expected to be finalized during the second half of 2011.

The Panel expressed the wish to have access to the NTP report before finalizing its opinion on phenol. It was therefore suggested to ask for an extension of the expected time for issuing an opinion.

7.3. First discussion on re-evaluation of dioctadecyl disulfide (Ref. No. 49840)
(EFSA-Q-2011-00079)

A first discussion took place on the draft opinion and changes were proposed. Based on these proposals, a new draft will be prepared.

7.4. Draft opinion on criteria for safety evaluation of PET recycling processes
(EFSA-Q-2010-01501)

The draft opinion was discussed and changes were proposed. Based on these proposals a new draft will be presented at the next Plenary.

8. EVALUATION OF THE SAFETY AND EFFICACY OF LACTIC ACID FOR THE REMOVAL OF MICROBIAL SURFACE CONTAMINATION OF BEEF CARCASSES, CUTS AND TRIMMINGS.

The state of the dossier evaluation was presented. The dossier was discussed during the WG of BIOHAZ unit, together with the rapporteur for CEF Panel.

9. A.O.B.

9.1. Literature update on BPA

BPA literature review by University of Parma
The collection of the scientific publications on BPA was presented. It will be updated until August 2011.

9.2. "Note for Guidance" of the Guidance of the CEF Panel on the Submission of Dossiers on Food Enzymes.

The status on the development of a "Note for Guidance" was presented.

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

R. Franz declared interest for PET recycling, as his organization (IVV) provides consultancy in this area for the preparation of applications. This is a conflict level B for the specific item. As this was a preliminary discussion on a first draft of this general opinion, he was allowed to stay in the room during the discussion, only to answer possible questions.

D. Wölfle 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).

D. Wölfle declared interest in (methyl methacrylate, butyl acrylate, styrene, glycidyl methacrylate) copolymer and in dioctadecyl disulfide, as his Institute (BfR) had prepared the evaluation reports of the substances under contract with EFSA. This was considered as a conflict of interest because he could not act at the same time as a representative of the contractor and as a member of the Panel with voting rights. He was allowed to stay in the room to answer to specific technical questions but he did not participate in the discussion of the opinions. Another Panel member presented the draft opinions.