Parma, 6 July 2012

MINUTES OF THE 27th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS AND PROCESSING AIDS (CEF)

Held in Parma on 22 - 24 May 2012
Adopted on 4 July 2012

AGENDA:

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MINUTES OF THE 27th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS & PROCESSING AIDS (CEF)

PARTICIPANTS

Panel Members:

Ulla Beckman Sundh, Mona-Lise Binderup (2nd and 3rd days), Leon Brimer, Laurence Castle, Karl-Heinz Engel, Roland Franz, Nathalie Gontard, Rainer Gürtler (2nd and 3rd days), Trine Husøy, Klaus-Dieter Jany, Catherine Leclercq, Jean-Claude Lhuguenot, Wim C. Mennes, Maria Rosaria Milana (1st day), Maria de Fátima Poças, Iona Pratt, Kettil Svensson, Fidel Toldrá, Detlef Wölfle.

Invited Experts, hearing experts:

Vibe Beltoft (item 6)

European Commission:

Sirkku Heinimaa (item 6)

Bastiaan Schupp (item 7)

EFSA FIP Unit:

Scientific staff: Alexandre Feigenbaum, Claudia Heppner, Dimitrios Spyropoulos, Anne Theobald, Eric Barthélémy, Cristina Croera, Kim Rygaard Nielsen, Anna F. Castoldi, Alina Lupu, Andrea Terron, Maria Carfi.

Administrative staff: Eva Maria Ferrari, Hanne Pedersen.

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 26TH PLENARY MEETING (20- 22 MARCH 2012)

The minutes of the 26th Plenary meeting were adopted after editorial changes.
They can be seen on:
http://www.efsa.europa.eu/en/events/event/120320b.htm

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

Claudia Heppner, appointed as Head of the FIP Unit from 1st June 2012, introduced herself to the Panel.

The programme of the EFSA Colloquium on low dose effects and non monotonic dose responses (June 14-15) was presented.

The Panel was informed that the Scientific Committee of EFSA has adopted on May 22nd its opinion on TTC.

The progress of the work of the two working groups on BPA (toxicity and exposure assessment) was presented.

6. FLAVOURINGS

Smoke flavouring Primary Product SmokEz C-10
(EFSA-Q-2012-00452)

The opinion on the primary product SmokEz C10 was presented and thoroughly discussed. The Panel requested further information on the representativeness of the primary product and suggested additions to the opinion.

The opinion will be re-discussed after appropriate changes at the July Panel meeting.

Smoke flavouring Primary Product SmokEz Enviro C-23
(EFSA-Q-2012-00453)

A similar argumentation and conclusion as for SmokEz C10 was brought forward for the smoke flavouring SmokEz enviro 23.

The opinion will be re-discussed after appropriate changes at the July Panel meeting.

6.1. Flavouring group evaluations

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

FGE.201Rev1

2-Alkylated aliphatic acyclic α,β-unsaturated aldehydes and precursors with or without additional double-bonds from chemical subgroup 1.1.2 of FGE.19.
(EFSA-Q-2012-00243, EFSA-Q-2012-00072, EFSA-Q-2012-00071, EFSA-Q-2012-00070, EFSA-Q-2011-01088, EFSA-Q-2011-01087, EFSA-Q-2011-01086, EFSA-Q-2011-01085, EFSA-Q-2011-01084, EFSA-Q-2011-01083, EFSA-Q-2011-01082)

The present FGE.201Rev1, corresponding to subgroup 1.1.2 of FGE.19, concerns eight α,β-unsaturated aldehydes, with or without additional double bonds, [FL-no: 05.033, 05.090, 05.095, 05.105, 05.107, 05.126, 05.130 and 05.178] and three precursors for such aldehydes [FL-no: 02.174, 09.177 and 09.931].

The genotoxicity concern with respect to this group of substances due to the presence of an α,β-unsaturated aldehyde group (or precursor for this) could not be ruled out based on the genotoxicity data and the (quantitative) structure-activity relationship (Q)SAR predictions available.

In response to the Panel request expressed in FGE.201, the Flavouring Industry has submitted additional genotoxicity data on two substances, 2-methylpent-2-enal [FL-no: 05.090] and 2 methylcrotonaldehyde [FL-no: 05.095], from this subgroup.

The new data were evaluated and the draft opinion was discussed and modified.

Based on the submitted data, the Panel concluded that there is some evidence for [FL-no: 05.095] and an indication for [FL-no: 05.090] to show a potency for the induction of gene mutations *in vitro*. Furthermore, the Panel considered that the mutagenicity hazard could not be cleared by the endpoints evaluated in the *in vivo* micronucleus assay and that further data are required in order to clarify the genotoxic potential of this subgroup. A Comet assay performed with [FL-no: 05.095] and performed on liver, blood and first site of contact was considered as a preferred option to further investigate the genotoxicity *in vivo*.

In conclusion, the available data do not rule out the concern for genotoxicity.

The draft opinion was adopted. The full opinion is available through:

http://www.efsa.europa.eu/en/efsajournal/pub/2749.htm

FGE.222

Consideration of genotoxicity data on representatives for α,β-unsaturated furyl derivatives with the α,β-unsaturation in the side chain from subgroup 4.6 of FGE.19.
(EFSA-Q-2012-00392, EFSA-Q-2012-00391, EFSA-Q-2012-00251, EFSA-Q-2012-00250, EFSA-Q-2012-00249, EFSA-Q-2012-00248)

The present FGE.222, corresponding to subgroup 4.6 of FGE.19, concerns six furyl derivatives with a α,β-unsaturated carbonyl in the side chain, which is structural alert for genotoxicity. The data on genotoxicity previously available did not rule out the concern for genotoxicity.

The Industry has submitted data concerning genotoxicity studies for the two representative substances, 3-(2-furyl)acrylaldehyde [FL-no: 13.034] and 4-(2-furyl)but-3-en-2-one [FL-no: 13.044], for this subgroup.

The new data were evaluated and the draft opinion was discussed and modified.

Based on the data submitted, the Panel considered that in order to clarify the clastogenic and aneugenic potential of 4-(2-furyl)but-3-en-2-one [FL-no: 13.044], an *in vivo* Comet assay should be performed and for 3-(2-furyl)acrylaldehyde [FL-no: 13.034], an *in vivo* combined Comet and micronucleus assay should be performed.

In conclusion, the available data do not rule out the concern for genotoxicity.

The draft opinion was adopted. The full opinion is available through:

http://www.efsa.europa.eu/en/efsajournal/pub/2748.htm

FGE.29Rev1

Styrene
(EFSA-Q-2011-01014)

A note on styrene was prepared by the genotoxicity working group and discussed at the Panel meeting. The Panel supported the outcome provided by the genotoxicity working group that the available data on genotoxicity for Styrene by oral route are insufficient to clear the genotoxicity concern and bring styrene through the Procedure as a flavouring substance. The genotoxicity working group is recommending an *in vivo* Comet assay in the rat in order to clear the genotoxicity concern of styrene by oral administration.

FGE.07Rev4

Saturated and unsaturated aliphatic secondary alcohols, ketones and esters of secondary alcohols and saturated linear or branched-chain carboxylic acids.
(EFSA-Q-2012-00510, EFSA-Q-2012-00509, EFSA-Q-2012-00508, EFSA-Q-2012-00507, EFSA-Q-2012-00506)

It will be on the Agenda of the July Panel meeting.

FGE.08Rev5

Aliphatic and alicyclic mono-, di-, tri-, and polysulphides with or without additional oxygenated functional groups.
(EFSA-Q-2012-00511)

Due to lack of time, the discussion was deferred to the next Panel meeting.

FGE.09Rev4

Secondary alicyclic saturated and unsaturated alcohols, ketones and esters containing secondary alicyclic alcohols.
(EFSA-Q-2011-01246, EFSA-Q-2011-01245 , EFSA-Q-2011-01244, EFSA-Q-2011-01243, EFSA-Q-2011-01242)

Due to lack of time, the discussion was deferred to the next Panel meeting.

FGE.94Rev1

Consideration of aliphatic amines and amides evaluated in addendum to the JECFA group aliphatic and aromatic amines and amides by JECFA (68th meeting).
(EFSA-Q-2012-00079, EFSA-Q-2011-01120)

The draft opinion was adopted. The full opinion is available through:
http://www.efsa.europa.eu/en/efsajournal/pub/2747.htm

FGE.99

Consideration of Furanone derivatives evaluated by the JECFA (63th and 65th meeting).
(EFSA-Q-2007-00608, EFSA-Q-2007-00597, EFSA-Q-2007-00595, EFSA-Q-2007-00594, EFSA-Q-2007-00577)

Due to lack of time, the discussion was deferred to the next Panel meeting.

FGE.312

3-[(4-Amino-2,2-dioxido-1H-2,1,3-benzothiadiazin-5-yl)oxy]-2,2-dimethyl-N-propylpropanamide.
(EFSA-Q-2012-00078)

Due to lack of time, the discussion was deferred to the next Panel meeting.

7. FOOD CONTACT MATERIALS

7.1. Phenol

The Panel discussed the re-assessment of the TDI for phenol and examined the draft report on phenol immunotoxicity in mice recently received from the US NTP/NIEHS. The Panel could not conclude on the TDI for phenol based on this draft report.

Both the Beyrouty and IITRI study reports (which the Panel wished to review in depth in order to conclude on a TDI) are only available at BfR. The scientific secretariat will ask BfR for a copy of these studies and will request an extension of the deadline.

7.2. Substances for use in plastics

FCM substance No 958
Methacrylic acid, 2,3-epoxypropyl ester, copolymer with acrylic and/ or methacrylic acid, alkyl (C1-C4) esters
(EFSA-Q-2006-00203)

The draft opinion was discussed, modified and adopted. The full opinion is available through:
http://www.efsa.europa.eu/en/efsajournal/pub/2744.htm

FCM substance No 995
2-Hydroxypropyl methacrylate
(EFSA-Q-2011-01239)

The draft opinion was discussed, modified and adopted. The full opinion is available through:
http://www.efsa.europa.eu/en/efsajournal/pub/2745.htm

7.3. Active and intelligent substances

Liquid absorber based on: open-cell expanded polystyrene, manufactured with talc and alkyl(C8-C22) sulphonic acid (salts)
(EFSA-Q-2011-00762)

The draft opinion was discussed, modified and adopted. The full opinion is available through: http://www.efsa.europa.eu/en/efsajournal/pub/2746.htm

7.4. Recycling processes

Reg. No RECYC008, RECYC025, RECYC024 and RECYC027
Draft grouped opinion on LuxPET, PolyQuest, Jayplas and CIER recycling processes based on Vacurema Prime technology
(EFSA-Q-2009-00773; EFSA-Q-2010-00022; EFSA-Q-2010-00003; EFSA-Q-2010-00048)

The draft opinion was discussed and changes were noted. A revised version will be scheduled for the next Panel meeting.

Reg. No RECYC004
PETUK SSP
(EFSA-Q-2009-00706)
The discussion was deferred to the next Panel meeting.

Reg. No RECYC012, RECYC042, RECYC054, RECYC068 and RECYC080
Draft grouped opinion on recycling processes Preformia, STF, MPTS, PET to PET and Eco Plastic based on Starlinger IV+ ® technology
(EFSA-Q-2010-00868, EFSA-Q-2009-00899, EFSA-Q-2009-00960, EFSA-Q-2011-01238, EFSA-Q-2010-01173)
The discussion was deferred to the next Panel meeting.

8. AOB

None.

ANNEX I: interests & actions resulting from the screening of specific declaration of interests

Dr. Franz declared interest for the draft group opinion on "recycling processes based on Vacurema Prime technology (LuxPET, PolyQuest, Jayplas and CIER)" as his organisation has prepared the dossiers for these applications. He declared the same interest for the draft group opinion on "recycling processes based on Starlinger IV+ ® technology (on Preformia, STF, MPTS, PET to PET and Eco Plastic)". This was considered a conflict of interest and the expert left the room when the opinion was discussed.

Dr. Franz also declared interest for the recycling process PETUK. Although he has not carried out any experimental contract work for the applicant, this interest presents a conflict since his laboratory has prepared many dossiers on PET recycling for other applicants. The expert left the room during the discussion.

Dr. Wölfle provided preparatory work documents in the field of food contact materials for the substances "methacrylic acid, 2,3-epoxypropyl ester, copolymer with acrylic and/ or methacrylic acid, alkyl (C1-C4) esters" and "2-hydroxypropyl methacrylate", in the context of the contract between EFSA and BfR. 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 opinion.

Dr. Castle declared interest for the substance "methacrylic acid, 2,3-epoxypropyl ester, copolymer with acrylic and/ or methacrylic acid, alkyl (C1-C4) esters" as his Institute received fees for work done under contract with the applicant for the substance under evaluation and these data have been included in the application. This was considered as a conflict and the expert left the room during the discussion.

Dr. Milana declared that she had been involved in a project funded by Istituto Superiore della Sanità (public organisation) and by a federation of food industries (mineral water) to assess the scope of recycled PET. Since this was a pre-normative research and as it was not run for the benefit of a single company but for the entire sector, this is not a conflict.