MINUTES OF THE 11th PLENARY MEETING
OF THE SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS AND PROCESSING AIDS (CEF)
Held in Parma on 26-28 January 2010
Adopted on 23 March 2010

AGENDA:

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ENZYMES, FLAVOURINGS & PROCESSING AIDS (CEF)

PARTICIPANTS

Panel Members:

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

Invited expert

Diane Benford (phone conference, 3rd day)

Apologies:

European Commission:

Sirkku Heinimaa (phone conference on 2nd day), Annette Schaefer (phone conference 3rd day)

EFSA:

Riitta Maijala (2nd day item 5)

CEF Unit:

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

Administrative staff: Hanne Pedersen, Marco Lannutti.

CONTAM Unit:

Claudia Heppner and Jean Lou Dorne (3rd day)
1. **WELCOME, APOLOGIES FOR ABSENCE**

The Chair informed the Members of the resignation of Pr. D. Bell from 15th January 2010.

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 10TH PLENARY MEETING, 24-26 NOVEMBER 2009**

   The minutes of the 10th Plenary meeting were adopted. They can be seen on [http://www.efsa.europa.eu/en/events/event/cef091124.htm](http://www.efsa.europa.eu/en/events/event/cef091124.htm)

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

   The Panel was informed on workflow in preparation and corresponding deadlines for flavouring substances in 2010 -2011.

   ESCO working group on non-plastics FCM: the first meeting will be held on 17 February.

   Information was given on INEX, Management Board decision on manual for Panels, chairs and rapporteurs, Management Plan 2010.

6. **FLAVOURINGS**

   According to Regulation 1565/2000 of 18 July 2000

6.1. **Flavouring group evaluations**

   6.1.1. **Flavouring Group Evaluation 81 (FGE.81):**

   Consideration of hydroxypropenylbenzenes evaluated by JECFA (61st meeting).

   *(EFSA-Q-2008-065).*

   This FGE.81 is a consideration of nine flavouring substances evaluated by the JECFA in the flavouring group of hydropropenylbenzenes. The Panel concluded that the six substances with a free phenol group [FL-no: 04.002, 04.004, 04.055, 09.030, 09.089 and 09.710] are structurally related to the ester of isoeugenol, 2-methoxy-4-(prop-1-enyl)phenyl 3-methylbutyrate, evaluated by EFSA in the Flavouring Group Evaluation 30 (FGE.30, see below).
The three methoxy ethers [FL-no: 04.013, 04.017, 04.018] may be anticipated to have other metabolic properties than the six substances with a free phenol group. Following available information, the Panel concluded that the ethers would be metabolised to innocuous products.

The Panel concluded that the available data on the candidate and supporting substances as well as the structure of the candidate substances do not give rise to safety concern with respect to genotoxicity.

The Panel agrees with the way the application of the Procedure has been performed by the JECFA for all nine substances considered in this FGE. However, for four substances [FL-no: 04.017, 04.055, 09.089 and 09.710], the JECFA evaluation is only based on Maximised Survey-derived Daily Intake (MSDI) values derived from production figures from the USA. EU production figures are needed in order to finalise the evaluation of these substances.

In order to determine whether the conclusion for the nine JECFA evaluated substances can be applied to the materials of commerce, it is necessary to consider the available specifications. Adequate specifications including complete purity criteria and identity are available for all nine JECFA evaluated substances. However, for eight substances [FL-no: 04.002, 04.004, 04.013, 04.017, 04.018, 09.030, 09.089 and 09.710] information on the isomeric composition has not been specified.

Thus, for all nine substances [FL-no: 04.002, 04.004, 04.013, 04.017, 04.018, 04.055, 09.030, 09.089 and 09.710] the Panel has reservations (no European production volumes available, preventing them to be evaluated using the Procedure, and/or missing data on isomerism).

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

### 6.1.2. Flavouring Group Evaluation 30 (FGE.30):

2-Methoxy-4-(prop-1-enyl)phenyl 3-methylbutyrate from chemical group 17
(EFSA-Q-2003-173)

The present Flavouring Group Evaluation deals with a phenolic ester, 2-Methoxy-4-(prop-1-enyl)phenyl 3-methylbutyrate [FL-no: 09.894].

The genotoxicity data available consisted in the summary of an NTP report and the summary of a study communicated in confidentiality by EMEA. These documents have been discussed by a task force which concluded that isoeugenol was not genotoxic. The Panel agrees with this conclusion.

On the basis of the default MSDI approach, it is considered that the candidate substance is not of safety concern at the estimated levels of intake arising from use as flavouring substance.

In order to determine whether the conclusion for the candidate substance can be applied to the material of commerce, it is necessary to consider the available specifications. Adequate specification, including complete purity criteria and identity, for the material of commerce, have been given for the candidate substance 2-methoxy-4-(prop-1-enyl)phenyl 3-methylbutyrate [FL-no: 09.894], except that information on geometrical isomerism has not been specified and the solubility in water has not been provided. Thus, the final evaluation of
the material of commerce for [FL-no: 09.894] cannot be performed pending further information on specifications.

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

6.1.3. **Flavouring Group Evaluation 74Rev1 (FGE.74Rev1):**
Consideration of simple aliphatic sulphides and thiols evaluated by JECFA (61st meeting).
*EFSA-Q-2009-00954*
Postponed due to lack of time. Will be on the Agenda for the March Plenary.

6.1.4. **Flavouring Group Evaluation 17Rev2 (FGE.17Rev2):**
Pyrazine derivatives from chemical group 24.
*(EFSA-Q-2010-00006)*
Postponed due to lack of time. Will be on the Agenda for the March Plenary.

6.1.5. **Flavouring Group Evaluation 50Rev1 (FGE.50Rev1):**
Consideration of pyrazine derivatives evaluated by JECFA (57th meeting).
*(EFSA-Q-2010-00007)*
Postponed due to lack of time. Will be on the Agenda for the March Plenary.

6.2. **Opinion on data needed for the evaluation of flavourings:**
*(EFSA-Q-2009-00004)*.

The public consultation on the Guidance document on the data required for the risk assessment of flavourings was finalised 14 December 2009.

**Comments on the public consultation:**

Three task force groups had been set up in January (genotoxicity, dietary exposure and specifications) and based on their work, an updated version of the Guidelines was made available for discussion at the current Plenary.

**Discussion in the Panel of the updated version of the Guidelines:**

The updated Guidelines will be available for the workshop with stakeholders in Brussels 4-5 March 2010, where a finalisation of the Guidelines with respect to flavourings other than flavouring substances (Part B of Guidelines) should be achieved before final adoption at the March Plenary.

6.3. **Comparison of data requested for evaluation of FCM and of Flavouring substances.**

A study is ongoing in the Unit to evaluate by Toxtree (software based on Cramer decision tree) Food Contact substances already evaluated in the past by EFSA or SCF. Preliminary
results based on 220 substances were presented. Suggestions were made by the Panel members. Complete results will be presented in a future meeting.

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:

<table>
<thead>
<tr>
<th>REF/ No.</th>
<th>Name of the substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>71943</td>
<td>Perfluoro acetic acid, a-substituted with the copolymer of perfluoro-1,2-propylene glycol and perfluoro-1,1-ethylene glycol, terminated with chlorohexafluoropropyloxy groups</td>
</tr>
<tr>
<td></td>
<td><em>EFSA-Q-2007-068</em></td>
</tr>
<tr>
<td></td>
<td>The CEF Panel concluded that there is no safety concern for the consumer if the substance is to be used only up to 0.5% w/w in the polymerisation of fluoropolymers that are processed at temperatures at or above 340°C and are for repeated use articles.</td>
</tr>
<tr>
<td>80345</td>
<td>Poly(12-dihydroxystearic acid) stearate</td>
</tr>
<tr>
<td></td>
<td><em>EFSA-Q-2004-040</em></td>
</tr>
<tr>
<td></td>
<td>The CEF Panel concluded that there is no safety concern for the consumer if the migration of the substance does not exceed 5 mg/kg food.</td>
</tr>
<tr>
<td>60027</td>
<td>Hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-decene and/or 1-dodecene and/or 1-tetradecene (Mw : 440-12000)</td>
</tr>
<tr>
<td></td>
<td><em>EFSA-Q-2009-00770</em></td>
</tr>
<tr>
<td></td>
<td>The CEF Panel concluded that there is no safety concern for the consumer if the substance complies with the given specifications (viscosity at 100°C ≥ 3.8 cSt, Mw&gt;440 Da) and its migration does not exceed 60 mg/kg food.</td>
</tr>
</tbody>
</table>

The draft opinion on the following substance was discussed, modified at the meeting then adopted by written procedure on 5 March:

<table>
<thead>
<tr>
<th>REF/ No.</th>
<th>Name of the substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>43730</td>
<td>5-Chloro-2-methyl-2H-isothiazol-3-one, mixture with 2-methyl-2H-isothiazol-3-one (3:1)</td>
</tr>
<tr>
<td></td>
<td><em>EFSA-Q-2009-00515</em></td>
</tr>
<tr>
<td></td>
<td>The CEF Panel concluded that there is no safety concern for the consumer if the maximum residual amount of the substance in the finished products does not exceed 25 μg/dm². Its use should not result in an anti-microbial effect at the surface of the polymer or on the food itself.</td>
</tr>
</tbody>
</table>
7.2. **DRAFT OPINION ON MELAMINE**
The draft opinion was discussed. Adoption is planned for the March Plenary in link with CONTAM.

7.3. **UPDATE FROM RECYCLING WORKING GROUP**
EFSA has received 65 applications for existing recycling processes mainly related to PET and some to polyolefins. Most of the processes are currently running in Europe or in USA. The REC WG held 4 meetings already. Evaluations are in progress.

7.4. **UPDATE ON BPA**
A letter of the Danish Ministry of Food has been received by EFSA. The Danish Minister encourages EFSA to evaluate some recent literature studies on BPA. However these require an expertise which is not in the scope of the Working Group. The Panel considered that it was not able to evaluate these studies pending completion of the current mandate of the Working Group.

8. **IRRADIATION: UPDATE FROM THE WG**
The Work is progressing and a draft opinion should be presented in one of the next Plenaries.

9. **A.O.B**
No other business
ANNEX 1: INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF SPECIFIC DECLARATION OF INTERESTS

Dr. K. Pfaff, K. Svensson, and D. Wölfle had declared interest on BPA, as they are advising their national authorities. According to EFSA policy on declarations of interest, this is not a conflict and they staid in the room and participated to the discussion. Dr. Franz declared interest on FCM Recycling, as his Institute has submitted applications. This is a conflict and he left the room during the discussion. Dr. C. Leclercq declared interest in the topic “flavouring guidelines”, as she had contributed to the development of the SPET method for dietary exposure assessment in JECFA. Since this is a past activity, it is not a conflict. Dr. M.R. Milana has declared an interest for the FCM substance PM Ref 43730 5-Chloro-2-methyl-2H-isothiazol-3-one, mixture with 2-methyl-2H-isothiazol-3-one (3:1), as she was involved in the risk assessment of this substance in her Institute several years ago. As this is a past activity, it is not a conflict.