Parma, 17 September 2010

MINUTES OF THE 13th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS AND PROCESSING AIDS (CEF)

Held in Parma on 18-20 May 2010

Adopted by written procedure on 15 September 2010

Table of Contents

1. Welcome, apologies for absence 3
2. Adoption of the agenda 3
3. Declarations of interest 3
4. Matters arising from the 12th Plenary Meeting, 23-25 March 2010 3
5. General information from the EFSA, the Commission and the Chair 3
6. Flavourings 3
   - 6.1 Flavouring group evaluations 3
     - 6.1.1 Flavouring Group Evaluation 32 (FGE.32) 3
     - 6.1.2 Flavouring Group Evaluation 17, Revision 2 (FGE.17Rev2) 4
     - 6.1.3 Flavouring Group Evaluation 50, Revision 1 (FGE.50Rev1) 4
     - 6.1.4 Flavouring Group Evaluation 74, Revision 1 (FGE.74Rev1) 4
     - 6.1.5 Evaluation of substances in Flavouring Group Evaluation 24Rev1 (FGE.24Rev1) 4
   - 6.2 Opinion on data needed for the evaluation of flavourings 5
7 Food contact materials 5
   - 7.1 Bisphenol A (BPA) 5
     - 7.1.1 Opinion on a study investigating the neurodevelopmental toxicity of bisphenol A 5
     - 7.1.2 Literature survey 6
   - 7.2 Update from recycling Working Group 6
9 Any other business 6

ANNEX 1: INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF SPECIFIC DECLARATION OF INTERESTS 7

MINUTES OF THE 13th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS & PROCESSING AIDS (CEF)

PARTICIPANTS

Panel Members:

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

Invited Experts, observers: Karin Nørby (item 6), Jörn Gry (item 6.1.1), Daniel Doerge (item 7.1.1)

Apologies: Arturo Anadón, Nathalie Gontard, Rosemary Waring

European Commission: Sirkku Heinimaa

EFSA: Laura Ciccolallo (item 7.1), Lucilla Gregoretti (item 6.2),

CEF Unit scientific staff: Alexandre Feigenbaum, Anne Theobald, Eric Barthélémy, Cristina Croera, Kim Rygaard Nielsen, Anna Castoldi, Alina Lupu, Roberta Pinalli, Dimitrios Spyropolous

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

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 12TH PLENARY MEETING, 23-25 MARCH 2010

The minutes of the 12th Plenary meeting were adopted. They can be seen on http://www.efsa.europa.eu/en/events/event/cef100323.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

6.1.1 Flavouring Group Evaluation 32 (FGE.32)

Flavonoids (flavanones and dihydrochalcones) from chemical groups 25 and 30.
(EFSA-Q-2008-036)

The rapporteur presented the FGE. The estrogenic effects of flavanones and dihydrochalcones, the flavanones interaction with drugs and the dihydrochalcones glucose interaction were discussed in detail.

The present Flavouring Group Evaluation 32 (FGE.32) deals with seven flavonoids [FL-no: 16.058, 16.061, 16.083, 16.097, 16.109, 16.110 and 16.112].

It is considered on the basis of the default Maximised Survey-derived Daily Intake (MSDI) approach, that the seven candidate substances will not give rise to safety concerns at the estimated levels of intake arising from their use as flavouring substances.

In order to determine whether the conclusion for the candidate 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 for the materials of commerce have been provided for six candidate substances. Information on stereoisomerism has not been specified for [FL-no: 16.083]. Thus, the final evaluation of the materials of commerce cannot be performed for [FL-no: 16.083], pending further information on isomerism. The remaining six substances [FL-no: 16.058, 16.061, 16.097, 16.109, 16.110 and 16.112] would present no safety concern based on 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.

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

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

Compared to FGE.17Rev1, the present FGE.17Rev2 includes the evaluation of one new substance 3,5 or 6-methoxy-2-ethylpyrazine [FL-no: 14.051].

In FGE.17Rev1, it was stated that two candidate substances, quinoxaline [FL-no: 14.147] and 2-methylquinoxaline [FL-no: 14.139] showed possible genotoxic potential *in vitro*. Additional genotoxicity data have now become available for the structurally related 5-methylquinoxaline [FL-no: 14.028] evaluated in FGE.50Rev2 (Item 6.1.3). In the discussion, it was considered that there are uncertainties on the result of the chromosome aberration assay of [FL-no: 14.028] at the cytotoxic concentration. It was to decided to scrutinise again these genotoxicity data which should be examined in a future meeting.

6.1.3 Flavouring Group Evaluation 50, Revision 1 (FGE.50Rev1)

Consideration of pyrazine derivatives evaluated by JECFA (57th meeting).
(*EFSA-Q-2010-00007*).

In the evaluation of FGE50, the Panel had concluded that it could agree in the way the application of the Procedure has been performed by the JECFA for 40 out of the 41 pyrazines derivatives. Additional data had been requested for 5-methylquinoxaline [FL-no: 14.028]. New genotoxicity data have now become available. In the discussion, it was considered that there are uncertainties on the result of the chromosome aberration assay of [FL-no: 14.028] at the cytotoxic concentration. It was to decided to scrutinise again these genotoxicity data which should be examined in a future meeting.

6.1.4 Flavouring Group Evaluation 74, Revision 1 (FGE.74Rev1)

Consideration of simple aliphatic sulphides and thiols evaluated by JECFA (53rd and 61st meeting) (*EFSA-Q-2009-00954*).

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

6.1.5 Evaluation of substances in Flavouring Group Evaluation 24Rev1 (FGE.24Rev1)

Note regarding data requirements for footnote 10 substances in FGE.24REV1.

In the conclusion of FGE.24Rev1, it was stated that a No Observed Adverse Effect Level (NOAEL) could not be derived for any of the seven candidate substances nor of related substances and that additional data were needed for 2-acetyl-1-furfurylpyrrole [FL-no: 13.100], 1-methylpyrrole [FL-no: 14.023], 2-acetyl-5-methylpyrrole [FL-no: 14.085], 2,5-dimethylpyrrole [FL-no: 14.107], pyrrole-2-carbaldehyde [FL-no: 14.145], 1-methylpyrrole-2-carboxaldehyde [FL-no: 14.163] and 1-ethyl-2-pyrrolecarboxaldehyde [FL-no: 14.169],

A 28-day study has been submitted on 1-methylpyrrole [Fl-no: 14.023]. Industry proposed to allocate a NOAEL for this substance on basis of this 28-day study and to apply it to five substances [FL-no: 14.023, 14.107, 14.145, 14.163 and 14.169] which could then be

evaluated at the B-side of the Procedure. However, the Panel reiterates that a 90-day study is a minimum requirement to allocate a NOAEL for flavourings in the Procedure. The submitted 28-day study is therefore not suitable to provide a NOAEL for the substances in FGE.24Rev1.

Furthermore, the five substances belong to different subgroups. The Panel emphasizes that a single study (this 28-day study) cannot cover substances in both subgroups I and II in FGE.24Rev1, since the metabolism of substances in these subgroups is different (see Annex III of FGE.24Rev1).

In conclusion, additional data are still required for the five substances [FL-no: 14.023, 14.107, 14.145, 14.163 and 14.169].

Suggested data requirements for the five substances in FGE.24Rev1:
Subgroup I: 90-day study preferably for [FL-no: 14.145 (or 14.107)]
Subgroup II: 90-day study preferably for [FL-no: 14.023] and a 90-day study on either [FL-no: 14.163 or 14.169].

6.2 Opinion on data needed for the evaluation of flavourings

(*EFSA-Q-2009-00004*).

The rapporteur presented the updated version of the guidance document. It was discussed in detail and changes were suggested.

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

6.3 PROPOSAL FROM THE SECRETARIAT TO HANDLE THE INFORMATION RECENTLY RECEIVED FOM INDUSTRY ON SUBSTANCES OF THE EVALUATION PROGRAMME

EFSA is receiving many specifications data and production figures on substances of the Flavouring Evaluation Programme. It has been decided to gather the specifications data in one Opinion. The data will be introduced in the corresponding FGE at the next major revision.

7 FOOD CONTACT MATERIALS

7.1 Bisphenol A (BPA)

7.1.1 Opinion on a study investigating the neurodevelopmental toxicity of bisphenol A

(EFSA-Q-2009-00864)

The draft opinion was introduced by the Rapporteur. The opinion deals with the evaluation of a dietary developmental neurotoxicity study in rats (Stump, 2009) and its relevance for the risk assessment of BPA, including the possible impact of the study on the current TDI of 0.05 mg BPA/kg body weight (b.w.)/day set by EFSA in 2006. The Stump study follows the recommendation of the Norwegian Food Safety Authority to carry out a GLP compliant study according to OECD guideline 426 in order to address uncertainties regarding potential neurodevelopmental effects of BPA at low doses.

7.1.2 Literature survey

The Rapporteur updated the Panel on the work concerning the screening and review of the scientific literature on BPA. The outcome of this work will be a part of the scientific opinion that should be adopted by the CEF Panel during its July Plenary.

This review focuses on toxicokinetics, human studies and in vivo animal toxicity studies. As a general rule, only papers fulfilling the following quality and study design criteria are used for risk assessment:

- Full research papers published in peer-reviewed journals available in public domains (2007 – May 2010)
- Publications with original data (no reviews, discussions or others)
- For the in vivo animal toxicity studies the focus was mainly on:
  - pre-, peri-, early post-natal exposure
  - oral route of exposure
  - several tested doses (plus a control) including at least one dose level lower than the current NOAEL of 5 mg/kg b.w. per day (low-doses).

7.2 Update from recycling Working Group

The progress of the recycling working group was presented.

8 Irradiation: presentation of the draft opinion

EFSA-Q-2006-034

F. Toldra, K. Svensson

The draft opinion prepared by the WG on Food Irradiation was introduced by the chair of the WG (Fidel Tondrà) and from a toxicologist of the WG (Kettil Svensson). It was discussed in detail and changes were suggested.

The changes to the text were noted. The new draft opinion will be forwarded to the Irradiation Working Groups members for a further revision.

9 ANY OTHER BUSINESS

No other business

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

Dr. K. Pfaff, K. Svensson, D. Wölfle and M.R. Milana 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. 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. This is not a conflict.