

---

FIP UNIT

**Scientific Panel on FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS, and  
PROCESSING AIDS (CEF)**

**Minutes of the 20<sup>th</sup> meeting of the Working Group on GENOTOXICITY**

**WEB/TELE-conference, 26 June 2014**

**(Agreed on 6 October 2014)**

**Participants**

- **Working Group Experts:**
  - Mona-Lise Binderup, Riccardo Crebelli, Rainer Gürtler (chair), Daniel Marzin, Pasquale Mosesso
  
- **Hearing Experts:**
  - Karin Nørby
  
- **European Commission and/or Member States representatives:**
  - None
  
- **EFSA:**
  - FIP Unit: Maria Carfi, Annamaria Rossi

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

Apologies were received from Claudia Bolognesi, Angelo Carere and Natália Kovalkovičová.

**2. Adoption of agenda**

The agenda was adopted without changes.

### **3. Declarations of interest**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

### **4. Agreement of the minutes of the 19<sup>th</sup> Working Group meeting held on 12-13 May 2014, Parma**

The minutes were agreed during the meeting and they will be published on the EFSA website: <http://www.efsa.europa.eu/en/fip/fipwqs.htm>

### **5. Scientific topics for discussion**

#### **5.1. FGE. 67Rev2 (EFSA-Q-2013-00853 to 00859)**

Due to lack of time, this item was postponed to the next meeting.

### **6. Any Other Business**

#### **6.1 Criteria for acceptability of negative studies**

The main challenges encountered during the evaluation of flavouring substances were presented and discussed. Some examples from existing FGEs were discussed.

### **7. Next meeting**

The next genotoxicity WG meeting will be in September or October, the date is not yet decided.

---

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

---

FIP UNIT

**Scientific Panel on FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS, and  
PROCESSING AIDS (CEF)**

**Minutes of the 19<sup>th</sup> meeting of the Working Group on GENOTOXICITY**

**Held on 12-13 May 2014, Parma  
(Agreed on 26 June 2014)**

**Participants**

- **Working Group Experts:**
  - Claudia Bolognesi , Angelo Carere, Riccardo Crebelli, Rainer Gürtler (chair), Natália Kovalkovičová, Daniel Marzin, Pasquale Mosesso
  
- **Hearing Experts:**
  - None
  
- **European Commission and/or Member States representatives:**
  - None
  
- **EFSA:**
  - FIP Unit: Maria Carfi, Annamaria Rossi
  - Kim Rygaard Nielsen, Marina Gomenou for item 6.2

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

Apologies were received from Mona-Lise Binderup.

**2. Adoption of agenda**

The agenda was adopted without changes.

### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

### 4. Agreement of the minutes of the 18<sup>th</sup> Working Group meeting held on 4-5 March, Schiphol - Amsterdam

The minutes were agreed during the meeting and they will be published on the EFSA website: <http://www.efsa.europa.eu/en/fip/fipwqs.htm>

### 5. Scientific topics for discussion

#### 5.1. FGE.200Rev1 (FGE.19 subgroup 1.1.1) (EFSA-Q-2013-00445 to 00518)

The draft opinion was presented and discussed. The text will be revised and presented at the next CEF Panel meeting.

#### 5.2. FGE. 67Rev2 (EFSA-Q-2013-00853 to 00859)

Additional argumentations provided by Industry were discussed. The draft opinion will be revised accordingly.

#### 5.3. FGE. 35Rev1 (EFSA-Q-2011-01033 to 01035)

Additional data on Ames and *in vitro* micronucleus assays submitted for quinine hydrochloride dihydrate (FL-no 14.155) were discussed. The draft opinion will be revised accordingly.

### 6. Any Other Business

#### 6.1 FGE.212Rev3 (FGE.19 subgroup 2.6 - B) (EFSA-Q-2013-00992, EFSA-Q-2013-00993, EFSA-Q-2013-01009 to 01011)

Due to lack of time, this item was postponed to the next genotoxicity WG meeting.

#### 6.2 Enzymes genotoxicity tests

The Ames assay used for testing enzymes was discussed.

#### 6.3 Criteria for acceptability of negative studies

Due to lack of time, this item was postponed to the next genotoxicity WG meeting.

### 7. Next meeting

The date for the next genotoxicity WG meeting will be probably in September. If needed a teleconference will be organised in June.

---

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

---

FIP UNIT

**Scientific Panel on FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS, and  
PROCESSING AIDS (CEF)**

**Minutes of the 18<sup>th</sup> meeting of the Working Group on GENOTOXICITY**

**Held on 4-5 March 2014, Schiphol - Amsterdam  
(Agreed on 12 May 2014)**

**Participants**

- **Working Group Experts:**
  - Claudia Bolognesi (1<sup>st</sup> day by teleconference), Angelo Carere, Rainer Gürtler (chair), Natália Kovalkovičová, Daniel Marzin, Pasquale Mosesso
  
- **Hearing Experts:**
  - Karin Nørby
  
- **European Commission and/or Member States representatives:**
  - Miguel-Angel Granero Rosell
  
- **EFSA:**
  - FIP Unit: Maria Carfi, Annamaria Rossi
  - Kim Rygaard Nielsen, Anne Theoblad, Marina Gomenou for item 6.2

**1. Welcome and apologies for absence**

The Chair welcomed the participants and dedicated one minute of silence for the passing of the good friends and treasured colleagues John Christian Larsen and Iona Pratt.

Apologies were received from Mona-Lise Binderup and Riccardo Crebelli.

**2. Adoption of agenda**

The agenda was adopted without changes.

### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

### 4. Agreement of the minutes of the 17<sup>th</sup> Working Group meeting held on 28-29 November 2013, Parma

The minutes were agreed during the meeting and they will be published on the EFSA website: <http://www.efsa.europa.eu/en/fip/fipwqs.htm>

### 5. Scientific topics for discussion

#### 5.1. FGE.200Rev1 (FGE.19 subgroup 1.1.1) (EFSA-Q-2013-00445 to 00518)

The draft opinion was presented and discussed. The text will be revised and presented at the next genotoxicity WG meeting.

#### 5.2. FGE.203Rev1 (FGE.19 subgroup 1.1.4) (EFSA-Q-2013-00373 to 00392)

The draft opinion was presented and discussed. The draft opinion will be presented at the next CEF Panel meeting.

#### 5.4. FGE.213Rev1 (FGE.19 subgroup 2.7- A- B) (EFSA-Q-2013-00102 to 00113 and EFSA-Q-2013-00554, 00560, 00561)

The draft opinion was presented and discussed. The draft opinion will be presented at the next CEF Panel meeting.

#### 5.5. FGE.215 (FGE.19 subgroup 3.2) (EFSA-Q-2013-00668 to 00673)

The draft opinion was presented and discussed. The draft opinion will be presented at the next CEF Panel meeting.

### 6. Any Other Business

#### 6.1 FGE.212Rev3 (FGE.19 subgroup 2.6 - B) (EFSA-Q-2013-00992, EFSA-Q-2013-00993, EFSA-Q-2013-01009 to 01011)

Due to lack of time, this item was postponed to the next genotoxicity WG meeting.

#### 6.2 Enzymes genotoxicity tests

Clarification on genotoxicity tests required for enzymes were discussed and on this basis the note of guidance for enzymes will be updated.

### 7. Next meeting

The date for the next genotoxicity WG meeting has to be decided.

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

---

FIP UNIT

**Scientific Panel on FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS, and  
PROCESSING AIDS (CEF)**

**Minutes of the 17<sup>th</sup> meeting of the Working Group on GENOTOXICITY**

**Held on 28-29 November 2013, Parma  
(Agreed on 4 March 2014)**

**Participants**

- **Working Group Experts:**
  - Claudia Bolognesi, Angelo Carere, Rainer Gürtler (chair), Natália Kovalkovičová, Daniel Marzin, Pasquale Mosesso (2<sup>nd</sup> day by teleconference)
  
- **Hearing Experts:**
  - None
  
- **European Commission and/or Member States representatives:**
  - None
  
- **EFSA:**
  - FIP Unit: Maria Carfi, Silvia Moretti, Annamaria Rossi

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

Apologies were received from Mona-Lise Binderup and Riccardo Crebelli.

**2. Adoption of agenda**

The agenda was adopted with a change in “any other business”. A clarification on the draft scientific opinion FGE.212 Rev2 was requested.

### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

### 4. Agreement of the minutes of the 16<sup>th</sup> Working Group meeting, WEB/TELE-conference

The minutes were agreed during the meeting and they will be published on the EFSA website: <http://www.efsa.europa.eu/en/fip/fipwqs.htm>

### 5. Scientific topics for discussion

#### 5.1. FGE.200Rev1 (FGE.19 subgroup 1.1.1) (EFSA-Q-2013-00445 to 00518)

Due to lack of time, the draft opinion was presented and only generally discussed. It will be discussed again at the next genotoxicity WG meeting.

#### 5.2. FGE.203Rev1 (FGE.19 subgroup 1.1.4) (EFSA-Q-2013-00373 to 00392)

The draft opinion was presented and discussed. It will be discussed again at the next genotoxicity WG meeting.

#### 5.3. FGE.210Rev1 (FGE.19 subgroup 2.4) (EFSA-Q-2013-00268 to 00276 and EFSA-Q-2013-00554 to 00559)

The draft opinion was presented and discussed. It will be presented at the next CEF Panel meeting.

#### 5.4. FGE.213Rev1 (FGE.19 subgroup 2.7) (EFSA-Q-2013-00102 to 00113 and EFSA-Q-2013-00554, 00560, 00561)

The draft opinion was presented and discussed. It will be discussed again at the next genotoxicity WG meeting.

#### 5.5. FGE.215 (FGE.19 subgroup 3.2) (EFSA-Q-2013-00668 to 00673)

The draft opinion was presented and discussed. It will be discussed again at the next WG meeting.

### 6. Any Other Business

#### 6.1 FGE.212Rev2 (FGE.19 subgroup 2.6 - A) - EFSA-Q-2013-00168 and 00169

A clarification on the stabiliser was presented. The draft opinion will be presented at the next CEF Panel meeting.

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>



## **7. Next meeting**

The proposed date for the next WG meeting is 13 February 2014.

---

FIP UNIT

**Scientific Panel on FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS, and  
PROCESSING AIDS (CEF)**

**Minutes of the 16<sup>th</sup> meeting of the Working Group on GENOTOXICITY**

**WEB/TELE-conference, 17 10 2013**

**(Agreed on 29 November 2013)**

**Participants**

- **Working Group Experts:**
  - Claudia Bolognesi, Rainer Gürtler (chair), Natália Kovalkovičová, Pasquale Mosesso
  
- **Hearing Experts:**
  - Karin Nørby
  
- **European Commission and/or Member States representatives:**
  - None
  
- **EFSA:**
  - FIP Unit: Maria Carfi, Cristina Croera (for point 6.1), Silvia Moretti, Annamaria Rossi

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

Apologies were received from Mona-Lise Binderup, Angelo Carere, Riccardo Crebelli, Daniel Marzin.

Claudia Bolognesi did not participate in agenda point 5.2 (FGE.213 Rev1), 6 (AOB) and 7 (next meeting).

**2. Adoption of agenda**

The agenda was adopted with a change in “any other business”:

a clarification on the draft scientific opinion FGE.210 Rev1 was requested.

Page 1 of 3

### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

### 4. Agreement of the minutes of the 15<sup>th</sup> Working Group meeting held in Copenhagen on 3-4 September 2013

The minutes were agreed during the meeting and they will be published on the EFSA website: <http://www.efsa.europa.eu/en/fip/fipwqs.htm>

### 5. Scientific topic(s) for discussion

#### 5.1 FGE.212 Rev2 (FGE.19 subgroup 2.6 - A) - EFSA-Q-2013-00168 and 00169

The draft opinion was presented and discussed. It was agreed that more information on the stabilizer are needed.

#### 5.2 FGE.213 Rev1 (FGE.19 subgroup 2.7- A- B) - EFSA-Q-2013-00102 to 00113 and EFSA-Q-2013-00554, 00560, 00561

The draft opinion was presented and discussed. The draft opinion will be scheduled for discussion at the next CEF Panel meeting.

---

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

## **6. Any Other Business**

### **6.1 BPA (EFSA-Q-2012-00423)**

Two recent publications on BPA genotoxicity were presented and discussed:

- 1) Tiwari D and Vanage G, 2013. Mutagenic effect of Bisphenol A on adult rat male germ cells and their fertility. *Reproductive Toxicology* 40, 60-68.
- 2) Fic A, Zegura B, Sollner Dolenc M, Filipic M, Peterlin Masic L, 2013. Mutagenicity and DNA damage of bisphenol A and its structural analogues in HepG2 cells. *Arh Hig Rada Toksikol* 64, 189-200.

### **6.2 FGE.210 Rev1 (FGE.19 subgroup 2.4- A- B), EFSA-Q-2013-00268 to 00276 and EFSA-Q-2013-00555 to 00559**

The conclusions section of the draft opinion was clarified and agreed. The draft opinion will be scheduled for discussion at the next CEF Panel meeting.

## **7. Next meeting**

The proposed date for the next meeting is 28-29 November 2013 in Parma.

---

FIP UNIT

**Scientific Panel on FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS, and  
PROCESSING AIDS (CEF)**

**Minutes of the 15<sup>th</sup> meeting of the Working Group on GENOTOXICITY**

**Held on 3-4 September 2013, Copenhagen  
(Agreed on 17 October 2013)**

**Participants**

- **Working Group Experts:**
  - Angelo Carere, Daniel Marzin, Pasquale Mosesso, Natália Kovalkovičová
  
- **Hearing Experts:**
  - Karin Nørby, Vibe Beltoft
  
- **European Commission and/or Member States representatives:**
  - Miguel-Angel Granero-Rosell (DG SANCO)
  
- **EFSA:**
  - FIP Unit: Kim Rygaard Nielsen, Annamaria Rossi

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

Apologies were received from Mona-Lise Binderup, Riccardo Crebelli, Rainer Gürtler.

**2. Adoption of agenda**

The agenda was adopted with/without changes.

**3. Declarations of interest**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding

---

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

#### **4. Agreement of the minutes of the 14<sup>th</sup> Working Group meeting held on 10-11 June 2013, Copenhagen**

The minutes were agreed during the meeting and they will be published on the EFSA website: <http://www.efsa.europa.eu/en/fip/fipwgs.htm>

#### **5. Scientific topics for discussion**

##### **5.1 FGE.213 Rev1 (FGE.19 subgroup 2.7) - EFSA-Q-2013-00102 to 00113 and EFSA-Q-2013-00554, 00560, 00561**

The draft opinion was presented and discussed. However, the working group was not able to reach a conclusion since evaluation of additional references is needed.

##### **5.2 FGE FGE.210 Rev1 (FGE.19 subgroup 2.4) - EFSA-Q-2013-00268 to 00276 and EFSA-Q-2013-00555 to 00559**

The draft opinion was discussed and endorsed for discussion in the CEF Plenary.

##### **5.3 FGE.212 Rev2 (FGE.19 subgroup 2.6) - EFSA-Q-2013-00168 and 00169**

The draft opinion was discussed, but due to the absence of the rapporteur additional clarification could not be provided. Therefore, the opinion will be further discussed at the next Genotoxicity WG meeting.

#### **6. Any Other Business**

None.

#### **7. Next meeting**

The date of the next meeting will be decided.

---

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

---

FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)**

**Minutes of the 14<sup>th</sup> meeting of the Working Group on Genotoxicity**

**Held on 10<sup>th</sup> – 11<sup>th</sup> June 2013, Copenhagen**

**(Agreed on 3 September 2013)**

**Participants**

- **Working Group Experts:**
  - Rainer Gürtler, Wilfried Bursch, Angelo Carere, Daniel Marzin, Pasquale Mosesso, Natália Kovalkovičová
  
- **Hearing Experts:**
  - Karin Nørby, Vibe Beltoft
  
- **European Commission and/or Member States representatives:**
  - No
  
- **EFSA:**
  - FIP Unit: Kim Rygaard Nielsen, Annamaria Rossi

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

Apologies were received from Mona-Lise Binderup, Claudia Bolognesi, Riccardo Crebelli.

**2. Adoption of agenda**

The agenda was adopted without changes.

Page 1 of 2

### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

### 4. Agreement of the minutes of the 13<sup>th</sup> Working Group meeting held on 22 May 2013, by TELE-conference.

The minutes were agreed during the meeting and they will be published on the EFSA website: <http://www.efsa.europa.eu/en/fip/fipwqs.htm>

### 5. Scientific topic(s) for discussion

#### 5.1 FGE.213 (FGE.19 subgroup 2.7 – Part A, EFSA-Q-2013-00102 to 00113)

The draft opinion was presented and discussed. The text will be revised and presented at the next WG meeting.

#### 5.2 FGE.216 (FGE.19 subgroup 4.4 – Part A, EFSA-Q-2013-00201 to 00204)

The draft opinion was presented and discussed. The text will be revised and presented at a forthcoming CEF Plenary meeting

#### 5.3 FGE.212 Rev2 (FGE.19 subgroup 2.6 – Part A, EFSA-Q-2013-00168 to 00169)

The discussion of the draft opinion was postponed to the next Genotoxicity WG meeting

#### 5.4 FGE.210 (19 subgroup 2.4 – Part A, EFSA-Q-2013-00268 to 00276)

The draft opinion was presented and discussed. The text will be revised and presented at the next WG meeting.

### 6. Any Other Business

None.

### 7. Next meeting

Next meeting will be on 3-4 September 2013 in Copenhagen, Denmark.

---

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>



---

FIP Unit

**Scientific Panel on FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS, and  
PROCESSING AIDS (CEF)**

**Minutes of the 13<sup>th</sup> meeting of the Working Group on GENOTOXICITY**

**Tele-conference, 22 May 2013**

**(Agreed on 10 June 2013)**

**Participants**

- **Working Group Experts<sup>1</sup>:**
  - Rainer Gürtler, Claudia Bolognesi, Wilfried Bursch, Angelo Carere, Riccardo Crebelli, Daniel Marzin, Pasquale Mosesso
  
- **Hearing Experts:**
  - Vibe Beltoft
  
- **European Commission and/or Member States representatives:**
  - No
  
- **EFSA:**
  - FIP: Maria Carfi, Kim Rygaard Nielsen

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Mona-Lise Binderup.

**2. Adoption of agenda**

The agenda was adopted without changes.

**3. Declarations of interest**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>2</sup> and the Decision of the Executive Director implementing this Policy regarding

---

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

Declarations of Interests<sup>3</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

#### **4. Minutes of the 12<sup>th</sup> Working Group meeting held on 11-12 April 2013, Parma**

The draft minutes were agreed.

#### **5. Scientific topics for discussion**

##### **5.1 FGE.217 (19 subgroup 4.1 – Part A, EFSA-Q-2013-00114 to 00122)**

The draft opinion was presented and discussed. The text will be revised and presented at the next CEF Plenary meeting in June 2013.

##### **5.2 FGE.220 (19 subgroup 4.4 – Part A, EFSA-Q-2013-00201 to 00204)**

The draft opinion was presented and discussed. The text will be revised and presented at the next CEF Plenary meeting in June 2013.

##### **5.3 FGE.216 (19 subgroup 3.3 – Part A, EFSA\_Q-2013-00170 to 00174)**

The draft Opinion will be discussed at the next Genotoxicity WG.

#### **6. Any Other Business**

None.

#### **7. Next meeting**

Next meeting will be on 10 – 11 June 2013 in Copenhagen, Denmark.

---

<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

FIP Unit

**Scientific Panel on FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS, and  
PROCESSING AIDS (CEF)**

**Minutes of the 12<sup>th</sup> meeting of the Working Group on GENOTOXICITY**

**Held on 11-12 April 2013, Parma**

**(Agreed on 22 May 2013)**

**Participants**

- **Working Group Experts:**
  - Rainer Gürtler, Claudia Bolognesi, Wilfried Bursch, Angelo Carere, Daniel Marzin
  - Mona-Lise Binderup and Pasquale Mosesso participated via teleconference.
  
- **Hearing Experts:**
  - No
  
- **European Commission and/or Member States representatives:**
  - No
  
- **EFSA:**
  - FIP: Cristina Croera, Kim Rygaard Nielsen, Annamaria Rossi

**1. Welcome and apologies for absence**

The Chair welcomed the participants, especially Claudia Bolognesi as a new member of the WG and Annamaria Rossi as a new EFSA staff member.

Apologies were received from Riccardo Crebelli.

**2. Adoption of agenda**

The agenda was adopted without changes.

### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

### 4. Minutes of the 11<sup>th</sup> Working Group meeting held on 5-6 March 2013, Copenhagen, Denmark

The draft minutes were agreed.

### 5. Scientific topics for discussion

#### 5.1 3-Acetyl-2,5-dimethylthiophene (FL-No 15.024)

The additional genotoxicity data submitted for FL-No 15.024 have been discussed. A scientific opinion will be developed and discussed at the next Flavouring WG (22-24 April 2013, Copenhagen).

#### 5.2 BPA Epigenetic data

The WG had extensive discussion on the BPA draft opinion sections regarding Genotoxicity and Epigenetics. Comments were raised by the WG members and revision of the text will be provided accordingly.

#### 5.3 FGE.213 (19 subgroup 2.7 – Part A, EFSA\_Q-2013-00102 to 00113)

The draft Opinion will be discussed in a future Genotoxicity WG.

#### 5.4 5.4 FGE.217 (19 subgroup 4.1 – Part A, EFSA-Q-2013-00114 to 00122)

The draft Opinion will be discussed at the next Genotoxicity WG.

#### 5.5 FGE.220 (19 subgroup 4.4 – Part A, EFSA\_Q-2013-00201 to 00204)

The draft Opinion will be discussed at the next Genotoxicity WG.

### 6. Any Other Business

#### 6.1 Additional Genotoxicity experts

The Genotoxicity WG has identified the need for additional experts to deliver on time high quality scientific opinions.

### 7. Next meeting(s)

Next meeting will be held via teleconference on 22 May 2013.

---

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

---

FIP UNIT

**Scientific Panel on FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS, AND  
PROCESSING AIDS (CEF)**

**Minutes of the 11<sup>th</sup> meeting of the Working Group on Genotoxicity**

**Held on 5-6 March 2013, Copenhagen, Denmark**

**Agreed on 11 April 2013**

**Participants**

- **Working Group Experts:**  
Rainer Gürtler, Mona-Lise Binderup, Wilfried Bursch, Angelo Carere.
- **Hearing Experts:**  
Karin Kristiane Nørby (FLAVIS).
- **EFSA:**  
FIP Unit: Kim Rygaard Nielsen.

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Maria Carfi, Riccardo Crebelli, Daniel Marzin, Pasquale Mosesso.

**2. Adoption of agenda**

The agenda was adopted.

**3. Declarations of interest**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

---

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

#### **4. Agreement of the minutes of the 10<sup>th</sup> Working Group meeting held on 17 January 2013 as a tele-conference**

The minutes were agreed by written procedure on 7 February 2013 and published on the EFSA website on 27 February 2013.

#### **5. Scientific topics for discussion**

##### **5.1 FGE.207 (FGE.19 subgroup 1.1.2, part B, and subgroup 2.1) (EFSA-Q-2013-00025 to 00678)**

The draft Opinion was presented and discussed. The draft Opinion was accepted for presentation at the Panel meeting in May.

##### **5.2 FGE. 213 (FGE.19 subgroup 2.7 – A) (EFSA-Q-2013-00102 to 00113)**

The draft Opinion was postponed due to lack of time.

##### **5.3 FGE.208 (FGE.19 subgroup 2.2) (EFSA-Q-2012-00828 to 00837)**

The draft evaluation was presented and discussed. The draft Opinion was accepted for presentation at the next Panel meeting (19-21 March 2013).

##### **5.4 FGE.217 (FGE.19 subgroup 4.1 - A) (EFSA-Q-2012-00114 to 00122)**

The draft evaluation was presented and discussed. Additional data on two substances were received just before the meeting. These data will be included and the draft Opinion will be presented at next meeting 11-12 April.

#### **6. Any Other Business**

##### **6.1 Quinine**

The draft document was presented and discussed. Several changes were agreed and the updated document will be submitted to the Flavouring WG for inclusion in FGE.35Rev1.

#### **7. Next meeting**

Next meeting 11<sup>th</sup> - 12<sup>th</sup> April 2013 in Parma.

---

FIP UNIT

**Scientific Panel on FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS, AND  
PROCESSING AIDS (CEF)**

**Minutes of the 10<sup>th</sup> meeting of the Working Group on Genotoxicity**

**WEB/TELE-conference, 17 January 2013**

**Agreed on 7 February 2013**

**Participants**

- **Working Group Experts:**

Rainer Gürtler, Mona-Lise Binderup, Wilfried Bursch, Angelo Carere, Riccardo Crebelli, Daniel Marzin, Pasquale Mosesso

- **Hearing Experts:**

Karin Kristiane Nørby (FLAVIS)

- **EFSA:**

FIP Unit: Maria Carfi

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

**2. Adoption of agenda**

The agenda was adopted without changes.

**3. Declarations of interest**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of

---

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

#### **4. Agreement of the minutes of the 9<sup>th</sup> Working Group meeting held on 7 December 2012, Brussels.**

The minutes were agreed by written procedure on 8 January 2013 and published on the EFSA website on 9 January 2013.

#### **5. Scientific topics for discussion**

##### **5.1 FGE. 224 (EFSA-Q-2012-00678)**

The draft Opinion was presented and discussed. On the basis of the studies analysed, 5-methyl-2-thiophenecarbaldehyde does not raise genotoxicity concerns. The draft opinion will be presented at the next CEF Panel meeting.

##### **5.2 FGE. 208 (EFSA-Q-2012-00828 to EFSA-Q-2012-00837)**

The draft Opinion was presented and discussed.

The FGE.208 corresponding to subgroup 2.2 of FGE.19, concerns three alicyclic aldehydes with the  $\alpha,\beta$ -unsaturation in ring / side-chain and seven precursors for such aldehydes. The representative substance for this subgroup is p-Mentha-1,8-dien-7-al. The draft opinion will be presented at the next CEF Panel meeting.

##### **5.3 Caffeine (EFSA-Q-2011-01015)**

The draft evaluation was presented and discussed. Some changes were suggested. The document will be updated and send o the flavouring WG, to be included in the evaluation of FGE.49.

#### **6. Any Other Business**

##### **6.1 Letter from Industry on flavouring substance FL 12.304**

The available data were discussed. The WG concluded that the genotoxicity section of FGE.08rev5 should be revised.

##### **6.2 Quinine**

The discussion was postponed to the next meeting due to lack of time.



## **7. Next meeting(s)**

The date for the next meeting has to be confirmed. The proposed date for the physical meeting is 5<sup>th</sup> -6<sup>th</sup> March 2013 in Copenhagen.

FIP UNIT

Parma, 8 January 2013

**SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS, AND  
PROCESSING AIDS (CEF)**

**Minutes of the 9<sup>th</sup> meeting of the Working Group on Genotoxicity**

**Brussels, 7 December 2012**

**EFSA/ FIP Unit /CEF Panel**

**Agreed by the WG on 8 January 2013**

**Participants**

WG Experts	Rainer Gürtler, Mona-Lise Binderup, Wilfried Bursch, Riccardo Crebelli, Daniel Marzin, Pasquale Mosesso
Hearing Experts	Vibe Beltoft (FLAVIS)
EFSA	Maria Carfi

**1. Welcome and apologies**

The Chair welcomed the participants. Apologies were received from Angelo Carere.

**2. Adoption of agenda**

The agenda was adopted after adding under AOB the discussion on quinine.

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and/or Specific Declaration of Interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process.

**4. Administrative matters – information from EFSA secretariat**

**4.1. Adoption of the minutes of the previous meeting**

Minutes of the 8<sup>th</sup> meeting (22 October 2012) of the genotoxicity WG were adopted by written procedure. They are available on:

<http://www.efsa.europa.eu/en/fip/fipwgs.htm>

## **5. Discussions**

### **FGE 224**

The draft Opinion was presented and discussed. Some further aspects will be discussed in the next Genotoxicity WG (January 2013).

### **FGE 208**

It will be discussed in the next meeting of the Genotoxicity WG (January 2013) due to lack of time and since the rapporteur could not participate in this meeting.

### **Caffeine**

The draft evaluation was presented and discussed. Some changes were suggested. A modified version will be presented at the next meeting.

### **AOB**

### **Letter from Industry on flavouring substance FL 12.304**

The letter was briefly discussed and the Working Group noted that the availability of data which were already requested still needs to be checked. Therefore, the letter will be discussed again at a forthcoming meeting.

### **Quinine**

The discussion was postponed to the next meeting due to lack of time.

## **6. Next meeting date**

The date for the next meeting has to be confirmed. The proposed date for the physical meeting is 31 January-1February 2013, but a teleconference will be organized before.

FIP UNIT

Parma, 14 November 2012

**SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS, AND  
PROCESSING AIDS (CEF)**

**Minutes of the 8<sup>th</sup> meeting of the Working Group on Genotoxicity**

**Teleconference, 22 October 2012**

**EFSA/ FIP Unit /CEF Panel**

**Agreed by the WG on 14 November 2012**

**Participants**

WG Experts	Rainer Gürtler, Mona-Lise Binderup, Wilfried Bursch, Angelo Carere, Riccardo Crebelli, Daniel Marzin, Pasquale Mosesso
Hearing Experts	Karin Nørby (FLAVIS)
EFSA:	Maria Carfi

**1. Welcome and apologies**

The Chair welcomed the participants.

**2. Adoption of agenda**

The agenda was adopted.

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and/or Specific Declaration of Interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process.

**4. Administrative matters – information from EFSA secretariat**

**4.1. Adoption of the minutes of the previous meeting**

Minutes of the 7<sup>th</sup> meeting (27-28 September 2012) of the genotoxicity WG were adopted by written procedure. They are available on:

<http://www.efsa.europa.eu/en/fip/fipwgs.htm>

## 5. Discussions

### **Scientific report on minimum criteria for the acceptance, interpretation and reporting of the *in vivo* alkaline Comet assay**

Comments received by EFSA Panels were discussed and the text was modified accordingly. The revised text will be circulated and discussed by Friday 26<sup>th</sup> October for a final agreement.

### **FGE 204**

The draft Opinion was presented and discussed. The draft Opinion will be discussed during the flavouring WG (24<sup>th</sup> – 26<sup>th</sup> October 2012) for chemistry issues.

## 6. AOB

### **Preparation for the stakeholder meeting in November**

The chair of the WG presented the proposal received by EFSA Application Desk for the preparation of the stakeholder meeting.

## 7. Next meeting date

The date for the next meeting has to be confirmed. The proposed date is 6-7 December 2012.

FIP UNIT

Parma, 23 October 2012

**SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS, AND  
PROCESSING AIDS (CEF)**

**Minutes of the 7<sup>th</sup> meeting of the Working Group on Genotoxicity**

**27 - 28 September 2012**

**EFSA/ FIP Unit /CEF Panel**

**Agreed by the WG on 19 October 2012**

**Participants**

WG Experts	Rainer Gürtler, Angelo Carere, Daniel Marzin, Pasquale Mosesso
Hearing Experts	Pia Lund (FLAVIS)
EFSA:	Kim Rygaard Nielsen, Maria Carfi

**1. Welcome and apologies**

The Chair welcomed the participants. Apologies were received from Riccardo Crebelli, Wilfried Bursch, Mona-Lise Binderup.

**2. Adoption of agenda**

The agenda was adopted.

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and/or Specific Declaration of Interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process.

**4. Administrative matters – information from EFSA secretariat**

The secretariat informed the WG on the need to resubmit Annual DoI because the new EFSA policy on DoI will be implemented.

**4.1. Presentation and agreement of the WG calendar for 2013**

It was postponed to the next meeting due to lack of time.

#### **4.2. Adoption of the minutes of the previous meetings**

Minutes of the 6<sup>th</sup> (4-5 September) genotoxicity WG were adopted after editorial changes. They are available on:

<http://www.efsa.europa.eu/en/fip/fipwgs.htm>

### **5. Discussions**

#### **Caffeine**

Discussion was postponed to the next meeting due to lack of time and since a new version of the working paper was still pending.

#### **FGE 204**

The draft Opinion was presented and discussed. A new revised version will be presented at the next genotoxicity WG.

#### **Scientific report on minimum criteria for the acceptance, interpretation and reporting of the *in vivo* alkaline Comet assay**

The draft scientific report has been presented to other units (FEEDAP Unit, CONTAM Unit, PRAS Unit, SCOM Unit), the Scientific Committee Panel (which suggested to collect comments by all Panels), the CEF Panel and two reviewers from other Panels. The draft was modified according to comments received by the two reviewers, by the Scientific Committee and according to comments received by PRAS Unit and the chair of NDA Panel.

Responses from other Panels were still pending. Possible comments will be discussed during a forthcoming meeting.

#### **Acceptance criteria for negative *in vivo* studies**

A table collecting some examples of previous evaluations of negative *in vivo* genotoxicity studies was presented and used as example to verify which criteria have been used in the past to accept a study as negative. Suggestions for acceptance criteria were discussed, however, this topic will have to be discussed again in a forthcoming meeting.

#### **Validity criteria for genotoxicity studies (as recommended in section 7.2 of the Scientific Committee (SC) opinion on genotoxicity testing strategy EFSA 2011)**

Discussion was postponed to the next meeting due to lack of time.

#### **Preparation for the stakeholder meeting in November**

Discussion was postponed to the next meeting due to lack of time.

#### **AOB**

None.

### **6. Next meeting date**

The next meeting will be on 22<sup>nd</sup> October 2012.

FIP UNIT

Parma, 28 September 2012

**SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS, AND  
PROCESSING AIDS (CEF)**

**Minutes of the 6<sup>th</sup> meeting of the Working Group on Genotoxicity**

**Copenhagen, 4 - 5 September 2012**

**EFSA/ FIP Unit /CEF Panel**

**Agreed by the WG on 28 September 2012**

**Participants**

WG Experts	Rainer Gürtler, Mona-Lise Binderup, Wilfried Bursch, Angelo Carere, Daniel Marzin, Pasquale Mosesso
Hearing Experts	Karin Nørby, Vibe Beltoft (FLAVIS)
EFSA:	Kim Rygaard Nielsen, Maria Carfi

**1. Welcome and apologies**

The Chair welcomed the participants. Apologies were received from Riccardo Crebelli.

**2. Adoption of agenda**

The agenda was adopted after the following change:

- Presentation and agreement of the WG calendar for 2013 was added under "Administrative matters"

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and/or Specific Declaration of Interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

**4. Administrative matters – information from EFSA secretariat.**

The secretariat informed the WG on the need to resubmit Annual DoI because the new EFSA policy on DoI will be implemented.



#### **4.1. Presentation and agreement of the WG calendar for 2013.**

It was postponed to the next meeting due to lack of time.

#### **4.2. Adoption of the minutes of the previous meetings**

Minutes of the 4<sup>th</sup> (24-25 May) and 5<sup>th</sup> (27 June) genotoxicity WG were adopted after editorial changes. They are available on:

<http://www.efsa.europa.eu/en/fip/fipwgs.htm>

### **5. Discussions**

#### **FGE 204**

The draft Opinion was presented and discussed. The text was changed, but additional amendments are needed. A new revised version will be presented at the next genotoxicity WG (27- 28 September 2012).

#### **FGE.205**

A new text revised was presented. Further changes have been included; the revised Opinion will be presented at the CEF Plenary meeting of September.

#### **FGE.312**

The genotoxicity section of the Opinion was discussed and modified. It was decided that more information are needed about the classification of the substance as flavouring enhancer (which would require evaluation as food additive), or as flavouring modifier (which would have to be evaluated as a flavouring substance).

#### **Scientific report on minimum criteria for the acceptance, interpretation and reporting of the *in vivo* alkaline Comet assay**

The scientific report was modified according to comments received by one reviewer. The revised text will be sent to the Scientific Committee for endorsement and to the CEF Panel. It will be sent also to the other Units involved for information.

#### **BPA**

A publication of Tiwari et al ("Clastogenic and mutagenic effects of bisphenol A: An endocrine disruptor." Mutation Research 743 (2012) 83– 90) indicating BPA as clastogenic was discussed. A statement on genotoxicity will be prepared and taken into consideration by the BPA working group.

#### **AOB**

None.

### **6. Next meeting date**

The 7<sup>th</sup> genotoxicity WG meeting will be on 27<sup>th</sup> -28<sup>th</sup> September 2012 in Parma.

FIP UNIT

Parma, 4 September 2012

**SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS, AND  
PROCESSING AIDS (CEF)**

**Minutes of the 5<sup>th</sup> meeting of the Working Group on Genotoxicity**

**Teleconference, 27 June 2012**

**EFSA/ FIP Unit /CEF Panel**

**Agreed by the WG on 4 September 2012**

**Participants**

WG Experts	Rainer Gürtler, Mona-Lise Binderup, Riccardo Crebelli, Angelo Carere, Daniel Marzin, Pasquale Mosesso, Wilfried Bursch
Hearing Experts	Karin Nørby (FLAVIS)
EFSA	Kim Rygaard Nielsen, Maria Carfi

**1. Welcome and apologies**

The Chair welcomed the participants.

**2. Adoption of agenda**

The agenda was adopted after the following changes:

- Discussion on FGE 205 was not necessary because the text of the Opinion was already agreed by written procedure
- FGE 204 was postponed to the next WG meeting

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and/or Specific Declaration of Interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

**4. Administrative matters – information from EFSA secretariat.**

None.

**5. Discussions**

**FGE 204**

It was postponed to the next meeting, due to lack of time.

**Technical report on minimum acceptance requirements for the *in vivo* Comet assay**

The text was discussed and modified. The new version will be circulated for further comments. The secretariat will collect comments and update the text accordingly. The updated Report will be sent to the Scientific Committee Panel for endorsement.

**AOB**

None.

**6. Next meeting date**

The WG meeting of 5-6 July 2012 has been cancelled. A meeting will be organised in Copenhagen on 4-5 September 2012.

FIP UNIT

Parma, 4 September 2012

**SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS, AND  
PROCESSING AIDS (CEF)**

**Minutes of the 4<sup>th</sup> meeting of the Working Group on Genotoxicity**

**Parma, 24-25 May 2012**

**EFSA / FIP Unit / CEF Panel**

**Agreed by the WG on 4 September 2012**

**Participants**

WG Experts	Rainer Gürtler, Mona-Lise Binderup, Riccardo Crebelli, Angelo Carere, Daniel Marzin
Hearing Experts	Vibe Beltoft (FLAVIS)
Observers	Sirkku Heinimaa (EC)
EFSA	Kim Rygaard Nielsen, Andrea Terron, Maria Carfi

**1. Welcome and apologies**

The Chair welcomed the participants. Apologies were received from Pasquale Mosesso and Wilfried Bursch.

**2. Adoption of agenda**

The agenda was adopted after the following changes:

- Discussion on FGE 205 was added
- FGE 204 was postponed to the next WG meeting
- Discussion on “use of historical control data in the genotoxicity studies” was postponed.

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and/or Specific Declaration of Interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

#### **4. Administrative matters – information from EFSA secretariat**

The secretariat informed on the Scientific Opinions adopted during the 27<sup>th</sup> CEF Panel meeting: FGE.201Rev1, FGE.222, FGE.94Rev1.

##### **4.1. Adoption of the minutes of the previous meeting**

Minutes of the 3<sup>rd</sup> meeting (22-23 March 2012) of the genotoxicity WG were adopted after editorial changes. They are available on:

<http://www.efsa.europa.eu/en/fip/fipwgs.htm>

#### **5. Discussions**

##### **FGE 200 Rev.2**

The item was presented and discussed. In particular micronucleus data were considered equivocal and it was proposed to request an *in vivo* comet assay.

##### **Acceptance criteria for negative *in vivo* studies: initial discussion and way forward**

The item was presented and discussed.

##### **Caffeine**

The item was presented and discussed. The text will be updated and presented in the next meeting.

##### **FGE 205**

The item was presented and discussed. The group concluded that based on the available data it was considered justified to ask for additional *in vivo* data.

##### **Styrene (FGE.29rev1)**

During the March meeting the working group agreed that additional *in vivo* investigations by oral route should be performed in order to clarify styrene genotoxicity by oral route.

A Note on genotoxicity was prepared and discussed.

##### **Technical report on minimum acceptance requirements for the *in vivo* Comet assay**

A new draft prepared from comments received by CONTAM, FEEDAP, Pesticides, Scientific Committee Unit, was discussed and comments addressed. An updated version will be presented at the next WG meeting.

##### **Letter from industry on flavouring substance FL 12.304**

Since the letter presents important issues related to chemistry, it was decided to discuss it at the Flavouring WG in June.

### **Validity criteria for genotoxicity studies**

The recommendations of the Scientific Committee (SC) (EFSA, 2011) to assess the quality and reliability of genotoxicity data was discussed. SC recommends the approach of Klimisch et al. (1997) that use a scoring system to assess the reliability of toxicological data.

### **AOB**

The chair thanked Andrea Terron, who will leave EFSA, for his valuable support provided to this working group.

### **6. Next meeting date**

The WG meeting of 5-6 July 2012 has been cancelled. A new date will be proposed.

Parma, 31<sup>st</sup> May 2012

**SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS, AND  
PROCESSING AIDS (CEF)**

**Minutes of the 3<sup>d</sup> meeting of the Working Group on Genotoxicity 22-23 March 2012  
EFSA / FIP Unit**

**Participants**

WG Experts	Rainer Gürtler, Mona-Lise Binderup, Riccardo Crebelli, Pasquale Mosesso, Angelo Carere, Daniel Marzin,
Hearing Experts	Pia Lund (FLAVIS).
Observers	None
EFSA:	Kim Rygaard Nielsen, Andrea Terron, Maria Carfi

**1. Welcome and apologies**

The Chair welcomed the participants. Apologies were received from Wilfried Bursch and Sirkku Heinimaa (EC).

**2. Adoption of agenda**

The agenda was adopted.

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and/or Specific Declaration of Interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process.

**4. Discussions**

**FGE 19 subgroup 1.2.2 (FGE 205)**

The item was presented and discussed. The group concluded that based on the available data it was considered justified to ask for additional in vivo data.

**FGE 19 subgroup 4.6 (FGE222)**

The item was presented and discussed. The group concluded that based on the available data it was considered justified to ask for additional in vivo data.

## **FGE 201 (FGE 1.1.2)**

Main discussion was concerning the acceptability criteria for negative in vivo studies.

### **Styrene**

The item was discussed and the working group agreed that additional in vivo investigations by oral route should be performed in order to clarify styrene genotoxicity by oral route.

### **Technical report on minimum acceptance requirements for the in vivo Comet assay**

A new draft was discussed and comments addressed. The draft will be circulate to others Unit/Panel for comments and feedback.

### **AOB**

None

## **5. Next meeting date**

The next WG meeting will be held in Parma on 24-25 May 2012



Parma, 26 March 2012

**SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES,  
FLAVOURINGS AND PROCESSING AIDS (CEF)**

**Minutes of the 2<sup>nd</sup> meeting of the  
Working Group on Genotoxicity  
23-24 January 2012  
EFSA / FIP Unit / Flavourings**

**Participants**

WG Experts	Rainer Gurtler, Mona-Lise Binderup, Riccardo Crebelli, Pasquale Mosesso, Angelo Carere, Daniel Marzin, Wilfried Bursch
Hearing Experts	Vibe Beltoft (FLAVIS), Pia Lund (FLAVIS), Karin Norby (FLAVIS), Raffaella Corvi (JRC), Gerrit Speijers.
Observers	Sirkku Heinimaa (EC)
EFSA:	Kim Rygaard Nielsen, Andrea Terron, Maria Carfi

**1. Welcome and apologies**

The Chair welcomed the participants. No apologies were received.

**2. Adoption of agenda**

The agenda was adopted.

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and/or Specific Declaration of Interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process.

**4. Discussions**

**FGE.19 General Information**

The status of FGE 19 substances was updated. New data on genotoxicity have been provided by Industry on subgroup 1.2.2, 4.6 and 1.1.1.

***In-vivo* Comet assay minimum requirements**

A draft document was presented and will be rediscussed at next working group meeting. The draft document will be then circulated for comments and endorsement to FEED, CONTAM, PESTICIDES and SCOM units.

### **Styrene**

The Genotoxicity Working Group discussed the genotoxicity issued described in the draft opinion of the FGE 29. Changes were suggested and will be discussed at the next meeting.

### **Complex Mixture**

The item was briefly discussed.

### **AOB**

#### **Evaluation of borderline Ames test results.**

The issue was introduced and discussed. The genotoxicity Working Group considered that tabulation of the data with an indication of reproducibility of results, fold increase, dose relationship and comparison with historical control would be very useful and should be appended to the opinion where necessary.

### **5. Next meeting date**

The next WG meeting will be held in Parma on 22-23 March 2012

Parma, 25 January 2011

**SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES,  
FLAVOURINGS AND PROCESSING AIDS (CEF)**

**Minutes of the 1st meeting of the  
Working Group on Genotoxicity  
27-28 October 2011  
EFSA/CEF Unit/Flavourings**

**Participants**

WG Experts	Rainer Guertler, Mona-Lise Binderup, Riccardo Crebelli, Pasquale Mosesso, Angelo Carere, Daniel Marzin, Wilfried Bursch
Hearing Experts	Vibe Beltoft, Pia Lund, Karin Norby
Observers	Sirkku Heinimaa (EC)
EFSA	Kim Rygaard Nielsen, Andrea Terron, Maria Carfi

**1. Welcome and apologies**

The Chair welcomed the participants. Apologies were received from Mona Lise Binderup, Vibe Beltoft, Pia Lund, Karin Norby and Sirkku Heinimaa.

**2. Adoption of agenda**

The agenda was adopted.

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and/or Specific Declaration of Interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process.

## 4. Discussions

### **FGE.19 General Discussion**

The group was made aware of the status of flavouring substances belonging to FGE.19, the evaluation strategy and the approach taken by the Flavouring Working Group in selecting reference substances to be tested in the genotoxicity assays.

### **FGE.201 subgroup 1.1.2**

Two substances belonging to this FGE were discussed in respect to their genotoxicity potential.

### **FL 16.118 (N-(2-(pyridine-2-yl)ethyl)-3-p-menthanecarboxamide). In vitro Chromosomal Aberration Assay in human lymphocyte**

Results on the extension of the evaluation of the *in-vitro* Chromosome Assay using human lymphocytes were presented and discussed.

**Strategy for testing complex mixtures of natural origin.**

***In-vivo* COMET assay minimal requirements**

## 5. Next meeting date

The next WG meeting will be held in Parma on 23-24 January 2012.

---