

## Minutes of the 7<sup>th</sup> meeting (as teleconference)

### Scientific Committee Working Group on Genotoxicity (Statement on genotoxicity of chemical mixtures)

**Held on 18 October 2018  
(Agreed on 1 November 2018)**

#### **Participants**

- **Working Group Members:**

Josef Schlatter (Chair), Gabriele Aquilina, Riccardo Crebelli, Diane Benford, Rainer Gürtler.

- **EFSA:**

SCER Unit: Daniela Maurici

FIP Unit: Maria Carfi, Carla Martino

NUTRI Unit: Annamaria Rossi

FEED Unit: Paola Manini

PESTICIDES Unit: Juan Parra Morte

#### **1. Welcome and apologies for absence**

The Chair welcomed the participants. No apologies were received.

#### **2. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup> EFSA screened the Annual Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

#### **3. Finalisation of the draft statement on genotoxicity assessment of chemical mixtures**

The participants worked on the last version of the statement that will be tabled for adoption at the Scientific Committee plenary meeting on 21 November. Once the statement is adopted, it will be published together with the technical report of the public consultation by end of 2018.

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

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

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

In line with EFSA procedures in relation to WG confirmation following Panel renewal, the WG Genotoxicity will be re-established. The composition may be slightly revised to complement the expertise needed.

Dates of next meetings remain to be determined. The WG will be probably resumed in December 2018 or in the beginning of 2019.

## Minutes of the 6<sup>th</sup> meeting (as teleconference)

### Scientific Committee Working Group on Genotoxicity (Statement on genotoxicity of chemical mixtures)

**Held on 3 October 2018  
(Agreed on 12 November 2018)**

#### **Participants**

- **Working Group Members:**

Josef Schlatter (Chair), Gabriele Aquilina, Riccardo Crebelli, Rainer Gürtler

- **Observers:**

Frank Le Curieux (ECHA)

- **EFSA:**

SCER Unit: Daniela Maurici

FIP Unit: Maria Carfi, Carla Martino

NUTRI Unit: Annamaria Rossi

FEED Unit: Paola Manini

PESTICIDES Unit: Juan Parra Morte

#### **1. Welcome and apologies for absence**

The Chair welcomed the participants. No apologies were received.

#### **2. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup> EFSA screened the Annual Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

#### **3. Addressing comments from public consultation for the finalisation of the statement**

The participants worked on an updated version of statement. The text was further amended after discussion of the comments received during the public consultation that was launched on 26<sup>th</sup> June and was closed on 9<sup>th</sup> September.

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

18<sup>th</sup> October 2018, as teleconference

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

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

## Minutes of the 5<sup>th</sup> meeting of the Scientific Committee Working Group on Genotoxicity (Statement on genotoxicity of chemical mixtures)

**Held on 13-14 September 2018, EFSA, Parma (Italy)  
(Agreed on 1 November 2018)**

### **Participants**

- **Working Group Members:**

Josef Schlatter (Chair), Gabriele Aquilina, Riccardo Crebelli, Rainer Gürtler

- **Observers:**

Frank Le Curieux (ECHA)

- **Hearing experts:**

Jan van Benthem

- **EFSA:**

SCER Unit: Daniela Maurici

FIP Unit: Maria Carfi, Carla Martino

NUTRI Unit: Annamaria Rossi

FEED Unit: Paola Manini

### **1. Welcome and apologies for absence**

The Chair welcomed the participants. No apologies were received.

### **2. Adoption of agenda**

The agenda was adopted as tabled.

### **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup> EFSA screened the Annual Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were 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/independencerules2014.pdf>

#### **4. Overview of the comments received during the public consultation of the statement on genotoxicity assessment of chemical mixtures**

The participants were informed about the outcome of the public consultation that was open from 26 June until 9 September 2018. 67 comments were received from 16 different organisations. The comments were addressed one by one and some amendments on the text were proposed. The majority of the comments were in relation to:

- Terminology of simple mixtures and complex mixtures – clarification is needed
- Purity of the mixture: what is the minimum? Which percentage of unidentified substances would be considered acceptable without further testing (cut-off value)? Definition for «Substantial fraction».
- When to consider the mixture as genotoxic? Consideration of exposure, matrix and potential anti-genotoxic properties of other constituents. Issue of mutagenic natural constituents in vegetables and food. Clarification is needed.
- Applicability of the statement for novel food and botanicals.
- When mixture contains structurally related substances, a representative substance could be tested. Should the representative substances be identified based on theoretical considerations or on experimental data?

#### **5. Technical hearing on genotoxicity assessment of mixtures (Brussels, 27 September 2018)**

The participants discussed how to structure the technical hearing that will be held in Brussels on 27 September in order to deliver the key messages and to stimulate active participation from the registered participants. EFSA received about 50 registrations including EFSA staff and panel members.

#### **6. Possible new mandates**

The participants were informed that the WG will be re-established for the duration of the mandate of the new Scientific Committee (2018-2021).

It is possible that the WG is tasked by the Scientific Committee to provide preparatory work on how to better assess aneugenicity.

Detailed Terms of reference will be discussed and agreed at one of the next Scientific Committee plenary. The activity will be probably initiated by end of 2018 or beginning of 2019.

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

- 3<sup>rd</sup> and 18<sup>th</sup> October, placeholder for teleconference

## Minutes of the 4<sup>th</sup> meeting of the Scientific Committee Working Group on Genotoxicity (Statement on genotoxicity of chemical mixtures – drafting group)

**Held on 7-8 May 2018, Rome (Italy)  
(Agreed on 18/05/2018)**

### **Participants**

- **Working Group Members:**

Josef Schlatter (Chairman), Gabriele Aquilina, Riccardo Crebelli, Rainer Gürtler, Jan van Benthem.

- **Observers:**

Not applicable

- **Hearing experts:**

Not applicable

- **EFSA:**

SCER Unit: Daniela Maurici, FIP Unit: Maria Carfi, Carla Martino<sup>1</sup>

### **1. Welcome and apologies for absence**

The Chair welcomed the participants. No apologies were received.

### **2. Adoption of agenda**

The agenda was adopted as tabled.

### **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup> EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

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<sup>1</sup> Attended only on day 1.

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

<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

#### **4. Update on the development of the statement on how to assess genotoxicity of chemical mixtures**

The chair summarised the discussion held at the last meeting. The updated draft statement was once again discussed and amended. A revised version has been produced and will be sent to the whole WG for possible comments.

Once finalised, it will be sent to the Scientific Committee in time before the plenary meeting scheduled for 28-29 May.

The statement will be tabled for possible endorsement for public consultation at the last meeting of the present Scientific Committee. The public consultation will be launched around mid-June and will last about 2 months. Finalisation of the statement is expected in autumn 2018.

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

- 13-14 September, Parma
- 28<sup>th</sup> September, placeholder for teleconference

## Minutes of the 3<sup>rd</sup> meeting of the Scientific Committee Working Group on Genotoxicity (Statement on genotoxicity of chemical mixtures)

**Held on 9-10 April 2018, Parma (Italy)  
(Agreed on 20 April 2018)**

### **Participants**

#### **• Working Group Members:**

Josef Schlatter (Chairman), Gabriele Aquilina, Diane Benford<sup>1</sup>, Riccardo Crebelli, Rainer Gürtler, Karen Ildico Hirsch-Ernst, Pasquale Mosesso, Elsa Nielsen, Roland Solecki<sup>2</sup>, Jan van Benthem.

#### **• Observers:**

Frank Le Curieux, ECHA

#### **• Hearing expert:**

Paul White<sup>1</sup> (Health Canada)

Karl-Heinz Engel<sup>3</sup> (CEF Panel)

#### **• EFSA:**

SCER Unit: Daniela Maurici

FIP Unit: Annamaria Rossi

Pesticides Unit: Juan Parra Morte

### **1. Welcome and apologies for absence**

The Chair welcomed the participants. No apologies were received.

### **2. Adoption of agenda**

The agenda was adopted as tabled.

### **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest<sup>4</sup> EFSA screened the Annual Declaration of Interest and the Specific

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<sup>1</sup> Participated via teleconference

<sup>2</sup> Participated on 10<sup>th</sup> April

<sup>3</sup> Participated only from 10-11 o'clock on 10 April

<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>



Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

#### **4. Update on the development of the statement on how to assess genotoxicity of chemical mixtures**

The chair summarised the discussion held at the last meeting. The updated draft statement was once again discussed, considering also the views of the WG developing the guidance on risk assessment of chemical mixture.

The discussion was focussing on chemical characterisation of the mixtures and examples from the different areas were tabled for gathering the experts' view. The applicability of the component-based approach and on the whole mixture approach in the different areas of EFSA's remit of activity were once again analysed in details.

The chair assigned tasks to members of the WG in order to update the statement for discussion and final agreement at the next meeting. The statement is intended to be finalised for possible endorsement for public consultation at the SC plenary in May 2018, last meeting of the present Scientific Committee. Finalisation of the statement is expected in autumn 2018.

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

- 7-8 May 2018, Rome
- 13-14 September, Parma
- 28<sup>th</sup> September, placeholder for teleconference

## Minutes of the 2<sup>nd</sup> meeting of the Scientific Committee Working Group on Genotoxicity (Statement on genotoxicity of chemical mixtures)

Held on 28<sup>th</sup> February - 1<sup>st</sup> March 2018, Parma (Italy)  
(Agreed on 20 April 2018)

### Participants

#### • Working Group Members:

Josef Schlatter (Chairman), Gabriele Aquilina, Diane Benford\*, Rainer Gürtler, Karen Ildico Hirsch-Ernst, Pasquale Mosesso, Elsa Nielsen, Roland Solecki\*, Jan van Benthem.

#### • Observers:

Frank Le Curieux, ECHA

#### • EFSA:

SCER Unit: Daniela Maurici

FIP Unit: Maria Carfi, Carla Martino

FEEDAP Unit: Paola Manini\*

### 1. Welcome and apologies for absence

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

### 2. Adoption of agenda

The agenda was adopted as tabled.

### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

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\*Participated on 1 March

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

<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

#### **4. Brainstorming about developing a document on how to assess genotoxicity of chemical mixtures**

The members discussed the issue of the assessment of genotoxicity in chemical mixtures.

The group exchanged views considering the development ongoing in the Scientific Committee WG on mixtures, where a full guidance on risk assessment of chemical mixtures is being prepared. The discussion was focussing on the applicability of the component-based approach and on the whole mixture approach in the different areas of EFSA's remit of activity. It was agreed that the statement would benefit from launching a public consultation to collect comments from different stakeholders. This additional step, not foreseen at the time of the discussion of the Terms of Reference, will be done at the same time of the launching of the public consultation of the draft guidance on risk assessment of chemical mixtures, namely in June 2018. Comments will be collected and addressed. The statement will be finalised by autumn 2018.

#### **5. Action for the next meeting.**

The chair assigned tasks to members of the WG to prepare some text to be discussed at the next meeting.

The statement is intended to be finalised for possible endorsement for public consultation at the SC plenary in May 2018, last meeting of the present Scientific Committee.

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

- 9-10 April 2018 – Parma
- 26 April 2018 – placeholder for teleconference

## Minutes of the kick off meeting of the Scientific Committee Working Group on Genotoxicity (Statement on genotoxicity of chemical mixtures)

**Held on 9-10 January 2018, Parma (Italy)  
(Agreed on 6 February 2018)**

### **Participants**

- **Working Group Members:**

Josef Schlatter (Chairman), Gabriele Aquilina, Diane Benford<sup>1</sup>, Riccardo Crebelli, Rainer Gürtler, Karen Ildico Hirsch-Ernst, Pasquale Mosesso, Elsa Nielsen, Roland Solecki<sup>1</sup>, Jan van Benthem.

- **Observers:**

Frank Le Curieux, ECHA

- **Hearing experts:**

Christer Hogstrand<sup>2</sup>

- **EFSA:**

SCER Unit: Daniela Maurici, Jean Lou Dorne<sup>1</sup>

FIP Unit: Maria Carfi, Carla Martino

### **1. Welcome and apologies for absence**

The Chair welcomed the participants. No apologies were received.

### **2. Adoption of agenda**

The agenda was adopted as tabled.

### **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

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<sup>1</sup> Participated only on 9<sup>th</sup> January from 16.00 h until end of meeting on 10<sup>th</sup> January

<sup>2</sup> Participated only on 10<sup>th</sup> January

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

<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

#### **4. Brainstorming about developing a document on how to assess genotoxicity of chemical mixtures**

The members discussed the issue of the assessment of genotoxicity in chemical mixtures.

The group exchanged views considering the development ongoing in the Scientific Committee WG on mixtures, where work is ongoing to develop a full guidance on risk assessment of chemical mixtures. The chair of the WG, Chris Hogstrand, presented the latest ongoing developments and informed the participants that a public consultation will be probably launched in late spring on the draft guidance.

#### **5. Action for the next meeting and roadmap to adoption.**

The chair assigned tasks to members of the WG in order to come to the next meeting with some preliminary bullet points to consider more in details.

The statement is intended to be finalised for presentation for possible adoption at the SC plenary in May 2018, last meeting of the present Scientific Committee.

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

- 28 February – 1 March 2018, Parma
- 26 March 2018 – placeholder for teleconference
- 26 April 2018 – placeholder for teleconference

## Minutes of the 7th meeting of the Scientific Committee Working Group on Genotoxicity

**Held on 4-5 October 2017, Berlin (Germany)  
(Agreed on 13 November 2017)**

### **Participants**

- **Working Group Members:**

Josef Schlatter (Chairman), Gabriele Aquilina, Riccardo Crebelli, Diane Benford<sup>1</sup>, Karen Ildico Hirsch-Ernst, Roland Solecki, Jan van Benthem, Pasquale Mosesso and Rainer Gürtler.

- **EC/EU Representatives:**

Frank Le Curieux<sup>2</sup>, ECHA

- **EFSA:**

SCER Unit: Daniela Maurici, Nikolaos Georgiadis

FIP Unit: Maria Carfi

PRAS Unit: Juan Manuel Parra Morte

### **1. Welcome and apologies for absence**

The Chair welcomed the participants. No apologies were received.

### **2. Adoption of agenda**

The agenda was adopted as tabled.

### **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>3</sup> and the Decision of the Executive Director on Declarations of Interest<sup>4</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

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<sup>1</sup> Participated via teleconference

<sup>2</sup> Participated via teleconference

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

<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

#### **4. Agreement of the minutes of the 6<sup>th</sup> meeting held on 12-13 September**

The minutes of the 6<sup>th</sup> meeting held on 12-13 September were agreed on 13 November.

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

##### **5.1 Feedback from the public consultation of the genotoxicity opinion and address of the comments received**

The members addressed the comments received during the public consultation. Final amendments were discussed and agreed. The new draft will be tabled at the Scientific Committee plenary on 15-16 November for final adoption.

##### **5.2 Follow up on the request of advice from FIP unit on smoke flavourings**

The members discussed the issue of the assessment of genotoxicity in chemical mixtures with examples of smoke flavourings.

There was a consensus among the experts that genotoxic substances are of safety concern, therefore they should not be added voluntarily to food. This also applies if they are part of a chemical mixture.

In principle, a mixture can be assessed either via a 'whole mixture' testing approach or via a 'component based' approach. The appropriate approach to follow should be chosen on a case by case basis, based on the weight of evidence principle.

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

- 9-10 January 2018, Parma
- 28 February 2018 – 1 March, Parma
- 26 March 2018 – placeholder for teleconference
- 26 April 2018 – placeholder for teleconference

# Minutes of the 6th meeting of the Scientific Committee Working Group on Genotoxicity

**Held on 12-13 September 2017, Parma (Italy)  
(Agreed on 13 November 2017)**

## **Participants**

### **• Working Group Members:**

Josef Schlatter (Chairman), Gabriele Aquilina, Riccardo Crebelli, Diane Benford, Karen Ildico Hirsch-Ernst, Roland Solecki, Jan van Benthem, Pasquale Mosesso<sup>1</sup> and Rainer Gürtler.

### **• EC/EU Representatives:**

Frank Le Curieux (ECHA)

### **• EFSA:**

SCER Unit: Daniela Maurici, Nikolaos Georgiadis

FIP Unit: Carla Martino, Maria Carfi

## **1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Elsa Nielsen.

## **2. Adoption of agenda**

The agenda was adopted as tabled.

## **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

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<sup>1</sup> Participated only in day 1

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

<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>



#### **4. Agreement of the minutes of the 5<sup>th</sup> meeting held on 19 June**

The minutes of the 5<sup>th</sup> meeting held on 19 June (teleconference) were agreed on 13 November.

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

##### **5.1 Feedback from the public consultation of the genotoxicity opinion and addressing of the comments received**

The members addressed the comments received during the public consultation on the draft opinion that closed on 6<sup>th</sup> September. More than 200 comments were received from different organisations. A revised draft was prepared that will be finalised during the next meeting.

##### **5.2 Implication of genotoxicity opinion on the already published assessments**

A preliminary consideration of the possible implication of the opinion clarifying genotoxicity assessment on already assessed substances was discussed. The members agreed that risk assessment is based on the data available at the time of the assessment and that it is virtually impossible to reconsider all the data that were used at the time of the assessment. However this will not be the case for new assessments, where the indication provided in the opinion should be followed.

##### **5.3 Request of advice from FIP unit on smoke flavourings**

The FIP unit requested advice from the standing WG with regards to smoke flavourings. The issues were discussed and further advice will follow.

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

n/a

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

- 4-5 October 2017- Berlin

## Minutes of the 5th meeting of the Scientific Committee Working Group on Genotoxicity (Teleconference)

**Held on 19 June 2017  
(Agreed on 13 November 2017)**

### **Participants**

#### **• Working Group Members:**

Josef Schlatter (Chairman), Gabriele Aquilina, Karen Ildico Hirsch-Ernst, Roland Solecki, Pasquale Mosesso, Elsa Nielsen and Rainer Gürtler.

#### **• EFSA:**

SCER Unit: Daniela Maurici, Nikolaos Georgiadis

FIP Unit: Maria Carfi

PRAS Unit: Juan Manuel Parra Morte

### **1. Welcome and apologies for absence**

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

### **2. Adoption of agenda**

The agenda was adopted as tabled.

### **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were 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/independencerules2014.pdf>

#### **4. Agreement of the minutes of the 4<sup>th</sup> meeting held in Rome on 10-11 May**

The minutes of the 4<sup>th</sup> meeting held on 10-11 May were agreed on 11 May.

#### **5. Scientific topic(s) for discussion: Finalisation of the genotoxicity opinion for submission to the EFSA Scientific Committee for endorsement**

The members discussed and finalised the draft opinion before submission for endorsement for public consultation to the EFSA Scientific Committee plenary meeting that will be held on 12-13 July 2017.

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

n/a

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

- 12-13 September 2017 - Parma
- 4-5 October 2017 - Berlin

# Minutes of the 4th meeting of the Scientific Committee Working Group on Genotoxicity

**Held on 10-11 May 2017, Rome (Italy)  
(Agreed on 11 May 2017)**

## **Participants**

### **• Working Group Members:**

Josef Schlatter (Chairman), Gabriele Aquilina, Riccardo Crebelli, Diane Benford<sup>1</sup>, Karen Ildico Hirsch-Ernst, Roland Solecki, Elsa Nielsen and Pasquale Mosesso.

### **• EFSA:**

SCER Unit: Daniela Maurici, Nikolaos Georgiadis

FIP Unit: Maria Carfi

PRAS Unit: Juan Manuel Parra Morte

## **1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Rainer Gürtler, Raffaella Corvi (observer from DG JRC), Franck Le Curieux (observer from ECHA).

## **2. Adoption of agenda**

The agenda was adopted as tabled.

## **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest 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.

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<sup>1</sup> Via teleconference

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

<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

#### **4. Agreement of the minutes of the 3<sup>rd</sup> meeting of the WG Genotoxicity held on 10-11 April, Berlin (Germany)**

The meetings of the 3<sup>rd</sup> meeting held on 10-11 April 2017 were agreed on 25 April.

(<http://www.efsa.europa.eu/sites/default/files/genotoxicity20152018.pdf>)

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

##### **5.1 Discussion on Question 1 of the mandate (in vivo UDS assay)**

The members provided their comments on the updated draft circulated and proposed further changes. The WG discussed the text providing explanation of the data analysis of the EURL ECVAM Genotoxicity & Carcinogenicity Consolidated database. As already mentioned in previous meetings, this is a structured master database that compiles available genotoxicity and carcinogenicity data for Ames positive chemicals originating from different sources (<https://eurl-ecvam.jrc.ec.europa.eu/databases/genotoxicity-carcinogenicity-db>). Conclusions were discussed and agreed.

##### **5.2 Discussion about Question 2 of the mandate (*in vivo* bone marrow (BM) exposure)**

The members provided their comments on the revised draft and proposed further changes. Conclusions were discussed and agreed.

##### **5.3 Discussion about Question 3 of the mandate (use of weight of evidence approach and setting of health based guideline values)**

The WG discussed the revised draft in relation to question 3 and proposed amendments. The members discussed the use of other toxicity studies on the genotoxicity assessment and the possibilities of derivation of health-based guidance values. Conclusions were discussed and agreed.

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

An extension of the mandate has been agreed with the DG Sante in order to accommodate a public consultation of the draft opinion. The draft opinion will be presented for possible endorsement for public consultation at the Scientific Committee plenary in July. If endorsed, the public consultation will be launched around end of July and will last for about 6 weeks. Finalisation of the opinion is expected by November 2017.

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

- 19 June: teleconference
- 12-13 September – Parma
- 4-5 October – Berlin

## Minutes of the 3<sup>rd</sup> meeting of the Scientific Committee Working Group on Genotoxicity

**Held on 10-11 April 2017, Berlin (Germany)  
(Agreed on 25 April 2017)**

### Participants

- **Working Group Members:**

Josef Schlatter (Chairman), Rainer Gürtler, Gabriele Aquilina, Karen Ildico Hirsch-Ernst, Roland Solecki, Elsa Nielsen and Pasquale Mosesso

- **Hearing Experts<sup>1</sup>:**

Jan van Benthem<sup>2</sup>

- **European Commission and/or Member States representatives:**

Raffaella Corvi<sup>3</sup> (JRC)

- **ECHA:**

Frank Le Curieux

- **EFSA:**

SCER Unit: Daniela Maurici, Nikolaos Georgiadis

FIP Unit: Maria Carfi

PRAS Unit: Juan Manuel Parra Morte

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<sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

<sup>2</sup> Participated only in Day 1

<sup>3</sup> Participated via teleconference only in question 1

## **1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Riccardo Crebelli, Christiane Vleminckx, Sandro Grilli and Diane Benford.

## **2. Adoption of agenda**

The agenda was adopted as tabled.

## **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>4</sup> and the Decision of the Executive Director on Declarations of Interest<sup>5</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were 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 2<sup>nd</sup> meeting of the WG Genotoxicity held on 9-10 March 2017, Parma (Italy)**

The minutes of the 2<sup>nd</sup> meeting held on 9-10 March 2017 were agreed.  
([http://www.efsa.europa.eu/sites/default/files/genotoxicity\\_20152018.pdf](http://www.efsa.europa.eu/sites/default/files/genotoxicity_20152018.pdf))

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

### **5.1. Discussion on Question 1 of the mandate (in vivo UDS assay)**

The members provided their comments on the draft circulated and proposed further changes. The WG discussed the preliminary analysis of the EURL ECVAM Genotoxicity & Carcinogenicity Consolidated database in order to explore the reliability of the *in vivo* UDS assay and agreed on amendments with regards to the display of the results. This is a structured master database that currently compiles available genotoxicity and carcinogenicity data for Ames positive chemicals originating from different sources (<https://eurl-ecvam.jrc.ec.europa.eu/databases/genotoxicity-carcinogenicity-db>).

### **5.2. Discussion about Question 2 of the mandate (in vivo bone marrow (BM) exposure)**

The members provided their comments on the provided draft and proposed further changes.

The WG focussed the discussion on how to verify the exposure of the bone marrow and which elements (i.e. lines of evidence) should be taken into

<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>5</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

consideration in order to justify it. The members discussed the direct and indirect evidence for exposure of the bone marrow and developed the answer accordingly.

The WG agreed on amendments.

### **5.3. Discussion about Question 3 of the mandate (use of weight of evidence approach and setting of health based guideline values)**

The WG discussed the provided draft of question 3 and proposed deletions and amendments. The members discussed the use of other toxicity studies for the genotoxicity assessment and possibilities of establishing health-based guidance values, as well as situations in which derivation of a health-based guidance value is not considered appropriate, neither fixed nor provisional.

## **6. Any Other Business**

Not applicable.

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

- 10-11 May – Rome
- 19 June: placeholder for a teleconference, to be confirmed at a later stage
- 12-13 September – Parma
- 4-5 October - Berlin



## Minutes of the 2<sup>nd</sup> meeting of the Scientific Committee Working Group on Genotoxicity

**Held on 9-10 March 2017, Parma (Italy)  
(Agreed on 25 April 2017)**

### **Participants**

- **Working Group Members:**

Josef Schlatter (Chairman), Riccardo Crebelli, Rainer Gürtler, Gabriele Aquilina, Karen Ildico Hirsch-Ernst, Roland Solecki<sup>1</sup>, Elsa Nielsen and Pasquale Mosesso

- **Hearing Experts<sup>2</sup>:**

Jan van Benthem, David Kirkland

- **European Commission and/or Member States representatives:**

Raffaella Corvi (JRC)

- **ECHA:**

Frank Le Curieux<sup>3</sup>

- **EFSA:**

SCER Unit: Daniela Maurici, Nikolaos Georgiadis

FIP Unit: Maria Carfi

PRAS Unit: Juan Manuel Parra Morte

FEED Unit: Maria Vittoria Vettori (only 9th March, pm)

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<sup>1</sup> Participated via teleconference only in Day 2 for the question 3

<sup>2</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:  
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

<sup>3</sup> Participated via teleconference only the last session of Day 2

## **1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Diane Benford, Christiane Vleminckx and Sandro Grilli.

## **2. Adoption of agenda**

The agenda was adopted as tabled.

## **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>4</sup> and the Decision of the Executive Director on Declarations of Interest<sup>5</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were 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 kick-off meeting held on 16-17 February 2017, Parma (Italy)**

The minutes of the kick-off meeting held on 16-17 February 2017 were agreed. ([http://www.efsa.europa.eu/sites/default/files/genotoxicity\\_20152018.pdf](http://www.efsa.europa.eu/sites/default/files/genotoxicity_20152018.pdf))

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

### **5.1. Discussion on Question 1 of the mandate (in vivo UDS assay)**

The members provided their comments on the draft circulated and proposed further changes. They were provided with information about the EURL ECVAM Genotoxicity & Carcinogenicity Consolidated database. This is a structured master database that currently compiles available genotoxicity and carcinogenicity data for Ames positive chemicals originating from different sources (<https://eurl-ecvam.jrc.ec.europa.eu/databases/genotoxicity-carcinogenicity-db>).

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<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>5</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

## **5.2. Discussion about Question 2 of the mandate (*in vivo* bone marrow (BM) exposure)**

The members provided their comments on the provided draft and proposed further changes.

The WG focussed the discussion on demonstration of the bone marrow exposure in the *in vivo* MN assay (assuming this test has been selected as the appropriate one to follow up a positive *in vitro* outcome).

Hence, the question raised here is how we verify the exposure to the bone marrow and which elements (i.e. lines of evidence) should we take into consideration as indicators of bone marrow exposure.

## **5.3. Discussion about Question 3 of the mandate (use of weight of evidence approach and setting of health-based guidance values)**

The WG discussed the provided draft of question 3 and proposed amendments.

## **6. Any Other Business**

Not applicable.

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

- 10-11 April – Berlin
- 10-11 May – Rome
- 19 June: placeholder for a teleconference, to be confirmed at a later stage

SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

## Minutes of the kick off meeting of the Scientific Committee Working Group on Genotoxicity (addressing EC mandate M-2017-0047)

**Held on 16-17 February 2017, Parma (Italy)  
(Agreed on 9 March 2017)**

### **Participants**

- **Working Group Members:**

Josef Schlatter (Chairman), Riccardo Crebelli, Rainer Gürtler, Gabriele Aquilina, Karen Ildico Hirsch-Ernest, Sandro Grilli, Roland Solecki

- **Hearing Experts<sup>1</sup>:**

Jan van Benthem, David Kirkland

- **European Commission and/or Member States representatives:**

Raffaella Corvi (JRC)

- **EFSA:**

SCER Unit: Daniela Maurici, Nikolaos Georgiadis, Dimitra Eleftheriadou<sup>2</sup>

FIP Unit: Maria Carfi

PRAS Unit: Juan Manuel Parra Morte

FEED Unit: Maria Vittoria Vettori

### **1. Welcome and apologies for absence**

The Chair welcomed the participants.

Apologies were received from Pasquale Mosesso, Christiane Vleminckx, Elsa Nielsen and Diane Benford.

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<sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

<sup>2</sup> Participated only in day 2

## **2. Adoption of agenda**

The agenda was adopted as tabled.

## **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

## **4. Scientific topic(s) for discussion**

### **4.1 Role and responsibilities of the different members of the WG**

The participants were briefly reminded about the rules that apply to the different roles such as hearing experts, observers and members.

### **4.2 Presentation of the EC mandate**

The chair of the WG presented the new mandate received from the EC in January (M-2017-0047, EFSA-Q-2017-00112: <http://registerofquestions.efsa.europa.eu/roqFrontend/wicket/page?1>) and accepted by EFSA. He explained that it consists of three main questions with sub questions and they must all be addressed by 21 July, as indicated in the aforementioned mandate.

The 3 questions, as part of the terms of reference, are:

1. The adequacy of the Unscheduled DNA Synthesis (UDS) Assay to follow up positive results in the in vitro gene mutation tests;
2. The adequacy to demonstrate target tissue exposure in in vivo studies, particularly in the micronucleus (MN) test;
3. The use of data in a weight of evidence approach to conclude on the genotoxic potential of substances and the consequent setting of health-based reference values for use in human health risk assessment.

#### **4.3 Short presentation of the 2011 SC guidance on genotoxicity testing strategy in relation to the new EC mandate**

The members were presented with the issues raised by the mandate in several key documents such as the OECD Test Guidelines, the ECHA guidance document on information requirements, the UK Committee on Mutagenicity guidance on a strategy for genotoxicity testing<sup>3</sup>, and the OECD overview of the set of genetic toxicology TG and corresponding updates performed in 2014-2015. The members were also reminded how the 3 issues are presented and discussed, even if partially, in the EFSA genotoxicity testing strategy opinion published in 2011 ([link here](#)).

#### **4.4 Brainstorming about Question 1 of the mandate (in vivo UDS assay) - Data requirements in the different EFSA legal frameworks**

According to the EFSA opinion on genotoxicity testing strategies (EFSA J. 2011) *"the in vivo UDS test allows the investigation of genotoxic effects of substances in the liver...However, UDS has a limited use for cells other than liver and its sensitivity has been questioned (Kirkland and Speit, 2008). It is resource intensive and the scoring time consuming"*.

According to the OECD "Overview of the set of OECD genetic Toxicology test Guidelines and updates performed in 2014-2015 (published in July 2016)"<sup>4</sup>, *"the UDS in vivo is a primary DNA damage test that identifies chemicals inducing DNA damage and subsequent repair (measured as unscheduled DNA synthesis versus normal S-phase scheduled synthesis) in liver cells. However, this test does not detect mutagenic consequences of the unrepaired genetic damage. Accordingly, the UDS test may be an appropriate test to detect DNA damage after exposure to chemicals that specifically target the liver and that were positive in the AMES test. The test responds positively ONLY to chemicals that induce the type of DNA damage that is repaired by nucleotide excision repairs (mainly bulky adducts) ... The UDS test should not be considered as a surrogate for a gene mutation test and it may be less reliable than other primary DNA damage tests (Kirkland and Speit, 2008)"*.

<sup>3</sup> [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/315800/in\\_vivo\\_testing\\_of\\_genotoxicity\\_of\\_chemicals.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/315800/in_vivo_testing_of_genotoxicity_of_chemicals.pdf)

<sup>4</sup> [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2016\)47&doc\\_language=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2016)47&doc_language=en).

Finally according to ECHA "Guidance on information requirements and chemical safety assessment (chapter R. 7a, December 2016)"<sup>5</sup> the UDS test should be used *"only when liver is the target organ"*. *"A positive result in the UDS assay can indicate exposure of the liver DNA and induction of DNA damage by the substance under investigation but it is not sufficient information to conclude on the induction of gene mutation by the substance. A negative result in a UDS alone is not a proof of that a substance does not induce gene mutation"*.

The working group discussed the next steps and the content of the first draft of a statement which will form the basis for discussion during the next working group meetings.

#### **4.5 Brainstorming about Question 2 of the mandate (in vivo bone marrow exposure)**

OECD TG 474 (version adopted in July 1997) states *"If there is evidence that the test substance, or a reactive metabolite, will not reach the target tissue, it is not appropriate to use this test"*. This TG was revised and the new version was adopted in July 2016. In relation to target tissue exposure, it states *"A blood sample should be taken at appropriate time(s) in order to permit investigation of the plasma level of the test substances for the purposes of demonstrating that exposure of the bone marrow occurred, where warranted and where other exposure data do not exist..."* *"Evidence of exposure of the bone marrow to a test substance may include a depression of the immature erythrocyte ratio or measurement of the plasma or blood level of the substance. In case of intravenous administration, evidence of exposure is not needed. Alternatively, ADME data, obtained in an independent study using the same route and the same species can be used to demonstrate bone marrow exposure. Negative results indicate that, under the test conditions, the test chemical does not produce micronuclei in the immature erythrocytes of the test species"*.

The working group discussed the next steps and how to prepare a first draft which will form the basis for discussion during the next working group meetings.

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<sup>5</sup> [https://echa.europa.eu/documents/10162/13632/information\\_requirements\\_r7a\\_en.pdf](https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf)

#### **4.6 Brainstorming about Question 3 of the mandate - (use of weight of evidence approach and setting of health based reference values)**

The working group discussed the use of the weight of evidence approach and setting of health based reference values.

The next steps and how to prepare a first draft which will form the basis for discussion during the next working group meetings were discussed. It was considered that this question should be discussed thoroughly when a more final form of the two previous questions have been drafted.

#### **5. Any Other Business**

Not applicable

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

- 9-10 March – Parma
- 10-11 April – Berlin
- 10-11 May – Rome



# Scientific Committee Minutes of the 3rd meeting of the Working Group on Genotoxicity

**Held on 23 November 2016, Parma (Italy)  
(Agreed on 23 December 2016)**

## Participants

- **Working Group Members:**

Riccardo Crebelli (Chairman), Pasquale Mosesso, Rainer Gürtler<sup>1</sup>, Gabriele Aquilina, Christiane Vleminckx, Karen Ildico Hirsch-Ernest, Diane Benford, Sandro Grilli, Elsa Nielsen<sup>2</sup>.

- **Hearing Experts<sup>3</sup>:**

Jan van Benthem

- **European Commission**

Not applicable

- **EFSA:**

- SCER Unit: Daniela Maurici, Nikolaos Georgiadis
- PRAS Unit: Juan Manuel Parra Morte (only for AOB)

## 1. Welcome and apologies for absence

The Chair welcomed the participants.

No apologies were received.

## 2. Adoption of the draft agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>4</sup> and the Decision of the Executive Director on

<sup>1</sup> Participated via teleconference

<sup>2</sup> Participated via teleconference

<sup>3</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:  
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

Declarations of Interest<sup>5</sup>, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

#### **4. Question #1 from the CONTAM panel**

The WG was presented with the background information focusing on the potential presence of genotoxic components in the low molecular weight subfractions and whether the available in vitro genotoxicity tests had sufficient sensitivity to detect them.

It was noted that the bacterial reverse mutation (Ames) assay is a sensitive assay for mutagen detection and is one of the most commonly used tests for identifying potential genotoxicity.

The in vitro chromosomal aberration assay is a useful and sensitive test for detection of genotoxic substances always taking into account that aberrations can occur secondary to toxicity, with compounds that do not react with DNA.

Feedback will be given by the secretariat of the WG to the respective requestors who may consider the advice given by the WG in order to finalise their work.

#### **5. Question #2 from the CONTAM panel**

The WG was presented with the background information focusing on how to develop approaches for the risk assessment of germ cell mutagens.

The WG confirmed that the Margin of Exposure (MOE) is an approach that can be used in general for somatic cell genotoxic substances in the scientific risk assessments of carcinogenic substances.

While a tentative preliminary quantitative assessment might be done to indicate high or low concern it is not feasible to establish cut-off values and thresholds for germ cell mutagens.

Finally, the WG recommended requesting an additional opinion by experts in in vivo transgenic mice assays on whether a quantitative assessment would be possible.

Feedback will be given by the secretariat of the WG to the respective requestors who may consider the advice given by the WG in order to finalise their work.

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<sup>5</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

## **6. Any Other Business**

### **Possible draft mandate on clarification and consideration of several aspects related to the assessment of genotoxicity**

The WG members were presented with a possible draft mandate calling for a clarification of general questions related to genotoxicity such as:

- The use of data in a weight of evidence approach to conclude on genotoxic potential of active substances and their metabolites
- The adequacy of the UDS assay as follow up of positive results in in vitro gene mutation tests
- The failure to adequately demonstrate target tissue exposure in in vivo studies, particularly in the micronucleus test.
- The setting of health-based reference values for use in human health risk assessment when genotoxic potential has not being concluded.

### **Note a posteriori:**

On 1 December 2016 the chair of the WG informed the secretariat that due to personal reasons, he will not be able to serve the WG as chair for the first 6 months of 2017. He therefore prefers to step back as chair but remain a member of the standing WG. The secretariat, in consultation with the head of unit, has decided to nominate Diane Benford as chair of the WG.

**Scientific Committee**

**Minutes of the 2<sup>nd</sup> meeting of the**

**Standing Working Group on Genotoxicity**

**Held on 21 June 2016, Parma (Italy)**

**(Agreed on 29 July 2016)**

**Participants**

- **Working Group Members:**

Riccardo Crebelli (Chairman), Pasquale Mosesso, Rainer Gürtler, Gabriele Aquilina, Christiane Vleminckx<sup>1</sup>, Karen Ildico Hirsch-Ernest.

- **Hearing Experts:**

Not Applicable

- **EFSA:**

SCER Unit: Daniela Maurici, Nikolaos Georgiadis

FIP Unit: Maria Carfi, Anna Maria Rossi

FEED Unit: Matteo Lorenzo Innocenti, Manuela Tiramani

PRAS unit: Marina Goumenou

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

Apologies were received from Elsa Nielsen and Sandro Grilli.

## **2. Adoption of agenda**

The agenda was adopted without changes

## **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

## **4. Question from the CEF Panel on the demonstration of bone marrow exposure in the *in vivo* micronucleus assay**

The WG was presented with an overview of the data on the *in vivo* micronucleus assay and the follow up in relation to bone marrow exposure. The WG discussed the data related to the investigation of the plasma level of the test substance for the purpose of demonstrating that exposure of the bone marrow occurred. It was noted that an activity is on-going at the OECD level to review the different genotoxicity testing guidance. It is therefore important to monitor the development of this activity and to wait for the outcome before recommending any further actions changing the testing strategy in place in EFSA. Meanwhile, in the presence of possible issues related to bone marrow exposure, the assessment of the substances will continue on a case by case basis. Feedback will be given by the secretariat of the WG to the requestor who may consider the advice given by the WG in order to finalise their work.

## **5. Question from the FEEDAP Panel on the genotoxicity dataset for feed additives**

The WG was presented with an overview of the genotoxicity dataset for the feed additive Ethoxyquin ([EFSA-Q-2010-01224](http://www.efsa.europa.eu/en/keydocs/docs/independencpolicy.pdf) and [EFSA-Q-2016-00267](http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf)).

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

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

## SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

The WG discussed the data submitted for consultation and a conclusion was drawn in line with what had already been highlighted at the previous point. Feedback will be given by the secretariat of the WG to the respective requestors who may consider the advice given by the WG in order to finalise their work.

### 6. Any Other Business

- **Importance of the purity of the substance tested – Genotoxicity testing for mixtures – Possible issues raised by the interpretation of results of in vivo Comet assay**

The WG was presented with an overview of the abovementioned issues, raised by a member of the WG for information and possible comments. Due to time constraint, the WG took note of the issues but recommendations were not provided on the best approach to follow.

### 7. Dates of the next meeting

No meeting is foreseen for the moment.

## Scientific Committee

### Minutes of the 1<sup>st</sup> meeting of the Standing Working Group on Genotoxicity

**Held on 6 November 2015 Parma (Italy)  
(Agreed on 15 December 2015)**

#### Participants

- **Working Group Members:**

Riccardo Crebelli (Chairman), Pasquale Mosesso, Rainer Gürtler, Gabriele Aquilina, Karen Ildico Hirsch-Ernest, Sandro Grilli, Christiane Vleminckx<sup>1</sup>

- **Hearing Experts:**

Not Applicable

- **European Commission and/or Member States representatives:**

Not Applicable

- **EFSA:**

- RASA Department : Hans Verhagen<sup>2</sup>
- SCER Unit: Daniela Maurici, Nikolaos Georgiadis
- Pesticides Unit : Andrea Terron<sup>3</sup>
- Nutrition Unit: Wolfgang Gelbmann<sup>4</sup>

- **Others:**

Not Applicable

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<sup>1</sup> Participated via teleconference

<sup>2</sup> Participated during the presentation about resveratrol in agenda point 6

<sup>3</sup> Participated in agenda point 5

<sup>4</sup> Participated via teleconference

## **1. Welcome and apologies for absence**

The Chair welcomed the participants.

No apologies were received.

## **2. Adoption of agenda**

The agenda was adopted without changes.

## **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>5</sup> and the Decision of the Executive Director on Declarations of Interest<sup>6</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

For further details on the outcome of the Oral Declaration of Interest made at the beginning of the meeting, please refer to the Annex.

## **4. Brief introduction to the mandate of the Gentox standing WG**

The participants were briefed about the mandate of the current standing working group. The duration of the working group is three years and the advice will be included in the current notes without being binding for the bodies who submitted the questions.

## **5. Question from the Pesticides Unit**

There was a presentation on the specific question raised by an EFSA colleague from the Pesticides Unit who requested advice related to the mandate for the preparation of a scientific opinion of the PPR panel investigating experimental toxicological properties of plant protection products having a potential link to Parkinson's disease and childhood leukaemia (EFSA-Q-2014-00480).

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<sup>5</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>6</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>



The WG discussed the data submitted for consultation and a conclusion was drawn. Feedback will be given by the secretariat of the WG to the respective requestors who may consider the advice given by the WG in order to finalise their work.

## **6. Question from the Nutrition Unit**

- Question in relation to Resveratrol

There was a presentation on a specific question raised by an expert of the Nutrition panel who requested advice related to the request for a scientific opinion on resveratrol as a novel food ingredient (EFSA-Q-2014-00232).

The WG discussed the data submitted for consultation and a conclusion was drawn. Feedback will be given by the secretariat of the WG to the respective requestors who may consider the advice given by the WG in order to finalise their work.

- Question in relation to 'Taxifolin'

There was a presentation on a specific question raised by an expert of the Nutrition panel who requested advice related to the request for a scientific opinion on 'Taxifolin' as a novel food ingredient (EFSA-Q-2012-00961).

The WG discussed the data submitted for consultation and a conclusion was drawn. Feedback will be given by the secretariat of the WG to the respective requestors who may consider the advice given by the WG in order to finalise their work.

## **7. Any Other Business**

### **7.1 Update of the guidance on genotoxicity**

The working group discussed the need to update the existing guidance document.

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

The date of the next meeting will be discussed once new requests for advice are received by the secretariat of the Scientific Committee WG.

## Annex I

Interests and actions resulting from the Oral Declaration of Interest done at the beginning of the meeting

With regard to this meeting, Riccardo Crebelli declared the following interest: Member of the working group of food contact materials in 2014 where resveratrol was one of the components of an application. The application was finally withdrawn and no opinion had been issued.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>7</sup> and the Decision of the Executive Director on Declarations of Interest<sup>8</sup>, and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a Conflict of Interest for the expert concerned.

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<sup>7</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>8</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>