

## SCIENTIFIC COMMITTEE UNIT

### **Minutes of the 9th meeting of the Working Group on Genotoxicity Testing Strategies, Parma, 29-30 June 2011 (agreed by the WG on 30 June 2011)**

#### **Participants**

WG Experts: BARLOW Susan (Chair), AQUILINA Gabriele, BINDERUP Mona Lise, BOLOGNESI Claudia<sup>1</sup>, CREBELLI Riccardo, Eugenia DOGLIOTTI, FILIPIC Metka, GUERTLER Rainer, HARTWIG Andrea, LOVELL David, Daniel MARZIN, Van BENTHEM Jan.

EFSA: MAURICI Daniela

JRC: CORVI Raffaella

#### **Welcome and apologies**

The Chair welcomed the participants. Apologies were received from Paul Brantom and Peter Kasper.

#### **1. Adoption of agenda**

The agenda was adopted as tabled.

#### **2. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and 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.

#### **3. Discussion**

The WG discussed the comments received after the public consultation of the draft opinion. The consultation closed in the beginning of June and more than 200 comments were received from 11 organisations. The opinion was revised taking into consideration the relevant comments and it will be proposed for adoption at the Scientific Committee plenary in September. Publication of the final opinion is foreseen by the end of September.

#### **4. Date of next meeting**

No other meetings are foreseen. The working group will be closed after the publication of the final opinion in autumn.

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<sup>1</sup> Only on 30/06

**SCIENTIFIC COMMITTEE AND ADVISORY FORUM UNIT**

**Minutes of the 8th meeting of the Working Group on Genotoxicity Testing Strategies,  
Brussels, 10-11 March 2011**

**(agreed by the WG on 11 March 2011)**

**Participants**

WG Experts: BARLOW Susan (Chair), AQUILINA Gabriele, BINDERUP Mona Lise, BOLOGNESI Claudia, CREBELLI Riccardo, FILIPIC Metka, GUERTLER Rainer, HARTWIG Andrea, KASPER Peter, LOVELL David, Van BENTHEM Jan.

EFSA: MAURICI Daniela

JRC: CORVI Raffaella

**Welcome and apologies**

The Chair welcomed the participants. Apologies were received from Paul Brantom, Eugenia Dogliotti and Daniel Marzin. The chair informed the WG that Corrado Galli resigned for personal reasons from the EFSA Scientific Committee and consequently he will no longer be a member of WG.

**1. Adoption of agenda**

The agenda was adopted as tabled.

**2. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and 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.

**3. Discussion**

The discussion at the meeting focused on revised chapters for the development of the draft opinion. The revised draft is now ready to be proposed to the Scientific Committee for endorsement for public consultation. If endorsed, the draft opinion will be published in April for public consultation for 6 weeks. The comments received will be addressed by the WG and the revised draft will be proposed for final adoption at the Scientific Committee plenary in September.

**4. Date of next meeting**

The next meeting will be held in Parma on 29-30 June 2011.

**SCIENTIFIC COMMITTEE AND ADVISORY FORUM UNIT**

**Minutes of the 7th meeting of the Working Group on Genotoxicity Testing Strategies,  
Parma, 11-12 January 2011**

**(agreed by the WG on 12 January 2011)**

**Participants**

WG Experts: BARLOW Susan (Chair), AQUILINA Gabriele, BINDERUP Mona Lise, BOLOGNESI Claudia, CREBELLI Riccardo, DOGLIOTTI Eugenia, FILIPIC Metka, GUERTLER Rainer, HARTWIG Andrea, KASPER Peter, LOVELL David, MARZIN Daniel, Van BENTHEM Jan

EFSA: MAURICI Daniela

JRC: CORVI Raffaella

**Welcome and apologies**

The Chair welcomed the participants. Apologies were received from Paul Brantom and Corrado Galli.

**1. Adoption of agenda**

The agenda was adopted as tabled.

**2. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and 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.

**3. Discussion**

The discussion at this WG meeting focused on revised chapters for the development of the draft opinion. The table of content was revised and a new structure has been agreed. A conference call will be held on 21 February to discuss conclusions and recommendations. The draft opinion will be proposed, most probably to the Scientific Committee plenary in April, for endorsement for public consultation.

**4. Date of next meeting**

The next meeting will be held in Bruxelles on 10-11 March 2011.

**SCIENTIFIC COMMITTEE AND ADVISORY FORUM UNIT**

**Minutes of the 6th meeting of the Working Group on Genotoxicity Testing Strategies,  
Brussels, 18-19 November 2010**

**(agreed by the WG on 19 November 2010)**

**Participants**

WG Experts: BARLOW Susan (Chair), AQUILINA Gabriele, BOLOGNESI Claudia, CREBELLI Riccardo, DOGLIOTTI Eugenia, FILIPIC Metka, GUERTLER Rainer, HARTWIG Andrea, LOVELL David, MARZIN Daniel and Van BENTHEM Jan

EFSA: MAURICI Daniela

JRC: CORVI Raffaella

**Welcome and apologies**

The Chair welcomed the participants. Apologies were received from, Mona Lise Binderup, Paul Brantom, Corrado Galli and Peter Kasper.

**1. Adoption of agenda**

The agenda was adopted as tabled.

**2. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and 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.

**3. Discussion**

The discussion at this WG meeting focused on revised chapters for the development of the draft opinion, in particular on the basic testing battery options for genotoxicity and on the follow up of positive results form a basic battery.

**4. Date of next meeting**

The next meeting will be held in Parma on 11-12 January 2011.

**SCIENTIFIC COMMITTEE AND ADVISORY FORUM UNIT**

**Minutes of the 5th meeting of the Working Group on Genotoxicity Testing Strategies,  
Brussels, 22-23 September 2010  
(agreed by the WG on 23 September 2010)**

**Participants**

WG Experts:	BARLOW Susan (Chair), AQUILINA Gabriele, BINDERUP Mona Lise, CREBELLI Riccardo, FILIPIC Metka <sup>1</sup> , GUERTLER Rainer, KASPER Peter <sup>2</sup> , LOVELL David, MARZIN Daniel, Van BENTHEM Jan
EFSA:	MAURICI Daniela
JRC:	CORVI Raffaella
Hearing Expert:	KIRKLAND David <sup>2</sup>

**Welcome and apologies**

The Chair welcomed the participants. Apologies were received from, Claudia Bolognesi, Paul Brantom, Eugenia Dogliotti, Corrado Galli, Andrea Hartwig.

**1. Adoption of agenda**

The agenda was adopted as tabled.

**2. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and 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.

**3. Discussion**

Work of the WG on Genotoxicity Testing Strategies is in progress. The WG already discussed a series of key issues identified in previous meetings and is now starting to collect contributions in order to draft the opinion. The WG aims to present the opinion at the SC plenary in April 2011 to be endorsed for public consultation.

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<sup>1</sup> Absent 22<sup>nd</sup>

<sup>2</sup> Absent 23<sup>rd</sup> pm

Scientific Committee and Advisory Forum Unit

**4. Date of next meeting**

The next meeting will be held in Brussels on 18-19 November 2010.

Parma, 21 July 2010

**SCIENTIFIC COMMITTEE AND ADVISORY FORUM UNIT**

**Minutes of the 4th meeting of the Working Group on Genotoxicity Testing Strategies,  
Amsterdam, 12 July 2010**

**(agreed by the WG on 12 July 2010)**

**Participants**

WG Experts: BARLOW Susan (Chair), AQUILINA Gabriele, BINDERUP Mona Lise, BOLOGNESI Claudia, CREBELLI Riccardo, DOGLIOTTI Eugenia, FILIPIC Metka, GALLI Corrado, GUERTLER Rainer, HARTWIG Andrea, LOVELL David, MARZIN Daniel, Van BENTHEM Jan

EFSA: MAURICI Daniela

Apologies: BRANTOM Paul, KASPER Peter, CORVI Raffaella

**Welcome and apologies**

The Chair welcomed the participants. Apologies were received from, Paul Brantom, Peter Kasper, Raffaella Corvi.

**1. Adoption of agenda**

The agenda was adopted as tabled.

**2. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and 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.

**3. Discussion**

The work of the WG on Genotoxicity Testing Strategies is ongoing. The group discussed among others, the following issues:  
Concept of threshold and no-threshold in genotoxicity, top dose concentration in *in vitro* tests, rationale of the genotoxicity testing and biological relevance of test methods, sensitivity versus specificity of *in vitro* tests, gold standard for genotoxicity testing.

**4. Date of next meeting**

The next meeting will be held in Brussels on 22-23 September 2010.

Parma, 3 June 2010

**SCIENTIFIC COMMITTEE AND ADVISORY FORUM UNIT**

**Minutes of the 3rd meeting of the Working Group on Genotoxicity Testing Strategies,  
Parma, 24-25 May 2010  
(adopted by the WG on 25 May 2010)**

**Participants**

WG Experts: BARLOW Susan (Chair), AQUILINA Gabriele, BINDERUP Mona Lise<sup>1</sup>, BOLOGNESI Claudia, BRANTOM Paul<sup>2</sup>, CREBELLI Riccardo, DOGLIOTTI Eugenia, GALLI Corrado, GUERTLER Rainer, KASPER Peter, MARZIN Daniel, Van BENTHEM Jan

EFSA: MAURICI Daniela

DG JRC CORVI Raffaella

Apologies: FILIPIC Metka, HARTWIG Andrea, LOVELL David

**Welcome and apologies**

The Chair welcomed the participants. Apologies were received from, Metka Filipic, Andrea Hartwig and David Lovell.

**1. Adoption of agenda**

The agenda was adopted as tabled.

**2. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and 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.

**3. Discussion**

The work of the WG on Genotoxicity Testing Strategies is ongoing. The group discussed among others, the following issues:

- Rationale of genotoxicity testing and the importance of the biological relevance;
- The number and the quality of the tests needed in relation to the level and the duration of the exposure;
- Sensitivity versus specificity in the different in vitro/in vivo genotoxicity testing.

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<sup>1</sup> Present only on 25<sup>th</sup> May

<sup>2</sup> Present only 24<sup>th</sup> May



Scientific Committee and Advisory Forum Unit

**4. Date of next meeting**

The next meeting will be held in Amsterdam on 12 July 2010.

Parma, 19 March 2010

**SCIENTIFIC COMMITTEE AND ADVISORY FORUM UNIT**

**Minutes of the 2nd meeting of the Working Group on Genotoxicity Testing Strategies,  
18 March 2010**

**(adopted by the WG on 18 March 2010)**

**Participants**

WG Experts: Barlow Susan (chair), Aquilina Gabriele, Binderup Monalisa, Bolognesi Claudia, Crebelli Riccardo, Galli Corrado, Andrea Hartwig, David Lovell, Guertler Rainer, Kasper Peter, Marzin Daniel, van Benthem Jan.

EFSA: Daniela Maurici

DG JRC Raffaella Corvi

**Welcome and apologies**

The Chair welcomed the participants. Apologies were received from Paul Brantom, Metka Filipic and Eugenia Dogliotti.

**1. Adoption of agenda**

The agenda was adopted as tabled.

**2. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and 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.

**3. Discussions**

The Chair introduced the discussion on the rationale of genotoxicity testing strategies and the importance of the biological relevance in the evaluation of the results. The discussion continued on how to optimise a basic test battery balancing sensitivity versus specificity. In the end, genotoxicity testing requirements in the different EFSA Panels were presented by different Panel members.

**4. Date of next meeting**

The next meeting will be held in Parma on 24-25 May 2010 (lunch time to lunch time).

Parma, 16 February 2010

**SCIENTIFIC COMMITTEE AND ADVISORY FORUM UNIT**

**Minutes of the 1st meeting of the Working Group on Genotoxicity Testing Strategies,  
20 January 2010  
(adopted by the WG on 20 January 2010)**

**Participants**

WG Experts: Barlow Susan (chair), Aquilina Gabriele, Binderup Monalisa, Bolognesi Claudia, Brantom Paul, Crebelli Riccardo, Dogliotti Eugenia, Filipic Metka, Galli Corrado, Lovell David, Guertler Rainer, Kasper Peter, Marzin Daniel, van Benthem Jan.

EFSA: Daniela Maurici

DG JRC Raffaella Corvi

**Welcome and apologies**

The Chair welcomed the participants. All the members of the WG were present at the meeting.

**1. Adoption of agenda**

The agenda was adopted as tabled.

**2. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and 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.

**3. Discussions**

The Chair presented the mandate and the relative terms of reference. The experts asked several clarifications on issues to be address while developing the opinion. The content of the draft opinion was discussed together with a tentative road map.

**4. Date of next meeting**

The next meeting will be held in Amsterdam on 18<sup>th</sup> March 2010.

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