

FIP UNIT

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

**Minutes of the 46<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**

**-Subgroup on Public Consultation outcome-**

**Held on 14 January 2015, by Teleconference**

**(Agreed on 28 January 2015)**

**Participants**

- **Working Group Experts:**
  - Andy Hart, Trine Husøy (Chair), Wim Mennes, Ralph Pirow and Detlef Wölflé
- **EFSA:**
  - FIP Unit: Anna Federica Castoldi, Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

**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 and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

**4. Scientific topic for discussion**

5.1 Bisphenol A (EFSA-Q-2012-00423)

The discussion was aimed to solve the editorial pending issues on the adopted opinion on Bisphenol A.

## **5. Next meetings**

This was the last meeting of the WG on BPA.

FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 45<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
**Subgroup on PBPKs**  
**Held on 18 November 2014, by Teleconference**  
**(Agreed on 28 November 2014)**

**Participants**

- **Working Group Experts:**
  - Daniel Doerge, Ursula Gundert-Remy, Trine Husøy (Chair), Wim Mennes and Ralph Pirow
- **EFSA:**
  - FIP Unit: Anna Federica Castoldi, Cristina Croera
- **Observers:**
  - Jonathan Briggs (EC)

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Andrew Hart.

**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 and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

**4. Scientific topic for discussion**

5.1 Bisphenol A (EFSA-Q-2012-00423)

The discussion dealt with the uncertainties in the comparison of the Fisher et al. and Mielke PBPK models.

**Next meetings**

The next WG meeting on BPA has not been fixed.

FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 44<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
**Subgroup on public consultation outcome**  
**Held on 14 November 2014, by Teleconference**  
**(Agreed on 28 November 2014)**

**Participants**

- **Working Group Experts:**
  - Diane Benford, Andrew Hart, Edel Holene, Trine Husøy (Chair), Ralph Pirow, Josef Schlatter, Detlef Woelfle and Rudolf Antonius Woutersen.
- **EFSA:**
  - FIP Unit: Anna Federica Castoldi, Cristina Croera
- **Observers:**
  - Jonathan Briggs (EC)

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Ursula Gundert-Remy, Paul Fowler, Wim Mennes and Nathalie Von Goetz.

**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 and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

### **4. Scientific topic for discussion**

#### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

The discussion dealt with the uncertainty evaluation for aggregate exposure and risk characterisation.

### **Next meetings**

The next WG meeting on BPA will be held on 18 November 2014, as a Teleconference.

**FIP UNIT**

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids  
Minutes of the 45th meeting of the Working Group on Bisphenol A Toxicology  
Subgroup on PBPKs  
Held on 18 November 2014, by Teleconference  
(Agreed on 28 November 2014)**

**Participants**

- **Working Group Experts:**
  - Daniel Doerge, Ursula Gundert-Remy, Trine Husøy (Chair), Wim Mennes and Ralph Pirow
- **EFSA:**
  - FIP Unit: Anna Federica Castoldi, Cristina Croera
- **Observers:**
  - Jonathan Briggs (EC)

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Andrew Hart.

**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 and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

**4. Scientific topic for discussion**

**5.1 Bisphenol A (EFSA-Q-2012-00423)**

The discussion dealt with the uncertainties in the comparison of the Fisher et al. and Mielke PBPK models.

**Next meetings**

The next WG meeting on BPA has not been fixed.



FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 44th meeting of the Working Group on Bisphenol A Toxicology**  
**Subgroup on public consultation outcome**  
**Held on 14 November 2014, by Teleconference**  
**(Agreed on 28 November 2014)**

**Participants**

- **Working Group Experts:**
  - Diane Benford, Andrew Hart, Edel Holene, Trine Husøy (Chair), Ralph Pirow, Josef Schlatter, Detlef Woelfle and Rudolf Antonius Woutersen.
- **EFSA:**
  - FIP Unit: Anna Federica Castoldi, Cristina Croera
- **Observers:**
  - Jonathan Briggs (EC)

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Ursula Gundert-Remy, Paul Fowler, Wim Mennes and Nathalie Von Goetz.

**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 and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

### **4. Scientific topic for discussion**

#### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

The discussion dealt with the uncertainty evaluation for aggregate exposure and risk characterisation.

### **Next meetings**

The next WG meeting on BPA will be held on 18 November 2014, as a Teleconference.

**FIP UNIT**

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 43<sup>rd</sup> meeting of the Working Group on Bisphenol A Toxicology**  
**Subgroup on public consultation outcome**  
**Held on 4-6 November 2014, in Oslo**  
**(Agreed on 28 November 2014)**

**Participants**

- **Working Group Experts:**
  - Diane Benford, Paul Fowler, Ursula Gundert-Remy, Andrew Hart, Edel Holene, Trine Husøy (Chair), Ralph Pirow, Josef Schlatter, Henk van Loveren<sup>1</sup>, Detlef Woelfle<sup>2</sup> and Rudolf Antonius Woutersen.
- **EFSA:**
  - FIP Unit: Anna Federica Castoldi, Cristina Croera
- **Observers:**
  - Jonathan Briggs (EC)

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Wim Mennes.

**2. Adoption of agenda**

The agenda was adopted.

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<sup>1</sup> Only on 4 and 5 Nov

<sup>2</sup> By phone (on 4 Nov)

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

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

### **4. Scientific topic for discussion**

#### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

The discussion mainly dealt with the revised chapter on NMDR, on hazard and risk characterisation, on neurotoxicity and on the conclusions. The uncertainty evaluation for the risk characterisation was presented and discussed. The section on Biomonitoring studies in the Exposure part of the opinion was also re-discussed due to a new revision. Specific tasks with deadlines were assigned to the WG experts.

### **Next meetings**

The next WG meeting on BPA will be held on 14 November 2014, as a Teleconference.

FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 42<sup>nd</sup> meeting of the Working Group on Bisphenol A Toxicology**  
**Subgroup on Uncertainties**  
**Held on 20-21 October 2014, in Brussels**  
**(Agreed on 28 November 2014)**

**Participants**

- **Working Group Experts:**
  - Diane Benford, Paul Fowler, Ursula Gundert-Remy, Andrew Hart, Edel Holene, Trine Husoy (Chair), Wim Mennes, Ralph Pirow, Josef Schlatter, Henk Van Loveren, Detlef Woelfle, Rudolph A. Woutersen.
- **EFSA:**
  - FIP Unit: Anna Federica Castoldi, Cristina Croera
- **Hearing Experts:**
  - Vittorio Silano (SC)

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

**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 and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

**4. Scientific topic for discussion**

5.1 Bisphenol A (EFSA-Q-2012-00423)

The discussion dealt with the revisions of the immunotoxicity and the general toxicity sections of the draft opinion. A detailed discussion on the uncertainties of the different endpoints for the hazard characterisation was held, and the draft text on the methodology applied for this was revised. Specific tasks with deadlines were assigned to the WG experts.

### **Next meetings**

The next WG meeting on BPA will be held on 04-06 November 2014 in Oslo.

FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 41<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
**Subgroup on Uncertainties**  
**Held on 25-26 September 2014, in Parma**  
**(Agreed on 03 October 2014)**

**Participants**

- **Working Group Experts:**
  - Diane Benford, Paul Fowler, Ursula Gundert-Remy, Andrew Hart, Trine Husoy (Chair), Wim Mennes, Ralph Pirow, Joseph Schlatter, Detlef Woelfle.
- **EFSA:**
  - FIP Unit: Anna Federica Castoldi, Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Edel Holene and Rudolf Antonius Woutersen.

**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 and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

**4. Scientific topic for discussion**

5.1 Bisphenol A (EFSA-Q-2012-00423)

The discussion dealt with uncertainties in developmental and reproductive toxicology and in metabolic effects; the graphs on uncertainties were revised accordingly. A discussion on NMDR was also held and specific tasks with deadlines were assigned to the WG experts.

### **Next meetings**

The next WG meeting on BPA will be held on 20-21 October 2014 in Brussels.



FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 40<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
**Subgroup on Uncertainties**  
**Held on 10-11 September 2014, in Edinburgh**  
**(Agreed on 11 September 2014)**

**Participants**

- **Working Group Experts:**
  - Andrew Hart, Trine Husoy (Chair), Edel Holene, Wim Mennes, Ralph Pirow, Rudolf Antonius Woutersen.
- **Hearing Experts:**
  - Vittorio Silano (CEF Panel)
- **EFSA:**
  - FIP Unit: Anna Federica Castoldi, Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Detlef Woelfle (others).

**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.

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

### **4. Scientific topic for discussion**

#### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

The discussion dealt with uncertainties in neurobehavioural effects.

The graphs on the uncertainties were revised. Specific tasks with deadlines were assigned to the WG experts.

### **Next meetings**

The next WG meeting on BPA will be held on 25-26 September 2014 in Parma.

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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/independencerules.pdf>

## **Annex I**

With regard to this meeting, Dr. Trine Husoy and Dr. Andy Hart declared the following interest: To have been invited to participate as speakers to the 50th Congress of the European Societies of Toxicology (Eurotox), giving presentations on the EFSA draft opinion on BPA, sent on Public Consultation on 17 January 2014. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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. The experts have been invited to update their Annual declaration of interest.

FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 39<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
**- Subgroup on Immunotoxicity -**  
**Held by teleconference on 27 August 2014 (pm)**  
**(Agreed on 11 September 2014)**

**Participants**

- **Working Group Experts:**
  - Trine Husøy (Chair), Henk van Loveren, Rudolf Antonius Woutersen
- **EFSA:**
  - FIP Unit: Anna Federica Castoldi

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Wim Mennes.

**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 and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

**4. Scientific topic for discussion**

**4.1 Bisphenol A (EFSA-Q-2012-00423).**

The discussion focussed on an immunotoxicity study that was not previously included in the draft opinion on BPA health risks. Specific tasks with deadlines were assigned to the WG experts.

## **5. Next meetings**

The next WG meeting on BPA will be held in Edinburgh on 10-11 September 2014.

FIP UNIT

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

**Minutes of the 38<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**

**- Subgroup on Public Consultation Outcome -**

**Held by teleconference on 27 August 2014 (am)**

**(Agreed on 11 September 2014)**

**Participants**

- **Working Group Experts:**

- Diane Benford, Ursula Gundert-Remy, Andrew Hart, Edel Holene, Trine Husøy (Chair), Wim Mennes, Ralph Pirow, Josef Schlatter, Detlef Woelfle, Rudolf Antonius Woutersen.

- **EFSA:**

- FIP Unit: Anna Federica Castoldi

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Paul Fowler.

**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 and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

**4. Scientific topic for discussion**

**4.1 Bisphenol A (EFSA-Q-2012-00423)**

The Working Group discussed the following issues: the general approach to uncertainty analysis and the uncertainties linked to BPA effects on the mammary gland and

neurobehaviour. A discussion was also held on uncertainties related to non monotonic dose response relationships. Specific tasks with deadlines were assigned to the WG experts.

## **5. Next meetings**

The next WG meeting on BPA will be held by Teleconference on the 27 August 2014 afternoon.

**FIP UNIT**

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 37<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
Subgroup on Uncertainties  
**Held on 1 July 2014, in Parma**  
**(Agreed on 28 July 2014)**

**Participants**

- **Working Group Experts:**
  - Paul Fowler, Ursula Gundert-Remy, Andrew Hart, Trine Husoy (Chair), Wim Mennes, Ralph Pirow<sup>1</sup>, Detlef Woelfle, Rudolf Antonius Woutersen.
- **EFSA:**
  - FIP Unit: Anna Federica Castoldi, Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

**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 and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

**4. Scientific topic for discussion**

**5.1 Bisphenol A (EFSA-Q-2012-00423)**

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<sup>1</sup> By phone.



The revised text on toxicokinetics included in the draft opinion was presented and discussed. The graph on the uncertainties related to the mammary gland proliferation was revised. Specific tasks with deadlines were assigned to the WG experts.

### **Next meetings**

The next WG meeting on BPA will be held by Teleconference on 27 August 2014.

FIP UNIT

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

**Minutes of the 36<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**

Subgroup on comments received on General issues, MoA and Methodology

**Held on 12 June 2014 (pm), by Teleconference**

**(Agreed on 28 July 2014)**

**Participants**

- **Working Group Experts:**
  - Andrew Hart, Trine Husoy (Chair), Wim Mennes, Ralph Pirow, Detlef Woelfle.
- **EFSA:**
  - FIP Unit: Anna Federica Castoldi, Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

**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 and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

**4. Scientific topic for discussion**

**5.1 Bisphenol A (EFSA-Q-2012-00423)**

The answers to the comments on Mode of Actions and Epigenetic mechanisms and on the Applied Methodology were presented and discussed. Specific tasks were assigned to the WG experts.

### **Next meetings**

The next WG meeting on BPA toxicology, subgroup on Uncertainties, will be held in Parma, on 1<sup>st</sup> July 2014 (am).

FIP UNIT

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

**Minutes of the 35<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**

Subgroup on comments received on HD-BMDL-RC and NMDR

**Held on 12 June 2014 (am), by Teleconference**

**(Agreed on 28 July 2014)**

**Participants**

- **Working Group Experts:**
  - Diane Benford, Andrew Hart, Trine Husoy (Chair), Wim Mennes, Ralph Pirow, Detlef Woelfle.
- **EFSA:**
  - FIP Unit: Anna Federica Castoldi, Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

**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 and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

**4. Scientific topic for discussion**

5.1 Bisphenol A (EFSA-Q-2012-00423)

The answers to the comments on Non-Monotonic Dose Response were presented and discussed. Specific tasks were assigned to the WG experts.

### **Next meetings**

The next WG meeting on BPA toxicology, subgroup on comments received on General issues, MoA and Methodology, will be held by Teleconference on 12 June 2014 (pm).

FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 34<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
Subgroup on Public Consultation outcome  
**Held on 5-6 June 2014, in Parma**  
**(Agreed on 28 July 2014)**

**Participants**

- **Working Group Experts:**
  - Paul Fowler, Andrew Hart, Trine Husoy (Chair), Ursula Gundert-Remy, Ralph Pirow, Rudolf Antonius Woutersen.
- **EFSA:**
  - FIP Unit: Anna Federica Castoldi, Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received by Wim Mennes and Detlef Woelfle,

**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 and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

**4. Scientific topic for discussion**

**5.1 Bisphenol A (EFSA-Q-2012-00423)**

The answers to the comments on toxicokinetics and on metabolic effects and the changes introduced in the draft opinion were presented and discussed. The uncertainties associated

to these ones and to the reprotoxicity endpoints were discussed. Specific tasks were assigned to the WG experts.

### **Next meetings**

The next WG meeting on BPA toxicology, subgroup on comments received on HC-BMDL-RC and NMDR will be held by Teleconference on 12 June 2014(am).

FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 33<sup>rd</sup> meeting of the Working Group on Bisphenol A Toxicology**  
Subgroup on Uncertainties  
**Held on 3-4 June 2014, in Parma**  
**(Agreed on 28 July 2014)**

**Participants**

- **Working Group Experts:**
  - Andrew Hart, Trine Husoy (Chair), Wim Mennes<sup>1</sup>, Ralph Pirow<sup>2</sup>, Natalie Von Goetz<sup>3</sup>, Detlef Woelfle, Rudolf Antonius Woutersen.
- **EFSA:**
  - FIP Unit: Anna Federica Castoldi, Cristina Croera
  - Data Unit: Davide Arcella<sup>4</sup>

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

**2. Adoption of agenda**

The agenda was adopted.

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<sup>1</sup> Only on 4<sup>th</sup> June am.

<sup>2</sup> By phone on 3<sup>rd</sup> June am, physically on 4<sup>th</sup> June.

<sup>3</sup> By phone on 3<sup>rd</sup> June am

<sup>4</sup> On 3<sup>rd</sup> June am.



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

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

### **4. Scientific topic for discussion**

#### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

The uncertainties associated to the use of a PBPK modelling and for the aggregate exposure were identified and discussed.

The animal studies on mammary proliferations were re-checked for strengths and weaknesses, reliability and relevance to human situation.

### **Next meetings**

The next WG meeting on BPA toxicology, subgroup on Public Consultation outcome, will be held in Parma on 5-6 June 2014.

FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 32<sup>nd</sup> meeting of the Working Group on Bisphenol A Toxicology**  
Subgroup on Carcinogenicity  
**Held on 27 May 2014 (pm) by Teleconference**  
**(Agreed on 28 July 2014)**

**Participants**

- **Working Group Experts:**
  - Trine Husoy (Chair), Paul Fowler, Wim Mennes.
- **EFSA:**
  - FIP Unit: Anna Federica Castoldi, Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Detlef Woelfle.

**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 and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

**4. Scientific topic for discussion**

**5.1 Bisphenol A (EFSA-Q-2012-00423)**

The discussion focussed on the answers given by the WG members to the comments received during the public consultation phase on the Reprotoxicity section. It was discussed how to integrate them into the draft opinion; specific indications and tasks were given to the WG members for the next meeting.

## **5. Next meetings**

The next WG meeting on BPA toxicology, subgroup on Uncertainties, will be held in Parma on 3-4 June 2014.

FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 31<sup>st</sup> meeting of the Working Group on Bisphenol A Toxicology**  
Subgroup on Carcinogenicity  
**Held on 27 May 2014 (am) by Teleconference**  
**(Agreed on 28 July 2014)**

**Participants**

- **Working Group Experts:**
  - Trine Husoy (Chair), Rudolf Antonius Woutersen, Detlef Woelfle.
- **EFSA:**
  - FIP Unit: Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

**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 and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

**4. Scientific topic for discussion**

**5.1 Bisphenol A (EFSA-Q-2012-00423)**

The discussion focussed on the answers given by the WG members to the comments received during the public consultation phase on the Carcinogenicity section. It was discussed how to integrate them into the draft opinion; specific indications and tasks were given to the WG members for the next meeting.

## **5. Next meetings**

The next WG meeting on BPA toxicology, subgroup on Reprotoxicity, will be held by teleconference on 27 May 2014 (pm).

FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 30<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
Subgroup on Public Consultation outcome  
**Held on 12-13 May 2014, in Oslo**  
**(Agreed on 21 May 2014)**

**Participants**

- **Working Group Experts:**
  - Anne Lise Brantsaeter<sup>1</sup>, Daniel Doerge<sup>2</sup>, Paul Fowler, Ursula Gundert-Remy, Andy Hart, Edel Holene<sup>3</sup>, Trine Husoy (Chair), Wim Mennes<sup>4</sup>, Ralph Pirow, Ruud Woutersen, Detlef Woelfle.
- **EFSA:**
  - FIP Unit: Anna F. Castoldi, Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Gemma Calamandrei.

**2. Adoption of agenda**

The agenda was adopted.

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<sup>1</sup> On 13 May.

<sup>2</sup> On 12 May, by phone.

<sup>3</sup> On 13 May.

<sup>4</sup> On 12 May, by phone.

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

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

### **4. Scientific topic for discussion**

#### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

The discussion focussed on the answers given by the WG members to the comments received during the public consultation phase. It was discussed how to integrate them into the draft opinion; specific indications and tasks were given to the WG members for the next meeting.

### **5. Next meetings**

The next WG meeting on BPA toxicology- Subgroup on Carcinogenicity will be held on 27<sup>th</sup> May 2014, by Teleconference.

FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 29<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
Subgroup on Public Consultation outcome  
**Held on 10-11 April 2014, in Brussels**  
**(Agreed on 21 May 2014)**

**Participants**

- **Working Group Experts:**
  - Paul Fowler, Ursula Gundert-Remy, Trine Husoy (Chair), Wim Mennes, Ralph Pirow, Ruud Woutersen, Detlef Woelfle.
- **EFSA:**
  - FIP Unit: Anna F. Castoldi, Cristina Croera
- **European Commission:**
  - Annette Schaefer<sup>1</sup>

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Gemma Calamandrei and Andrew Hart.

**2. Adoption of agenda**

The agenda was adopted.

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<sup>1</sup> Only on 10th April.



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

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

### **4. Scientific topic for discussion**

#### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

The discussion focussed on some of the comments received during the public consultation phase. Approaches to deal with them were decided and specific tasks were assigned to the WG members for the next meeting.

### **5. Next meetings**

The next WG meeting on BPA toxicology will be held in Oslo, on 12-13 May 2014.

FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 28<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
Subgroup on Public Consultation outcome  
**Held on 31 March 2014 by Teleconference**  
**(Agreed on 11 April 2014)**

**Participants**

- **Working Group Experts:**
  - Gemma Calamandrei<sup>1</sup>, Paul Fowler, Ursula Gundert-Remy, Andrew Hart, Trine Husoy (Chair), Wim Mennes, Ralph Pirow, Ruud Woutersen, Detlef Woelfle.
- **EFSA:**
  - FIP Unit: Anna F. Castoldi, Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

**2. Adoption of agenda**

The agenda was adopted.

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<sup>1</sup> From 11h00 to 12h00

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

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

For further details on the outcome of the Oral Declaration of Interests made at the beginning of the meeting, please refer to the Annex II (a)

### **4. Scientific topic for discussion**

#### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

The meeting focused on two main topics:

- Presentation and first discussion of the comments from the Public Consultation

Priorities to tackle in the next meetings were identified.

### **5. Next meetings**

The next WG meeting on BPA toxicology will be held in Brussels, on 10-11 April 2014.

## **Annex II**

### **Interests and actions resulting from the oral declarations of interests done at the beginning of the meeting**

- a) With regard to this meeting, Prof. Paul Fowler declared the following interest: “He was invited to participate in Endocrine Society-sponsored meeting on Health and Economic Consequences of Endocrine Disrupting Chemicals, on April 28-29 in Paris”.

In accordance with EFSA’s Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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. The expert was invited to declare this interest in his ADOI under IX (others).

FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 27<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
Subgroup on Uncertainties  
**Held on 6-7 February 2014 in Berlin**  
**(Agreed on 11 February 2014)**

**Participants**

- **Working Group Experts:**
  - Andrew Hart, Wim Mennes, Ralph Pirow, Detlef Wölfle (Chair)
- **EFSA:**
  - FIP Unit: Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

**2. Adoption of agenda**

The agenda was adopted, including in the AoB, a short discussion of the new studies from Churchwell et al. (2014) and Delclos et al (2014).

**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 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. Scientific topic for discussion**

**5.1 Bisphenol A (EFSA-Q-2012-00423)**

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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/independencerules.pdf>

The meeting discussion mainly focused on the approach to deal with the uncertainties related to the mammary gland proliferation effect (considered as “likely”) and to other endpoints for which the effects were considered as “as likely as not”.

Also the new studies published by Churchwell et al. (2014) on low-dose BPA dosimetry and by Delclos et al (2014) and the BPA toxicological effects in a 90-day subchronic study in rats were briefly discussed.

The experts also discussed how to deal with the new biomonitoring studies by Mendonca et al. (2014), Migeot et al. (2013) and Yi et al. (2013) in human milk.

Specific tasks were assigned to the experts.

## **5. Next meetings**

The next WG meeting on BPA toxicology has not yet been fixed.

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FIP UNIT

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

**Minutes of the 26<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
Subgroup on risk characterisation

**Held on 25-26 November 2013 in Parma**

**(Agreed on 23 January 2014)**

**Participants**

- **Working Group Experts:**
  - Andrew Hart, Trine Husøy (Chair), Iona Pratt and Detlef Wölfle
- **Hearing Experts:**
  - Diane Benford
- **EFSA:**
  - FIP Unit: Anna F. Castoldi and Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Jan Alexander (HE) and Annette Schaefer (EC).

**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 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. Scientific topic for discussion**

#### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

The meeting discussion focused on the BMDLs reports on general toxicity and mammary proliferation endpoints, and on the text on Risk characterisation and the related uncertainties. Revisions of the text were proposed and specific tasks were assigned to the WG members.

### **5. Next meetings**

The next WG meeting on BPA toxicology will be held in Berlin, on 6-7 February 2014.

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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/independencerules.pdf>



**FIP UNIT**

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 25<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
Subgroup on approach to risk characterisation  
**Held on 19-21 November 2013 in Oslo**  
**(Agreed on 23 January 2014)**

**Participants**

- **Working Group Experts:**
  - Trine Husøy (Chair), Paul Fowler, Ursula Gundert-Remy<sup>1</sup>, Ralph Pirow, Iona Pratt, Detlef Wölflé and Ruud Woutersen
- **Hearing Experts:**
  - Jan Alexander, Diane Benford
- **EFSA:**
  - FIP Unit: Anna F. Castoldi and Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Andrew Hart, Annette Schaefer (EC), and Joseph Schlatter (HE).

**2. Adoption of agenda**

The agenda was adopted without changes.

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<sup>1</sup> Present on 19<sup>th</sup> and 21<sup>th</sup> November

### **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 Declarations of Interests<sup>3</sup>, EFSA screened the Annual 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. Scientific topic for discussion**

#### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

The meeting discussion focused in detail on the Reprotoxicity and the Metabolic sections of the draft opinion. Specific comments were raised and revision of the text suggested. A new text on Risk characterisation was also discussed and changes were introduced.

### **5. Next meetings**

The next WG meeting on BPA toxicology will be held in Parma, on 25-26 November 2013.

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

<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**  
**Minutes of the 24<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
Subgroup on Risk characterisation  
**Held on 15 November 2013 by Teleconference**  
**(Agreed on 23 January 2014)**

**Participants**

- **Working Group Experts:**
  - Trine Husøy (Chair), Andrew Hart, Iona Pratt, Detlef Wölfle and Ruud Woutersen
- **Hearing Experts:**
  - Diane Benford
- **EFSA:**
  - FIP Unit: Anna F. Castoldi and Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Annette Schaefer (EC).

**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 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. Scientific topic for discussion**

#### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

The discussion focused on the Risk characterisation approach for the risk assessment of BPA. The conclusions from hazard identification were discussed in detail and proposals for revision of the text on hazard characterisation and risk characterisation were provided by the WG members.

### **5. Next meetings**

The next WG meeting on BPA toxicology will be held in Oslo, on 19-21 November 2013.

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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/independencerules.pdf>

**FIP UNIT**

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

**Minutes of the 23<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology –  
Subgroups on Mammary proliferation, Neurotoxicity, Metabolic effects and Toxicokinetics  
Held on 05-07 November 2013, Parma**

**(Agreed on 23 January 2014)**

**Participants**

- **Working Group Experts:**
  - Claire Beausoleil<sup>1</sup>, Gemma Calamandrei<sup>2</sup>, Ursula Gundert-Remy<sup>3</sup>, Trine Husøy (Chair), Ralph Pirow<sup>4</sup>, Iona Pratt<sup>5</sup>, Wout Slob<sup>6</sup>, Henk Van Loveren<sup>7</sup>, Natalie von Goetz<sup>8</sup>, Detlef Wölflé<sup>9</sup> and Ruud Woutersen<sup>10</sup>
- **Hearing Experts:**
  - Jan Alexander<sup>11</sup>, Diane Benford<sup>12</sup>, Edel Holene<sup>13</sup> and Josef Schlatter<sup>14</sup>
- **EFSA:**
  - FIP Unit: Anna F. Castoldi and Cristina Croera

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<sup>1</sup> Present by phone on 5<sup>th</sup> November

<sup>2</sup> Present on 6<sup>th</sup> November

<sup>3</sup> Present on 7<sup>th</sup> November

<sup>4</sup> Present by phone on 7<sup>th</sup> November

<sup>5</sup> Present on 5<sup>th</sup> November and by phone on 7<sup>th</sup> November

<sup>6</sup> Present on 5<sup>th</sup> November

<sup>7</sup> Present on 6<sup>th</sup> November

<sup>8</sup> Present by phone on 7<sup>th</sup> November

<sup>9</sup> Present on 5<sup>th</sup> November

<sup>10</sup> Present on 5<sup>th</sup> November

<sup>11</sup> Present by phone on 5<sup>th</sup> November

<sup>12</sup> Present by phone on 5<sup>th</sup> and 6<sup>th</sup> November

<sup>13</sup> Present on 6<sup>th</sup> November

<sup>14</sup> Present on 6<sup>th</sup> November

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

The Chair welcomed the participants. Apologies were received from Daniel Doerge and Annette Schaefer (EC).

## **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>15</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>16</sup>, EFSA screened the Annual 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 22<sup>th</sup> Working Group meeting held on 14-16/10/2013 in Brussels.**

The minutes of the 22th Working Group meeting were agreed on 16 October 2013.

## **5. Scientific topic for discussion**

### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

The discussion mainly focused on the following topics:

- Carcinogenicity/mammary gland proliferation
- Neurological, neurodevelopmental and neuroendocrine effects
- Metabolic effects
- Toxicokinetics and Metabolism
- Risk characterisation

The WG discussed each topic in detail, proposed revisions of the opinion and specific actions were assigned to each WG member.

## **6. Next meetings**

The next WG meeting on BPA toxicology will be held on 15 November 2013, in the form of a teleconference.

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<sup>15</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>16</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 22<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
**Held on 14-16 October 2013, Brussels**  
**(Agreed on 16 October 2013)**

- Claire Beausoleil, Gemma Calamandrei<sup>1</sup>, Paul Fowler, Ursula Gundert-Remy, Trine Husøy (Chair), Ralph Pirow, Iona Pratt, Josef Schlatter, Natalie von Goetz, Henk van Loveren, Detlef Wölflé and Ruud Woutersen
- 
- **Hearing Experts:**
  - Jan Alexander, Diane Benford and Josef Schlatter
- **European Commission and/or Member States representatives:**
  - Annette Schäfer (EC)
- **EFSA:**
  - FIP Unit: Anna F. Castoldi and Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Anne Lise Brantsaeter, Daniel Doerge, Edel Holene (HE), Andrew Hart, Wim Mennes, Maria de Fatima Poças and Alfonso Siani (HE).

**2. Adoption of agenda**

The agenda was adopted without changes.

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<sup>1</sup> Present by phone on 16 October from 9.00 to 11.00 hrs

### **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 Declarations of Interests<sup>3</sup>, EFSA screened the Annual 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 21<sup>th</sup> Working Group meeting held on 08/10/2013 via Teleconference.**

The minutes of the 21th Working Group meeting were agreed on 16 October 2013.

### **5. Scientific topic for discussion**

#### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

The discussion mainly focused on the following topics:

- Reprotoxicity
- Neurological, neurodevelopmental and neuroendocrine effects
- Toxicokinetics and Metabolism
- Metabolic effects
- Carcinogenicity
- Risk characterisation

The WG revised the text of the opinion and discussed the approach to risk characterisation.

### **6. Next meetings**

The next WG meeting on BPA toxicology will be held in Parma, on 5-7 November 2013.

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

<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**  
**Minutes of the 21<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology –  
Teleconference- Subgroup on Toxicokinetics**  
**TELE-conference 08 10 2013**  
**(Agreed on 16 October 2013)**

**Participants**

- **Working Group Experts:**
  - Daniel Doerge, Ursula Gundert-Remy<sup>1</sup>, Andrew Hart<sup>2</sup>, Trine Husøy (Chair), Ralph Pirow, Iona Pratt, Natalie von Goetz
- **EFSA:**
  - FIP Unit: Anna F. Castoldi and Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants. The WG members invited to this WG were specifically address to discuss on the toxicokinetics of BPA and if and how to use the data on dermal exposure for risk characterisation.

**2. Adoption of agenda**

The agenda was adopted without changes.

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<sup>1</sup> Present from 15.30 hrs

<sup>2</sup> Present from 15.30 hrs

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

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>3</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>4</sup>, EFSA screened the Annual 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 20<sup>th</sup> Working Group meeting held on 11-13/09/2013, in Oslo.**

The minutes of the 20th Working Group meeting were agreed on 16 October 2013.

### **5. Scientific topic for discussion**

#### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

A specific discussion whether and how exposures estimate via dermal should be integrated into a composite exposure estimate (external dermal dose) which can be used for the risk assessment of BPA was held.

### **6. Next meetings**

The next WG meeting on BPA toxicology will be held in Brussels, on 14<sup>th</sup>-16<sup>th</sup> October 2013.

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

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

**FOOD INGREDIENTS & PACKAGING UNIT**

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 20<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
**Held on 11-13 September 2013, Oslo**  
**(Agreed on 16 October 2013)**

**Participants**

- **Working Group Experts:**

- Claire Beausoleil<sup>1</sup>, Anne Lise Brantsaeter<sup>2</sup>, Gemma Calamandrei<sup>3</sup>, Daniel Doerge, Ursula Gundert-Remy<sup>4</sup>, Edel Holene<sup>5</sup>, Trine Husøy (Chair), Ralph Pirow<sup>6</sup>, Iona Pratt, Alfonso Siani<sup>7</sup>, Josef Schlatter, Natalie von Goetz<sup>8</sup>, Detlef Wölflé<sup>9</sup> and Ruud Woutersen<sup>10</sup>

- **Hearing Experts:**

- Jan Alexander, Diane Benford<sup>11</sup>, Claude Emond<sup>12</sup>, Edel Holene and Josef Schlatter

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

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- **EFSA:**

- FIP Unit: Anna F. Castoldi and Cristina Croera

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<sup>1</sup> Present on 13 September

<sup>2</sup> Present on 11 and 12 September

<sup>3</sup> Present by phone on 11 September

<sup>4</sup> Present on 12 and 13 September

<sup>5</sup> Present on 11 and 12 September

<sup>6</sup> Present on 12 and 13 September

<sup>7</sup> Present by phone on 12 September from 9.00 to 13.00 hrs

<sup>8</sup> Present on 12 and 13 September

<sup>9</sup> Present on 13 September

<sup>10</sup> Present by phone on 13 September from 13.30 hrs

<sup>11</sup> Present on 12 and 13 September

<sup>12</sup> Present on 12 and 13 September

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

The Chair welcomed the participants. Apologies were received from Andy Hart, Maria de Fatima Poças, Paul Fowler, Wim Mennes, Annette Schäfer (EC) and Henk van Loveren.

## **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>13</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>14</sup>, EFSA screened the Annual 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 25-26 June 2013, Oslo.**

The minutes of the 19<sup>th</sup> Working Group meeting were agreed on 13 September 2013.

## **5. Scientific topic for discussion**

The meeting was organized in parallel sessions addressing different topics (as well as in plenary sessions where the rapporteur of each session reported back to all the participants the outcome of his discussion group. The discussion mainly focused on the following topics:

- Toxicokinetics and Metabolism
- Neurological, neurodevelopmental and neuroendocrine effects (Anxiety)
- Metabolic effects
- Carcinogenicity (mammary proliferation)

The individual studies were discussed by the WG and strengths and weaknesses highlighted. The WG felt the need to address more in depth the adversity of some effects seen in animal studies and their relevance to humans.

New tasks regarding the hazard/risk characterisation section were assigned to the working group experts.

## **6. Any Other Business**

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

The next meeting of the Working Group on BPA Toxicology will be held on 8<sup>th</sup> October 2013, by Teleconference.

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<sup>13</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>14</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

**FOOD INGREDIENTS & PACKAGING UNIT**

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 19<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
**Held on 25-26 June 2013, Oslo**  
**Agreed on 13 September 2013**

**Participants**

- **Working Group Experts:**
  - Claire Beausoleil<sup>1</sup>, Anne Lise Brantsaeter, Gemma Calamandrei, Daniel Doerge<sup>2</sup>, Paul Fowler<sup>3</sup>, Trine Husøy (Chair), Ralph Pirow, Iona Pratt, Natalie von Goetz, Henk van Loveren<sup>4</sup> and Detlef Wölflé
- **Hearing Experts:**
  - Jan Alexander, Diane Benford<sup>5</sup> and Josef Schlatter
- **European Commission and/or Member States representatives:**
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- **EFSA:**
  - FIP Unit: Anna F. Castoldi and Claudia Heppner<sup>6</sup>

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Andy Hart, Catherine Leclercq, Maria de Fatima Poças, Ursula Gundert-Remy, Edel Holene, Wim Mennes, Alfonso Siani, Emanuela Testai, Anthony Hardy, Kirsi Mjöhänen (ECHA) and Annette Schäfer (EC).

**2. Adoption of agenda**

The agenda was adopted without changes.

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<sup>1</sup> Present after 11.00 hrs

<sup>2</sup> Present by phone on 25 June after 14.00 hrs

<sup>3</sup> Present by phone on 25 June after 11.00 hrs

<sup>4</sup> Present on 25 June until 15.15 hrs

<sup>5</sup> Present by phone on 25 June from 11.00 hrs

<sup>6</sup> Present by phone on 25 June after 14.00 hrs

### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>7</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>8</sup>, EFSA screened the Annual 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 04-05 June 2013, Brussels.

The minutes of the 18<sup>th</sup> Working Group meeting were agreed on 05 June 2013.

### 5. Scientific topic for discussion

The discussion mainly focused on the following topics:

- Toxicokinetics and Metabolism
- Neurological, neurodevelopmental and neuroendocrine effects
- Metabolic effects
- Carcinogenicity
- Assessment factors
- Approach to risk characterisation

The WG felt the need to address more in depth the adversity of some effects seen in animal studies and their relevance to humans.

New tasks regarding the hazard/risk characterisation section were assigned to the working group experts.

### 6. Any Other Business

The WG was informed that the new NTP 90 day study report had been finalized and could be requested to FDA and distributed to the WG members.

### 7. Next meeting(s)

The next meeting of the Working Group on BPA Toxicology will be held on 11-13 September 2013 in Oslo, Norway.

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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/independencerules.pdf>

**FOOD INGREDIENTS & PACKAGING UNIT**

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 18<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
**Held on 04-05 June 2013, Brussels**

**Agreed on 05 June 2013**

**Participants**

- **Working Group Experts:**
  - Claire Beausoleil<sup>1</sup>, Maria de Fatima Poças, Paul Fowler, Trine Husøy (Chair), Catherine Leclercq, Iona Pratt, Ralph Pirow, Natalie van Goetz, Henk van Loveren<sup>2</sup> and Detlef Wölflé
- **Hearing Experts:**
  - Andrew Hart<sup>3</sup>
- **European Commission and/or Member States representatives:**
  - Annette Schaefer
- **EFSA:**
  - FIP Unit: Anna F. Castoldi, Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Anne Lise Brantsaeter, Gemma Calamandrei, Wim Mennes, Ursula Gundert-Remy, Emanuela Testai (SCENHIR), Kirsi Myohanen (ECHA).

**2. Adoption of agenda**

The agenda was adopted without changes.

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<sup>1</sup> Present only on 04 May

<sup>2</sup> Present only on 04 May

<sup>3</sup> Present only on 04 May

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

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>4</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>5</sup>, EFSA screened the Annual 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 13-14 May 2013.**

The agreement of the minutes of the 17<sup>th</sup> Working Group meeting was done by written procedure on 02 June 2013.

### **5. Scientific topic for discussion**

#### **○ 5.1 Bisphenol A (EFSA-Q-2012-00423)**

The discussion of the draft opinion focused on the following topics: toxicokinetics, systemic toxicity, genotoxicity, carcinogenicity, risk characterization and draft conclusions for all endpoints. Revisions were made to the draft sections and new tasks and deadlines were assigned to the group experts.

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

The WG identified the need for additional experts with expertise in pathology, toxicokinetics and neurobehavioral toxicity. In addition, the WG felt that Andy Hart, initially invited as hearing expert to present an approach expressing uncertainties in risk assessment, should become a full member of the WG, as the approach presented by the expert served as a basis for developing the weight of evidence approach applied to the hazard identification of BPA. The WG chair supported these two requests. EFSA staff indicated that they will follow up on these two requests in line with EFSA's rules and procedures.

### **7. Next meeting**

The next meeting of the Working Group on Toxicology - Subgroup on risk characterisation is planned for June 24-25, Oslo.

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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/independencerules.pdf>



**FOOD INGREDIENTS & PACKAGING UNIT**

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 17<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
**Held on 13-14 May 2013, Parma**  
**Agreed on 02 June 2013**

**Participants**

- **Working Group Experts:**
  - Gemma Calamandrei, Paul Fowler, Ursula Gundert-Remy, Trine Husøy (Chair), Catherine Leclercq, Iona Pratt and Ralph Pirow
- **Hearing Experts:**
  - Andrew Hart (FERA)
- **European Commission and/or Member States representatives:**
- **EFSA:**
  - FIP Unit: Anna F. Castoldi, Cristina Croera, Alina Lupu and Anne Theobald

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Claire Beausoleil, Anne Lise Brantsaeter, Wim Mennes, Fatima Pocas, Natalie van Goetz, Henk van Loveren, Detlef Wölflé, Emanuela Testai (SCENIHR), Annette Schaefer (EC), and Kirsi Myohanen (ECHA).

Peter Greaves resigned from the WG due to possible conflicts of interest. The WG noted that another expert with expertise in animal and human pathology would be needed in the WG to cover this specific area.

**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.

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

#### **4. Agreement of the minutes of the 16<sup>th</sup> Working Group meeting held on 2-3 May 2013, Berlin.**

The minutes of the 16<sup>th</sup> Working Group meeting were agreed by written procedure on 02 06 2013.

#### **5. Scientific topic for discussion**

##### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

During the WG meeting the section on hazard characterization for neurobehavioural endpoints was discussed and some revisions were proposed. Furthermore, the approach to risk characterization was discussed for the various endpoints, population groups and exposure scenarios. New tasks on risk characterization were assigned to the Working Group members and EFSA secretariat.

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

The next meetings of the Working Group on Toxicology - Subgroup on Risk characterisation is planned for June 4-5, in Brussels.

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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/independencerules.pdf>

## Annex I

### Interests and actions resulting from the oral declarations of interests done at the beginning of the meeting

With regard to this meeting **DR. TRINE HUSØY** declared the following interest: **TWO COLLEAGUES OF HERS WORKING AT NIPH (NORWEGIAN INSTITUTE OF PUBLIC HEALTH, OSLO, NORWAY) HAVE PERFORMED A RESEARCH WORK ON BPA AND HAVE RECENTLY PUBLISHED A PAPER ON THIS WORK<sup>3</sup>. DR HUSØY HAS NOT PROVIDED ANY CONTRIBUTION TO THIS WORK.** In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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>3</sup> Bodin J, Bolling AK, Samuelsen M, Becher R, Lovik M, Nygaard UC. (2013). Long-term bisphenol A exposure accelerates insulinitis development in diabetes-prone NOD mice. Immunopharmacology and Immunotoxicology, 35, 349-358.

**FOOD INGREDIENTS & PACKAGING UNIT**

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 16<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
**Held on 02-03 May 2013, Berlin**

**Agreed on 02 June 2013**

**Participants**

- **Working Group Experts:**
  - Anne Lise Brantsaeter, Ursula Gundert-Remy, Trine Husøy (Chair), Paul Fowler, Iona Pratt, Henk van Loveren<sup>1</sup> and Detlef Wölflé
- **Hearing Experts:**
  - Andrew Hart (FERA), Daniel Doerge (FDA)<sup>2</sup>, Emanuela Testai (SCENIHR)<sup>3</sup>
- **European Commission and/or Member States representatives:**
  -
- **EFSA:**
  - FIP Unit: Anna F. Castoldi, Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Claire Beausoleil, Gemma Calamandrei, Peter Greaves, Wim Mennes, Annette Schaefer (EC) and Kirsi Myohanen (ECHA).

**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>4</sup> and the Decision of the Executive Director implementing this Policy regarding

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<sup>1</sup> Only on 2<sup>nd</sup> May.

<sup>2</sup> By phone on 3rd May (from 2pm to 3pm)

<sup>3</sup> By phone on 3rd May (from 2pm to 3pm)

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

Declarations of Interests<sup>5</sup>, EFSA screened the Annual 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 on 08 04 2013 March 2013, Amsterdam.**

The minutes of the 15<sup>th</sup> Working Group- Subgroup on risk characterisation meeting were agreed by written procedure and published on the EFSA website on 09 05 2013.

#### **5. Scientific topic for discussion**

##### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

The discussion focused mainly on the human studies and the endpoints revised were immunotoxicity and reproductive and developmental toxicity. Furthermore, the toxicity endpoints for the hazard characterization and their selection for the risk characterisation were also discussed.

New tasks regarding the hazard/risk characterisation section were assigned to the working group experts.

#### **6. Any Other Business (if applicable)**

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

The next meeting of the Working Group on Toxicology - Subgroup on risk characterisation is planned for 13-14 May, Parma.

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

**FOOD INGREDIENTS & PACKAGING UNIT**

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 15<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
**Held on 08 April 2013, Amsterdam**  
**(Agreed on 9 May 2013)**

**Participants**

- **Working Group Experts:**

- Claire Beausoleil<sup>1</sup>, Ursula Gundert-Remy, Trine Husøy (Chair), Catherine Leclercq<sup>2</sup>, Ralph Pirow, Iona Pratt, Nathalie van Goetz and Henk van Loveren

- **Hearing Experts:**

- 

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

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- **EFSA:**

- FIP Unit: Anna F. Castoldi

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Anne Lise Brantsaeter, Gemma Calamandrei, Maria de Fatima Poças, Peter Greaves, Paul Fowler, Wim Mennes and Detlef Wölfe.

**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>3</sup> and the Decision of the Executive Director implementing this Policy regarding

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<sup>1</sup> Present after 11.00 am

<sup>2</sup> Present until 14.30 pm

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

Declarations of Interests<sup>4</sup>, EFSA screened the Annual 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 04 04 2013 March 2013, Amsterdam.**

The agreement of the minutes of the 14<sup>th</sup> Working Group meeting was deferred.

### **5. Scientific topic for discussion**

#### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

After an introductory presentation by Husøy the discussion mainly focused on the potential approaches to risk characterization for BPA. The toxicity endpoints to be selected for the hazard and risk characterization were also a topic for discussion.

The experts were informed that the sections of the draft BPA opinion concerning reproductive and developmental toxicity, neurotoxicity and exposure assessment would be presented to, and discussed by, the CEF Panel over the following three days of Plenary meeting.

New tasks regarding the hazard/risk characterisation section were assigned to the working group experts.

#### **6. Any Other Business (if applicable)**

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

The next meeting of the Working Group on Toxicology - Subgroup on risk characterisation is planned for May 2-3, Berlin.

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

**FOOD INGREDIENTS & PACKAGING UNIT**

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 14<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
**Held on 04-05 April 2013, Amsterdam**  
**(Agreed on 30 April 2013)**

**Participants**

- **Working Group Experts:**
  - Anne Lise Brantsaeter, Claire Beausoleil, Gemma Calamandrei, Paul Fowler<sup>1</sup>, Ursula Gundert-Remy, Trine Husøy (Chair), Iona Pratt and Henk van Loveren
- **Hearing Experts:**
  - Andrew Hart (FERA)
- **European Commission and/or Member States representatives:**
- **EFSA:**
  - FIP Unit: Anna F. Castoldi

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Peter Greaves, Wim Mennes and Detlef Wölflé.

**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 Declarations of Interests<sup>3</sup>, EFSA screened the Annual Declaration of interest filled in by the experts invited for the present meeting. No conflicts of interests related to the issues

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<sup>1</sup> Only present on April 4

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

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



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 6-8 March 2013, Rome.**

The minutes of the 13<sup>th</sup> Working Group meeting were agreed on 04 04 2013 and published on the EFSA website on 16 04 2013.

### **5. Scientific topic for discussion**

#### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

Pratt reported back on the outcome of the presentation and discussion of the BPA opinion at the 33<sup>rd</sup> CEF Plenary meeting in Brussels. She informed the WG members that overall the feedback of the CEF Panel was positive on the use of the weight of evidence (WOE) approach for hazard identification.

During the WG meeting the sections on the opinion dealing with human studies, reproductive toxicity, neurotoxicity, immunotoxicity, toxicokinetics and PBPK modelling were presented, discussed and revised.

New tasks on hazard identification were assigned to the Working Group members and EFSA secretariat.

### **6. Any Other Business (if applicable)**

The experts were informed that Catherine Leclercq, Nathalie Van Gotz, Maria de Fatima Poças and Ralph Pirow had joined the Working Group on Toxicology - Subgroup on risk characterisation

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

The next meetings of the Working Group on Toxicology - Subgroup on risk characterisation are planned for April 8, Amsterdam and May 2-3, Berlin.

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**FIP UNIT**

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 13<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
**Held on 06-08 March 2013, Rome**  
  
**(Agreed on 05 April 2013)**

**Participants**

- **Working Group Experts:**
  - Gemma Calamandrei, Paul Fowler<sup>1</sup>, Peter Greaves<sup>2</sup>, Trine Husøy (Chair), Wim Mennes<sup>3</sup>, Iona Pratt, Henk van Loveren<sup>4</sup> and Detlef Wölfle<sup>5</sup>
- **Hearing Experts:**
  - Andrew Hart (FERA)
  - Emanuela Testai (SCENIHR)
  - Pasquale Mosesso<sup>6</sup>
- **European Commission:**
  - Annette Schaefer
- **EFSA:**
  - FIP Unit: Anna Federica Castoldi, Cristina Croera

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<sup>1</sup> Only on 6<sup>th</sup> (full day) and 7<sup>th</sup> March (till h14.00).

<sup>2</sup> Only on 6<sup>th</sup> and 7<sup>th</sup> March.

<sup>3</sup> Only on 8<sup>th</sup> March.

<sup>4</sup> Only on 6<sup>th</sup> and 7<sup>th</sup> March.

<sup>5</sup> Only on 6<sup>th</sup> and 7<sup>th</sup> March

<sup>6</sup> Only on 7<sup>th</sup> March.

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

The Chair welcomed the participants. Apologies were received from Claire Beausoleil, Anne Lise Brantsaeter and Ursula Gundert-Remy.

## **2. Adoption of agenda**

The agenda was adopted with the following change: the draft opinion section on the immunotoxic effect and carcinogenicity were added as matter of discussion.

## **3. Declarations of interest**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>7</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>8</sup>, EFSA screened the Annual 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 12<sup>th</sup> Working Group meeting held on 15/02/2013 (by Teleconference).**

The minutes of the 12<sup>th</sup> Working Group meeting were agreed by written procedure on 26 02 2013.

## **5. Scientific topic for discussion**

### **4.1 Bisphenol A (EFSA-Q-2012-00423)**

The updated sections of the draft opinion were discussed and some revisions were proposed. Specific drafting tasks were addressed to the WG members for the finalisation of the hazard characterisation of their respective endpoint.

A joint session with the members of the WG on BPA exposure was held. The Chairs of the two WGs provided an update on the status of the work of the two respective parts of the draft opinion and agreed on a future work plan to finalise the risk assessment on BPA which includes the drafting of the risk characterisation, conclusions, recommendations and summary. It was agreed that the WG BPA toxicology will work on the finalisation of the risk assessment and that some experts from the WG BPA exposure, including the chair of this WG, should be invited to become members of the WG on BPA toxicology. The members of the WG on BPA exposure who will be invited to join the WG on BPA toxicology were selected on the basis of their availability, taking care that different areas involved in the exposure assessment are represented, and clearance of their annual declarations of interest by EFSA.

## **6. Next meetings**

The next WG meeting on BPA toxicology will be held in Amsterdam on 04-05 April 2013.

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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/independencerules.pdf>

FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 12<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology –  
Subgroup on Genotoxicity and Epigenetics**  
**Teleconference, 15 02 2013**

**(Agreed on 26 02 2013)**

**Participants**

- **Working Group Experts:**
  - Trine Husøy (chair) and Iona Pratt
- **Hearing Experts:**
  - Wilfried Bursch, Rainer Gürtler, Pasquale Mosesso
- **EFSA:**
  - FIP Unit: Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Riccardo Crebelli and Wim Mennes. The WG members invited to this WG were specifically requested to discuss the Genotoxicity and Epigenetics of BPA.

**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

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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/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 11<sup>th</sup> Working Group meeting held on 11-12 February 2013, Oslo.**

The minutes of the 11<sup>th</sup> Working Group meeting were agreed by written procedure on 26 02 2013.

#### **5. Scientific topic for discussion**

##### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

The Genotoxicity and Epigenetics sections of the draft opinion on BPA were discussed and revisions were introduced. Application of the weight of evidence approach to these sections was discussed.

#### **6. Next meetings**

The next WG meeting on BPA toxicology will be held in Rome, on 6-8<sup>th</sup> March 2013.

FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 11<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
**Held on 11-12 February 2013, Oslo**  
**(Agreed on 26 02 2013)**

**Participants**

- **Working Group Experts:**
  - Claire Beausoleil, Anne Lise Brantsaeter, Gemma Calamandrei<sup>1</sup>, Paul Fowler<sup>2</sup>, Ursula Gundert-Remy, Trine Husøy (chair), Iona Pratt, Henk van Loveren and Detlef Wölflé
- **Hearing Experts:**
  - Andrew Hart (FERA)
- **European Commission:**
- **EFSA:**
  - FIP Unit: Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Peter Greaves and Wim Mennes.

**2. Adoption of agenda**

The agenda was adopted with the following change: the draft opinion section on immunotoxic effects was added as a matter for discussion.

**3. Declarations of interest**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>3</sup> and the Decision of the Executive Director implementing this Policy regarding

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<sup>1</sup> On telephone

<sup>2</sup> From 1pm on 11<sup>th</sup> February.

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

Declarations of Interests<sup>4</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 10<sup>th</sup> Working Group meeting held on 08 02 2013 (by Teleconference).**

The minutes of the 10<sup>th</sup> Working Group meeting were agreed by written procedure on 26 02 2013.

#### **5. Scientific topic for discussion**

##### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

The updated sections of the draft opinion were discussed and some revisions were proposed. In particular, the weight of evidence approach for different toxicological endpoints was discussed; new suggestions were made by all the experts who will test the approach in their respective sections and will provide the updated versions to the EFSA secretariat.

#### **6. Next meetings**

The next WG meeting on BPA toxicology (subgroup on Genotoxicity and Epigenetics), will be held as a conference call on 15<sup>th</sup> February 2013.

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

FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 10<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology –  
Subgroup on Toxicokinetics**  
**Teleconference, 08 02 2013**

**(Agreed on 26 02 2013)**

**Participants**

- **Working Group Experts:**
  - Claire Beausoleil, Gemma Calamandrei, Paul Fowler, Ursula Gundert-Remy, Trine Husøy (chair), Wim Mennes, Iona Pratt and Detlef Wölflé
- **Hearing Experts:**
  - Catherine Leclercq, Emanuela Testai (SCENIHR)
- **EFSA:**
  - FIP Unit: Anna F. Castoldi, Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants. The WG members invited to this WG were specifically requested to discuss the toxicokinetics of BPA and on the integration via various routes into a composite exposure estimate (either internal or external).

**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

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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/independencerules.pdf>



interests related to the issues discussed in this meeting have been identified during the screening process.

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

#### **4. Agreement of the minutes of the 9<sup>th</sup> Working Group meeting held on 16/01/2013, in Parma.**

The minutes of the 9<sup>th</sup> Working Group meeting were agreed by written procedure on 26/02/2013.

#### **5. Scientific topic for discussion**

##### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

A specific discussion whether and how exposures via various routes (oral, dermal and inhalation) should be integrated into a composite exposure estimate (either internal or external), which can be used for the risk assessment of BPA, was held. A table with conversion factors for total exposure to BPA will be prepared by the experts.

#### **6. Next meetings**

The next WG meeting on BPA toxicology will be held in Oslo, on 11<sup>th</sup>-12<sup>th</sup> February 2013.

## **Annex II**

### **Interests and actions resulting from the oral declarations of interests done at the beginning of the meeting**

With regard to this meeting, Dr. Ursula Gundert-Remy declared the following interest: she is a co-author of a paper presenting the results of a PBPK modelling study on Bisphenol A in human plasma, which has been accepted for publication.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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.

FIP UNIT

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

**Minutes of the 9<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology- “Drafting  
subgroup”**

**Held on 16 01 2013, Parma**

**(Agreed on 26 02 2012)**

**Participants**

- **Working Group Experts:**
  - Trine Husøy (Chair), Wim Mennes, Iona Pratt
- **Hearing Experts:**
- **European Commission:**
- **EFSA:**
  - FIP Unit: Anna F. Castoldi, Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants. The WG members invited to this WG were specifically requested to “draft parts of the opinions”.

**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.

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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/independencerules.pdf>

#### **4. Agreement of the minutes of the 8<sup>th</sup> Working Group meeting held on 14-15/01/2013, in Parma.**

The minutes of the 8<sup>th</sup> Working Group meeting were agreed by written procedure on 28 02 2012.

#### **5. Scientific topic for discussion**

##### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

The strategy to apply for writing the risk characterization section was discussed. Some sections of the Appendix 1 and 2 of the draft opinion were checked, compared, discussed and re-drafted.

#### **6. Next meetings**

The next WG meeting on BPA toxicology (subgroup on Toxicokinetics) will be held as a conference call, on 8<sup>th</sup> February 2013.

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FIP UNIT

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings  
and Processing Aids**  
**Minutes of the 8<sup>th</sup> meeting of the Working Group on Bisphenol A Toxicology**  
**Held on 14-15 01 2013, Parma**  
**(Agreed on 26 02 2012)**

**Participants**

- **Working Group Experts:**
  - Claire Beausoleil, Anne Lise Brantsaeter, Gemma Calamandrei, Paul Fowler, Ursula Gundert-Remy, Trine Husøy (chair), Wim Mennes, Iona Pratt, Henk van Loveren and Detlef Wölflle
- **Hearing Experts:**
- **European Commission:**
  - Annette Schaefer
- **EFSA:**
  - FIP Unit: Anna F. Castoldi, Cristina Croera

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Peter Greaves.

**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

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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/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 7<sup>th</sup> Working Group meeting held on 18-19/12/2012, in Oslo.**

The minutes of the 7<sup>th</sup> Working Group meeting were agreed by written procedure on 21/12/2012.

#### **5. Scientific topic for discussion**

##### **5.1 Bisphenol A (EFSA-Q-2012-00423)**

The text of the draft opinion was discussed and changes were proposed. The experts will provide revised versions of their respective sections to EFSA secretariat.

The weight of evidence approach was further discussed. Additional suggestions were made by all the experts, who will now test the approach in their respective sections.

The members of the WGs on BPA exposure and toxicology joined for a common session in which their respective parts of the draft opinion were presented by the 2 WGs' Chairs.

#### **6. Next meetings**

The next WG meeting on BPA toxicology (subgroup on Toxicokinetics), will be held as a conference call on 8<sup>th</sup> February 2013.

**FIP UNIT**

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

**Minutes of the 7<sup>th</sup> meeting of the Working Group (WG) on Bisphenol A Toxicology**

**Held on 18-19 December 2012, Oslo**

**(Agreed on 21 January 2013)**

**Participants**

- **Working Group Experts:**
  - Claire Beausoleil, Anne Lise Brantsaeter, Paul Fowler, Trine Husøy (chair), Wim Mennes, Iona Pratt and Henk van Loveren
- **Hearing Experts:**
  - Andrew Hart (FERA)
- **EFSA:**
  - FIP Unit: Anna F. Castoldi, Cristina Croera

**1. Welcome and apologies for absense**

The Chair welcomed the participants. Apologies were received from Gemma Calamandrei, Peter Greaves, Ursula Gundert-Remy and Detlef Wölfle.

**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

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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/independencerules.pdf>

during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

**4. Agreement of the minutes of the 6<sup>th</sup> Working Group meeting held on 28-30/11/2012, Rome.**

**5. Discussions**

The text of the draft opinion was discussed and changes were proposed. The experts will provide revised versions of their respective sections to EFSA secretariat and a revised version of the opinion will be prepared accordingly.

A presentation on the approaches used to deal with uncertainties in hazard characterization was given by Andrew Hart.

**6. Next meeting date**

The next WG meeting will be held on 14-15 January 2013 in Parma.



FIP UNIT

Parma, 07 January 2013

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

**Minutes of the 6<sup>th</sup> meeting of the Working Group (WG) on Bisphenol A Toxicology**

**Rome, 28-30 November 2012**

**EFSA / FIP Unit**

**Agreed by the WG on 18 December 2012**

**Participants**

WG Experts	Claire Beausoleil, Anne Lise Brantsaeter, Gemma Calamandrei, Paul Fowler <sup>1</sup> , Peter Greaves, Ursula Gundert-Remy, Trine Husøy (chair), Wim Mennes, Iona Pratt and Henk van Loveren
Hearing Experts	Catherine Leclercq, Ralph Pirow <sup>2</sup>
Observers	Kirsi Myohanen (ECHA), Emanuela Testai (SCENIHR)
EFSA	Anna F. Castoldi, Cristina Croera

**1. Welcome and apologies**

The Chair welcomed the participants. Apologies were received from Detlef Wölflé.

**2. Adoption of agenda**

The agenda was adopted without changes.

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) 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. Feedback from scientific events /info of interest to the WG BPA tox**

Dr Pratt provided a summary of the outcome of the national experts meeting on BPA held at EFSA on 29-30 October 2012.

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<sup>1</sup> Present from 29<sup>th</sup> November

<sup>2</sup> On the phone from 14.00 to 15.00 on 28<sup>th</sup> November

## **5. Discussion of the structure of the opinion**

The texts of some paragraphs of the draft opinion were discussed and changes were proposed. The experts will provide revised versions of their respective sections to EFSA secretariat and a revised version of the opinion will be prepared accordingly.

## **6. Next meeting dates**

The next WG meeting will be held on 18-19 December 2012 in Oslo.

Parma, 03<sup>rd</sup> December 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 (WG) on Bisphenol A Toxicology  
Held in Søborg, Denmark, and via Teleconference, 26<sup>th</sup> October 2012  
EFSA / FIP Unit**

**Agreed by the WG on 12 December 2012**

**Participants**

WG Experts	Mona-Lise Binderup, Wilfried Bursch, Angelo Carere, Rainer Gürtler (Chair), Trine Husoy, Daniel Marzin <sup>1</sup> , Wim Mennes, Pasquale Mosesso
Hearing Experts	Karin Kristiane Nørby
Observers	-
EFSA	Cristina Croera <sup>1</sup> , Maria Carfi <sup>1</sup>

**1. Welcome and apologies**

The Chair welcomed the participants. Apologies were received from Riccardo Crebelli and Iona Pratt. The following experts in the area of genotoxicity were specifically appointed for this ad-hoc working group meeting, dealing with BPA genotoxicity: Rainer Gürtler (who chaired this specific WG, being the chair of the genotoxicity WG), Mona-Lise Binderup, Wilfried Bursch, Angelo Carere, Daniel Marzin and Pasquale Mosesso.

**2. Adoption of agenda**

The agenda was adopted, without changes.

**3. Declarations of interest**

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

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<sup>1</sup> Participated in parts of the meeting via teleconference.

#### **4. Discussions**

The studies on BPA genotoxicity were discussed by the experts. Suggestions for modifications of the text for the draft opinion were made and a new version will be prepared.

#### **5. Next meeting dates**

The next WG meeting on BPA toxicology will be held on 28-30 November 2012 in Rome.

FIP UNIT

Parma, 05 October 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 (WG) on Bisphenol A Toxicology  
Teleconference, 05 October 2012  
EFSA / FIP Unit**

**Agreed by the WG on 8 October 2012**

**Participants**

WG Experts	Peter Greaves, Trine Husøy (chair), Iona Pratt
Hearing Experts	-
Observers	-
EFSA	Anna F. Castoldi, Cristina Croera

**1. Welcome and apologies**

The Chair welcomed the participants. Apologies were received from Wim Mennes.

**2. Adoption of agenda**

The agenda was adopted, adding in AOB to fix the deadline for submitting the revised text to the whole WG members.

**3. Declarations of interest**

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

The structure of the main text in the draft opinion, and of appendices 1 and 2 were discussed for the carcinogenicity section and changes were proposed. The experts will provide written comments to the EFSA secretariat and a revised version will be prepared accordingly.

## 5. **Next meeting dates**

The next WG meeting will be held on 26 October 2012 in Copenhagen.

FIP UNIT

Parma, 24 September 2012

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

**Minutes of the 3<sup>rd</sup> meeting of the Working Group (WG) on Bisphenol A Toxicology  
Amsterdam, 17-18 September 2012  
EFSA / FIP Unit**

**Agreed by the WG on 24 September 2012**

**Participants**

WG Experts	Claire Beausoleil, Anne Lise Brantsaeter, Gemma Calamandrei <sup>1</sup> , Paul Fowler, Peter Greaves, Ursula Gundert-Remy, Trine Husøy (chair), Wim Mennes, Iona Pratt <sup>2</sup> , Henk van Loveren and Detlef Wölfle
Hearing Experts	-
Observers	-
EFSA	Anna F. Castoldi, Cristina Croera

**1. Welcome and apologies**

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 Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) and 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.

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<sup>1</sup> On the phone from 14.00-15.00 on 18<sup>th</sup> September 2012

<sup>2</sup> Only present on 17<sup>th</sup> September 2012.

#### **4. Discussions**

The structure of the opinion and the contributions from the experts were discussed and updated. New articles to be reviewed were assigned to the WG members. Individual tasks, including revisions of the draft opinion, and deadlines were defined.

The members of the WG on BPA Toxicology and of the WG on BPA Exposure met for a joint session of one hour to discuss common topics and the future work program.

#### **5. Next meeting dates**

The next WG meeting will be held on 28-30 November 2012 in Rome.



Parma, 05 July 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 (WG) on Bisphenol A Toxicology  
Amsterdam, 26 June 2012  
EFSA / FIP Unit**

**Agreed by the WG on 12 July 2012**

**Participants**

WG Experts	Claire Beausoleil, Anne Lise Brantsaeter, Gemma Calamandrei, Paul Fowler, Peter Greaves, Ursula Gundert-Remy, Trine Husøy (Chair), Wim Mennes, Iona Pratt, Henk van Loveren and Detlef Wölflé
Hearing Experts	-
Observers	-
EFSA	Anna F. Castoldi, Cristina Croera

**1. Welcome and apologies**

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 Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) 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. Discussions**

The structure and the table of content of the opinion were discussed and updated. The criteria to be used for study inclusion/exclusion from the new risk assessment opinion were defined.

New individual tasks and deadlines were assigned to the WG members. In particular, a selection of the articles not yet evaluated was made and rapporteurs and co-rapporteurs were defined for each article.

#### **5. Next meeting dates**

The next WG meeting will be held on 17-18 September 2012 in Amsterdam.

Parma, 18<sup>th</sup> May 2012

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

**Minutes of the 1<sup>st</sup> meeting of the Working Group (WG) on BPA Toxicology  
Oslo, 2<sup>nd</sup> May 2012  
EFSA / FIP Unit**

**Agreed by the WG on 5<sup>th</sup> June 2012**

**Participants**

WG Experts	Claire Beausoleil <sup>1</sup> , Anne Lise Brantsaeter, Gemma Calamandrei <sup>2</sup> , Ursula Gundert-Remy, Trine Husøy (Chair), Wim Mennes, Iona Pratt, Henk van Loveren and Detlef Woelfle
Hearing Experts	-
Observers	-
EFSA	Anna F. Castoldi

**1. Welcome and apologies**

The Chair welcomed the participants. All the participants introduced themselves and presented their scientific background. Apologies were received from Peter Greaves and Annette Schaefer (EC).

**2. Adoption of agenda**

The agenda was adopted without changes.

**3. Declarations of interest**

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

The Chair of the WG introduced the self mandate on BPA, consisting of a full risk assessment of BPA which will be carried out by two WGs in parallel, the WG BPA Tox

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<sup>1</sup> Joined by telephone from 2.00 to 4.00 pm

<sup>2</sup> Joined by telephone from 2.00 to 3.30 pm

and the WG BPA exposure. Once BPA hazard characterization and exposure assessments are finalized by the two WGs independently, the WGs will jointly perform the risk characterization and draw the conclusions. The overall deadline of the opinion is 31 May 2013.

The discussion partly focussed on the criteria to be used for study inclusion in the new risk assessment opinion. Also the draft structure of the opinion was discussed and individual tasks and deadlines were assigned to the WG members.

## **5. Next meeting date**

The next WG meeting was planned for the 26<sup>th</sup> June 2012.