

**ASSESSMENT METHODOLOGY UNIT**

Parma, 14- 15 June 2010

**ASSESSMENT METHODOLOGY UNIT**

**Draft Minutes of the 7th meeting of the EFSA ESCO Working Group on Isoflavones**

**Parma, 14 and 15 June 2010**

**(adopted by the WG on 30<sup>th</sup> July 2010 )**

**Participants**

WG Experts: Julius Brtko (JB), Maria Campos (MC), Aedin Cassidy (AC), Marina Heinonen (MH), Peter Hollman (PH), Angel Gil-Izquierdo (AGI), Josef Köhrle (JK), Alfonso Lampen (AL), Irène Margaritis (IM), José Luis Penalvo (JLP), Ruth Travis (RT), Claudine Manach (CM), Otto Meyer (OM)

Expert via telephone: Günter Vollmer (GV)

Contractor (S-IN): Arianna Bassan (AB), Lorenza Broccardo (LB)

EFSA: Eugen Christoph (EC), Miriam Jacobs (MJ) (Chair), Eleni Pantiora (EP), Liisa Valsta (LV), Didier Verloo (DV)

**1. WELCOME AND APOLOGIES**

The Chair welcomed the participants. Apologies were given for Günter Vollmer (GV) who was not able to be physically present in the meeting. Instead, GV's participation to the WG meeting was established on the 15<sup>th</sup> June via teleconference.

**2. ADOPTION OF AGENDA**

The agenda was adopted with minor amendments.

**3. DECLARATIONS OF INTEREST**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) previously completed 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 were declared at the beginning of this meeting.

No other additional interests were added to those already declared by the participants in their annual and special declarations of interests.

**4. APPROVAL OF THE MINUTES**

The minutes from the 6th meeting, were agreed.

**5. GENERAL DISCUSSIONS AND ISSUES**

- Update and discussion of sub-group activities and draft chapters (ALL).
- S-IN's presentation on *'Retrieval, collation and entry of isoflavone data in an excel-spreadsheet and access database created by the contractor'* (AB, LB).
- Presentation on the *'INCA 2'* AFSSA project (IM).

**6. NEXT MEETING DATES:**

- Soy Infant Formula sub-group meeting: 17th- 18th September 2010, Parma, Italy
- 8th WG meeting: 5th-7th October 2010, Parma, Italy

**7. CLOSE OF MEETING**

The meeting was adjourned at 6pm, on the 15 June 2010.

22-23 April 2010

**ASSESSMENT METHODOLOGY UNIT**

**Draft Minutes of the 6th meeting of the EFSA ESCO Working Group on Isoflavones**

**22 and 23 April 2010- held as tele and web conference**

**(adopted by the WG on 14 June 2010)**

**Participants**

WG Experts: Julius Brtko (JB), Maria Campos (MC), Angel Gil-Izquierdo (AGI), Josef Köhrle (JK), Alfonso Lampen (AL), Irène Margaritis (IM), Claudine Manach (CM), Otto Meyer (OM), Günter Vollmer (GV).

Contractor (S-IN): Filippo Magnaguagno (FM), Lorenza Broccardo (LB).

EFSA: Eugen Christoph (EC), Miriam Jacobs (MJ) (Chair), Eleni Pantiora (EP), Liisa Valsta (LV).

**1. MEETING ADJUSTMENT AND APOLOGIES**

Special apologies were given to the WG, as due to the difficult flight situation caused by the volcanic eruption in Iceland, (which took place on the 14<sup>th</sup> April 2010), the WG meeting planned to take place on Thursday 22 to Friday 23 April 2010, in Parma was cancelled.

Instead the 6<sup>th</sup> meeting took place as a series of web conferences during the same dates.

Aedin Cassidy, Jose Penalvo, Peter Hollman, Ruth Travis, Marina Heinonen gave their apologies and did not participate in this meeting.

**2. ADOPTION OF AGENDA**

The draft agenda was adapted to accommodate the separate sub-working teleconferences.

Two separate teleconferences were held on the morning of 22 April:

- Group 3/4 working on in vivo and in vitro data: JB, JK, AL, IM, CM, OM, GV, MJ, EP
- Interactions table for Group 5: MC, AGI, EC, MJ

**3. DECLARATION OF INTEREST**

In accordance with EFSA's Policy on Declaration of Interest, EFSA screened the Annual Declaration of Interest (ADoI) previously completed 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 were declared at the beginning of this meeting.

No other additional interests were added to those already declared by the participants in their annual and special Declaration of Interest.

#### **4. APPROVAL OF THE MINUTES**

The minutes from the 5th meeting were agreed.

#### **5. GENERAL DISCUSSIONS AND PROGRAMME OF WORK**

- Group 3/4: review and agreement on the Mode of Action tables.
- Interactions table for Group 5: progress in compiling the isoflavones interaction table.
- S-IN presentation: briefing on the database project's progress.

#### **6. NEXT MEETING DATES:**

7<sup>th</sup> meeting: 14- 15 June 2010, Parma, Italy.

#### **7. CLOSE OF MEETING**

The group 3/4 web conference was adjourned on Friday 23rd April 2010, at 12pm.

The sub- group 5 web conference was adjourned on Thursday 22nd April 2010, at 6pm.

**ASSESSMENT METHODOLOGY UNIT**

Parma, 18-19 February 2010

**ASSESSMENT METHODOLOGY UNIT**

**Draft Minutes of the 5th meeting of the EFSA ESCO Working Group on Isoflavones**

**Parma, 18 and 19 February 2010**

**(adopted by the WG on 16 March 2010)**

**Participants**

WG Experts: Julius Brtko (JB), Maria Campos (MC), Aedin Cassidy (AC), Marina Heinonen (MH), Peter Hollman (PH), Angel Gil-Izquierdo (AGI), Josef Köhrle (JK), Alfonso Lampen (AL), Irène Margaritis (IM), José Luis Penalvo (JLP), Ruth Travis (RT), Claudine Manach (CM), Otto Meyer (OM)

Hearing Expert: Kristina Thayer (KT)

Contractor (S-IN): Arianna Bassan (AB), Lorenza Broccardo (LB)

EFSA: Eugen Christoph (EC), Miriam Jacobs (MJ) (Chair), Eleni Pantiora (EP), Liisa Valsta (LV), Didier Verloo (DV)

**1. WELCOME AND APOLOGIES**

The Chair welcomed the participants. Apologies were given for Günter Vollmer (GV) who was not able to be present in the meeting. Special apologies were given for KT. Her participation was instead established as web conferencing presentation- discussion. Additional apologies were given for Sari Mäkelä.

**2. ADOPTION OF AGENDA**

The agenda was adopted with minor amendments.

**3. DECLARATIONS OF INTEREST**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) previously completed 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 were declared at the beginning of this meeting.

No other additional interests were added to those already declared by the participants in their annual and special declarations of interests.

**4. APPROVAL OF THE MINUTES**

The minutes from the 4th meeting, were agreed.

**5. GENERAL DISCUSSIONS AND ISSUES**

- Update and discussion of sub-group activities and draft chapters (ALL).
- Web conference presentation on conclusions of the “NTP soy infant formulae expert group, December 2009” (KT).
- Presentation on the “PHENOL-EXPLORER” database (CM).
- S-IN’s presentation on the updated workplan: Retrieval, collation and entry of isoflavone data in an excel-spreadsheet and access database created by the contractor (AB, LB).

**6. NEXT MEETING DATES:**

6th meeting: 22-23 April 2010, Parma, Italy.

**7. CLOSE OF MEETING**

The meeting was adjourned at 5pm, on the 19 February 2010.

**ASSESSMENT METHODOLOGY UNIT**

Parma, 18-19 February 2010

**ASSESSMENT METHODOLOGY UNIT**

**Draft Minutes of the 4th meeting of the EFSA ESCO Working Group on Isoflavones**

**Parma, 12 and 13 November 2009**

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

**Participants**

WG Experts: Julius Brtko (JB), Maria Campos (MC), Aedin Cassidy (AC), Marina Heinonen (MH), Peter Hollman (PH), Angel Gil-Izquierdo (AGI), Josef Köhrle (JK), Alfonso Lampen (AL), Irène Margaritis (IM), José Luis Penalvo (JLP), Ruth Travis (RT), Günter Vollmer (GV).

EFSA: Eugen Christoph (EC), Miriam Jacobs (MJ) (Chair), Aisling Naughton (AN), Eleni Pantiora (EP), Didier Verloo (DV).

**1. WELCOME AND APOLOGIES**

The Chair welcomed the participants.

**2. ADOPTION OF AGENDA**

The agenda was adopted without changes.

**3. DECLARATIONS OF INTEREST**

No other additional interests were added to those already declared by the participants in their annual and special declarations of interests.

**4. APPROVAL OF THE MINUTES**

The minutes of the 3<sup>rd</sup> meeting were discussed and approved after a few amendments.

**5. GENERAL DISCUSSIONS AND ISSUES**

- Extension of the final deadline was discussed and later agreed by the mandate review committee to be extended to the end of December 2010.
- Two new WG members (Claudine Manach and Otto A. Meyer) were recruited to the WG and they will attend the 5<sup>th</sup> WG meeting.

- Preliminary chapter drafts are being prepared by the subgroups incorporating recent literature research.

**6. NEXT MEETING DATES:**

5th meeting: 18-19 February 2010, Parma, Italy

**7. CLOSE OF MEETING**

The meeting was adjourned at 3.30pm, on the 13 November 2009.



**ASSESSMENT METHODOLOGY UNIT**

Parma, 12-13 November 2009

**ASSESSMENT METHODOLOGY UNIT**

**Draft Minutes of the 3<sup>rd</sup> meeting of the EFSA ESCO Working Group on Isoflavones**

**Parma, 15, 16, 17 and 18 September 2009**

**(adopted by the WG on 12 November 2009)**

**Participants**

WG Experts: Julius Brtko (JB), Maria Campos (MC), Aedin Cassidy (AC), Marina Heinonen (MH), Peter Hollman (PH), Klaus Richter (KR), Angel Gil-Izquierdo (AGI), Josef Köhrle (JK), Irène Margaritis (IM), José Luis Penalvo (JLP), Ruth Travis (RT), Günter Vollmer (GV).

EFSA: Eugen Christoph (EC), Miriam Jacobs (MJ) (Chair).

**1. WELCOME AND APOLOGIES**

The Chair welcomed the participants.

**2. ADOPTION OF AGENDA**

The agenda was adopted without changes.

**3. DECLARATIONS OF INTEREST**

No other additional interests were added to those already declared by the participants in their annual and special declarations of interests.

**4. APPROVAL OF THE MINUTES**

The minutes from the 2nd meeting were agreed. .

**5. GENERAL DISCUSSIONS AND ISSUES**

Satellite meetings of the 5 subgroups for the different topic areas of the mandate were held on 15-17 September 2009, with the main meeting on 17-18 September 2009.

For each subgroup a lead and co-lead were nominated to present to the main meeting and lead drafting of the initial chapters for subsequent meetings discussions. It was agreed that the group leading chapter 5, concerning human data from epidemiological and clinical trials would direct and prioritise the work of the other chapters.

The isoflavones database specific call for tender was discussed as an aid to the work of the group and the group collectively developed draft criteria for the call for tender criteria as well as industry input on composition of products entering the European market.

The status-quo of abstract review of each subgroup was ascertained and second and arbitrator reviews of abstracts were completed where necessary. All groups completed the abstract reviews during the meeting and agreed all key papers and papers to go for further review.

Due to the heavy workload, the WG requested an extension for the submission for the final report, and also continued dedicated scientific and clerical support from EFSA. The Steering Group on Cooperation and the mandate review committee provisionally agreed on the extension of the report to December 2010.

### **Presentations**

- AC gave an update from the US Isoflavones NIH research meeting held in July 2009.
- Daniel Doerge from the US FDA discussed published and unpublished data re: thyroid endpoints and isoflavones.
- IM gave an overview of three AFSSA opinions on isoflavones

### **6. NEXT MEETING DATES:**

4<sup>th</sup> meeting: 12-13 November, 2009 Parma, Italy and 5<sup>th</sup> meeting: 18-19 February 2010, Parma, Italy

### **7. CLOSE OF MEETING**

The meeting was adjourned at 5pm, on the 18 September 2009.

Parma, 13-15 July 2009

**Minutes of the 2<sup>nd</sup> meeting of the EFSA ESCO Working Group on Isoflavones by a series of five teleconference calls**

**Parma, 13-15 July 2009**

**(adopted by the WG on 16 September 2009)**

**Participants**

WG Experts: Julius Brtko (JB), Aedin Cassidy (AC), Angel Gil-Izquierdo (AGI), Josef Köhrle (JK), Sari Mäkelä (SM), José Luis Penalvo (JLP), Ruth Travis (RT), Ilona Kryspin Sørensen (IKS), Marina Heinonen (MH);

EFSA: Miriam Jacobs (MJ) (Chair), Eugen Christoph (EC), (Co-Chair group 1).

**1. Welcome and apologies**

The Chair welcomed the participants. A new member, IKS was welcomed to the group and also MH, who had been unable to attend the first meeting.

Apologies were received from Olle Söder, Peter Hollman, Günter Vollmer.

Maria Campos (MC) was available to join the agreed teleconference, but several attempts by EFSA to call the number provided by MC, at the time agreed, were unsuccessful. The Chair welcomed the participants. Apologies were received from Marina Heinonen.

**2. Adoption of agenda**

The agendas were structured similarly for each of the five sub group teleconferences and were 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.

**4. Discussions**

- Approval of the minutes
- MJ introduced IKS, who has been recruited to the WG to provide expertise on mammary gland density. Her contribution to the WG will be predominantly in this area. IKS gave an overview of her work and the risk assessment implications with respect to isoflavone consumption and breast cancer risk

- Discussion of the problems with the applied search strings and related updates
- Treatment of abstracts
- Evaluation criteria for full papers
- Eurofir database access
- Group specific discussions
- Next meeting date: 15-18 September 2009, Parma, Italy

Parma, 11 and 12 May 2009

ASSESSMENT METHODOLOGY UNIT

**Minutes of the 1<sup>st</sup> meeting of the EFSA ESCO Working Group on Isoflavones**

**Parma, 11 and 12 May 2009**

**(adopted by the WG on 29 May 2009)**

**Participants**

WG Experts: Julius Brtko, Maria Campos, Aedin Cassidy, Peter Hollman, Klaus Richter, Angel Gil-Izquierdo, Josef Köhrle, Sari Mäkelä, Irène Margaritis, José Luis Penalvo, Ruth Travis, Günther Vollmer.

EFSA: Elisa Aiassa (first day), Andrea Altieri (first day), Davide Arcella (first day), Eugen Christoph, Miriam Jacobs (Chair).

**1. Welcome and apologies**

The Chair welcomed the participants. Apologies were received from Marina Heinonen.

**2. Adoption of agenda**

The agenda was adopted without changes.

**3. Declarations of interest**

No other additional interests were added to those already declared by the participants in their annual and special declarations of interests.

**4. Discussions**

- Presentation of the isoflavones ESCO WG mandate, its interpretation, the timeline, deliverables and the remit for the working group members.
- Assigning WG members to subgroups for the different topic areas of the mandate.
- Consumption data for infants fed infant formula, application for soy infant formula fed babies.
- Systematic review.
- EuroFir Database.
- Mode of Action risk assessment methodology.
- Search strings for bibliographic research, EndNote Web and Science Net.
- Organizing the chapters. Additional experts to assist the subgroups proposed.
- Planning next meetings.