

SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

## Scientific Committee

### Minutes of the 4<sup>th</sup> meeting of the Standing Working Group on Guidance Review

**Held on 6-7 October 2016, Parma (Italy)  
(Agreed on 11 December 2016)**

#### **Participants**

- **Working Group Members:**

Tony Hardy  
Vittorio Silano  
Theo Brock  
Claude Lambré  
Sirpa Kärenlampi  
Andrew Chesson  
Michael Jeger  
Diane Benford  
Josef Schlatter participated on 7 October

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

Not Applicable

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

Not Applicable

- **EFSA:**

Scientific Committee and Emerging Risks Unit: Tilemachos Goumperis, Daniela Maurici, Dimitrios Spyropoulos

Executive Director Office: Juliane Kleiner

Assessment Methodological Support Unit: Elisa Aiassa and Olaf Mosbach-Schulz participated in agenda item 5.3

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

- **Others:**

Not Applicable

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

The Chair welcomed the participants.

Apologies were received from Yolanda Sanz and Andrew Chesson.

## **2. Adoption of agenda**

The agenda was adopted without changes.

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

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

## **4. Agreement of the minutes of the 3<sup>rd</sup> Standing Working Group meeting held on 31 May-1 June 2016, Parma**

The minutes of the 3<sup>rd</sup> meeting of the Standing Working Group held on 31 May-1 June 2016 were agreed<sup>4</sup>.

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

### **5.1. Draft scientific opinion on motivations, criteria and procedures to update and re-open EFSA scientific assessments**

A first reading of the draft scientific opinion took place in the Scientific Committee (SC) Plenary in September 2016. The group discussed the comments received from the SC and amended the document accordingly. In particular, a list of criteria was produced that will be incorporated into the document.

A time plan was agreed with a view to prepare a new draft by 3 November 2016 that will be tabled for discussion and possible endorsement in the SC Plenary on 16 November 2016.

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

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

<sup>4</sup> <http://www.efsa.europa.eu/sites/default/files/wggguidancereview.pdf>

## **5.2. Guidance development and guidance lifecycle in ECHA and EMA (for information)**

EFSA presented the processes the European Chemical Agency (ECHA) and European Medicines Agency (EMA) have in place for guidance development and guidance lifecycle.

By benchmarking from ECHA and EMA processes and complementing what is already ongoing in the SWG on guidance review, a step forward would be to develop a procedure in EFSA for guidance development.

The SWG welcomed the idea of EFSA developing such a procedure.

## **5.3. Discussion on the ToR point: Review existing EFSA cross-cutting guidance documents**

The group continued reviewing the list of the 23 cross-cutting guidance documents listed in Appendix A of the Opinion published in 2015<sup>5</sup> to confirm whether they are in use and scientifically up to date or need revision.

## **5.4. Discussion on the ToR point: Develop a plan for and assist in the implementation and use of the cross-cutting EFSA guidance documents across EFSA**

The Scientific Committee and Emerging Risks unit briefed the SWG on the discussion with other EFSA units or teams on how to promote implementation and use of cross-cutting guidance documents.

Based on the feedback received, the Scientific Committee and Emerging Risks unit will organise a number of pilot trainings early 2017.

The SWG was supportive of the approach with a view to have a plan for the Panel renewal in 2018.

## **6. Any Other Business**

Not Applicable.

## **7. Next meeting**

The next meeting will take place beginning of 2017. The exact day will be decided in due time based on the progress on the draft opinion on updating scientific assessments and other matters arising.

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<sup>5</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/4080>

SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

## Scientific Committee

### Minutes of the 3<sup>rd</sup> meeting of the Standing Working Group on Guidance Review

**Held on 31 May-1 June 2016, Parma (Italy)  
(Agreed on 6 October 2016)**

#### **Participants**

- **Working Group Members:**

Diane Benford  
Tony Hardy participated by teleconference  
Vittorio Silano,  
Theo Brock,  
Claude Lambré,  
Sirpa Kärenlampi  
Michael Jeger

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

Not Applicable

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

Not Applicable

- **EFSA:**

Scientific Committee and Emerging Risks Unit: Tilemachos Goumperis,  
Daniela Maurici, Dimitrios Spyropoulos and Lesley Koschel  
Advisory Forum and Scientific Cooperation Unit: Djien Liem  
Assessment Methodological Support Unit: Elisa Aiassa  
Food Ingredients and Packaging Unit: Magdalena Andryszkiewicz

- **Others:**

Not Applicable

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

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

The Chair welcomed the participants.

Apologies were received from Yolanda Sanz, Andrew Chesson and Josef Schlatter.

## **2. Adoption of agenda**

The agenda was adopted without changes.

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

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

## **4. Agreement of the minutes of the 2nd Standing Working Group meeting held on 22-23 March 2016, Parma**

The minutes of the 2<sup>nd</sup> meeting of the Standing Working Group held on 22-23 March 2016 were agreed<sup>4</sup>.

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

### **5.1. Criteria to update a scientific assessment/guidance when new information becomes available**

The Standing Working Group discussed the criteria and agreed on a time plan to prepare a draft document that will be tabled for discussion in the Scientific Committee Plenary in September 2016.

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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/independencerules2014.pdf>

<sup>4</sup> <http://www.efsa.europa.eu/sites/default/files/wgguidancereview.pdf>

## **5.2. Draft EFSA Standard Operating Procedure on review of guidance documents**

The group discussed the draft EFSA Standard Operating Procedure (SOP) on review and revision of guidance documents and provided proposals for improvement.

The SOP was based on the 2015 Scientific Opinion of the SC on guidance on the review, revision and development of EFSA's cross-cutting guidance documents<sup>5</sup>.

## **5.3. Discussion on the ToR point: Review existing EFSA cross-cutting guidance documents**

The group reviewed the list of the 23 cross-cutting guidance documents listed in Appendix A of the Opinion published in 2015<sup>5</sup> to confirm whether they are in use and scientifically up to date or need revision.

This discussion will continue at the next meeting of the group.

## **5.4. Discussion on the ToR point: Develop a plan for and assist in the implementation and use of the cross-cutting EFSA guidance documents across EFSA**

The group discussed developing an implementation plan that would assist the communication, dissemination and uptake of cross-cutting guidance by Panels and units across EFSA's domains.

At the moment, relevant ongoing activities include outsourced training organised for experts and staff for some guidance documents. Also, during the induction training for new Panels, guidance documents are presented.

Further discussion of this item will take place at the next meeting of the group.

## **6. Any Other Business**

Not Applicable

## **7. Next meeting**

The next meeting will take place on 6-7 October 2016.

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<sup>5</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/4080>

SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

## Scientific Committee

### Minutes of the 2<sup>nd</sup> meeting of the Standing Working Group on Guidance Review

**Held on 22-23 March 2016, Parma (Italy)  
(Agreed on 31 May 2016)**

#### **Participants**

- **Working Group Members:**

Tony Hardy

Josef Schlatter

Vittorio Silano

Theo Brock

Claude Lambré

Sirpa Kärenlampi

Andrew Chesson

Yolanda Sanz participated on 22 March

Michael Jeger participated by teleconference on 22 March

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

Not Applicable

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

Not Applicable

- **EFSA:**

Scientific Committee and Emerging Risks Unit: Tilemachos Goumperis, Daniela Maurici, Dimitrios Spyropoulos

Advisory Forum and Scientific Cooperation Unit: Djien Liem

Assessment Methodological Support Unit: Elisa Aiassa participated in agenda item 4.3

Food Ingredients and Packaging Unit: Magdalena Andryszkiewicz participated in agenda item 4.4

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

- **Others:**

Not Applicable

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

The Chair welcomed the participants.

Apologies were received from Diane Benford.

## **2. Adoption of agenda**

The agenda was adopted without changes.

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

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

## **4. Scientific topics for discussion**

### **4.1. Fine-tune the Terms of Reference of the Standing Working Group**

The Standing Working Group discussed its mandate and fine-tuned it as follows.

The broad objectives of the Standing Working Group on Guidance Review are:

- To provide recommendations and to propose priorities for the preparation of new EFSA cross-cutting guidance documents produced or endorsed by the Scientific Committee;
- To review existing EFSA cross-cutting guidance documents to confirm whether they are relevant and scientifically up to date, and to identify whether revision or replacement guidance should be developed;
- To develop a plan for and to assist in the implementation and use of the above mentioned EFSA guidance documents across EFSA;

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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/independencerules2014.pdf>



- To assist in the development of advanced scientific training programs in cross-cutting scientific issues/guidance documents for experts of the Scientific Committee, Panels and EFSA Scientific Units.

Specifically the Standing Working Group is asked to propose:

- Priority topics for the development of risk assessment guidance by the Scientific Committee in 2016-2018;
- Criteria to update a scientific assessment/guidance when new information becomes available.

The Scientific Opinion on priority topics (point 4.2 below) addresses the first specific request.

#### **4.2. Scientific opinion on priorities of the SC for guidance development in 2016-2018<sup>4</sup>**

The Standing Working Group prepared a draft of the scientific opinion on priorities of the Scientific Committee for guidance development in 2016-2018. The draft will be tabled for discussion and possible adoption in the Scientific Committee Plenary on 20-21 April.

#### **4.3. Preliminary feedback from Prometheus survey (deliverable 2) including discussion**

Preliminary results of Prometheus project survey were presented, in particular related to the needs for new guidance.

#### **4.4. Discussion on developing a guidance on criteria and steps to update a risk assessment when relevant new information becomes available**

The group discussed on past examples in which risk assessments were updated in the light of new information.

Further discussion of this item is going to take place at the next meeting of the group.

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

Not Applicable

### **6. Next meeting**

The next meeting will take place on 31 May-1 June 2016.

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<sup>4</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00129>

SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

## Scientific Committee

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

**Held on 25-26 February 2016, Parma (Italy)  
(Agreed on 22 March 2016)**

#### **Participants**

- **Working Group Members:**

Tony Hardy

Michael Jeger

Diane Benford

Josef Schlatter

Yolanda Sanz

Vittorio Silano

Theo Brock

Claude Lambré has participated via teleconference

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

Not Applicable

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

Not Applicable

- **EFSA:**

Scientific Committee and Emerging Risks Unit: Tilemachos Goumperis,  
Daniela Maurici, Dimitrios Spyropoulos, Lesley Koschel

Advisory Forum and Scientific Cooperation Unit: Djien Liem

Assessment Methodological Support Unit: Elisa Aiassa

Food Ingredients and Packaging Unit: Magdalena Andryszkiewicz

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

- **Others:**

Not Applicable

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

The Chair welcomed the participants.

Apologies were received from Sirpa Kärenlampi and Andrew Chesson.

## **2. Adoption of agenda**

The agenda was adopted without changes.

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

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

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

### **4.1. Presentation of the mandate of the Standing Working Group**

The Chair introduced the mandate (M-2016-0038) of the Standing Working Group (SWG).

Cross-cutting Guidance Documents (GDs) are the ones relevant to more than one Scientific Panel opposite to sectorial GDs that are used only by one Panel. In some cases, a sectorial GD can be used as such by other Panels or developed further to serve the work of other Panels. It is the responsibility of this SWG to monitor such activities in the interest of harmonisation and consistency across EFSA.

### **4.2. Implementation of the SC guidance documents and the procedure to review them**

The group discussed the conclusions and recommendations of the Scientific Opinion on "Guidance on the review, revision and development of EFSA's cross-cutting guidance documents" that was prepared by the previous SWG on Guidance Review and published in April 2015.

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

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

The SWG proposed that EFSA shall develop a Standard Operating Procedure on implementation and review of DGs.

#### **4.3. Discussion on developing a guidance on criteria and steps to update a risk assessment when relevant new information becomes available**

The group discussed on criteria and steps to update a risk assessment when relevant new information becomes available.

The discussion was broaden up and included (i) published risk assessments and (ii) finalised, but not yet published, risk assessments. It was agreed that the step forward would be to map past examples and discuss further the need for developing such a GD.

#### **4.4. Scientific opinion on priorities of the SC for guidance development in 2016-2018<sup>4</sup>**

The Scientific Committee of EFSA asked the SWG to draft a Scientific Opinion on priority topics for which guidance documents should be developed in 2016-2018.

The group started drafting the Scientific Opinion and will continue in the next meeting.

#### **4.5. Fine-tune the Terms of Reference of the Standing Working Group**

Due to time constrains, the discussion of this item is going to take place at the next meeting of the group.

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

Not Applicable

### **6. Next meeting**

The next meeting will take place on 22-23 March 2016.

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<sup>4</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00129>