

Scientific Committee

Minutes of the 17th meeting of the Standing Working Group on Guidance Review

Held as teleconference on 6/5/2015

(Agreed on 18 May 2015)

Participants

- **Working Group Experts:**

Tony Hardy (chair), Diane Benford, Josef Schlatter and Robert Luttik

- **EFSA:**

Daniela Maurici (SCER), Elisa Aiassa (AMU), Roy Kirby (RASA), Pablo Romero Barrios (BIOCONTAM), Federica Barrucci (AMU)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Michael Jeger, Sirpa Kärenlampi, Chris Hogstrand, Claude Lambré, Hans Verhagen and Hans-Herman Thulke.

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², 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 were identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

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

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

4. Update on PROMETHEUS project

The group provided feedback on the draft questionnaire prepared by the Assessment Methodological Unit for the second deliverable of the PROMETHEUS project. The questionnaire will be used to:

- a. Collect the views of experts and staff on the way that EFSA works in relation to the principles and process identified in PROMETHEUS, deliverable 1.
- b. Identify which EFSA (e.g. cross-cutting EFSA Guidance) and non-EFSA methodological documents are used and for which purpose.

5. AOB

This was the last meeting of this WG. No further meetings are foreseen before the end of the mandate of this standing WG. The WG will be closed and probably re-established under the new Scientific Committee that will have its inaugural meeting on 23rd July 2015.

Scientific Committee
Minutes of the 16th meeting of the Standing Working Group on Guidance Review
Held on 20-21/04/2015
(Agreed on 12 May 2015)

Participants

- **Working Group Experts:**

Tony Hardy (chair), Michael Jeger, Diane Benford, Josef Schlatter, Sirpa Kärenlampi, Claude Lambré, Robert Luttik, Hans Verhagen * and Chris Hogstrand*

- **EFSA:**

Daniela Maurici (SCER), Tilemachos Goumperis (SCER), Roy Kirby (RASA)**, Elisa Aiassa (AMU)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Hans-Herman Thulke.

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², 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 were identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

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

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

*participated by teleconference

** participated on 20 April

4. Update on PROMETHEUS project

Elisa Aiassa updated the group on the developments of the PROMETHEUS project. The group provided feedback on the draft questionnaire that will be used to collect information from EFSA staff and experts. Due to time constraints, the discussion in this meeting will be complimented with a teleconference dedicated to this issue on 6 May 2015.

5. Possible renewal of the standing WG for 2015-2018, and preliminary discussion on Terms of Reference

The group discussed possible Terms of Reference for a renewal of the Standing WG on Guidance Review under the new Scientific Committee. The proposed Terms of Reference will be provided for discussion and possible endorsement at the Scientific Committee plenary in June 2015.

6. Discussion on possible follow up in relation to “template for opinions/statements”, revised structure for guidance documents

The group studied the structure of several published guidance documents and the template that is in place for all EFSA outputs. They proposed changes that could be applied to the structure of the later in case of guidance documents. These suggestions will be further discussed with the EFSA editorial team.

7. Finalisation of list of cross-cutting Guidance documents (GDs) that need to be reviewed/revised

The WG discussed which guidance documents may need review or revision. A list will be provided for final endorsement at the Scientific Committee plenary in June 2015.

8. AOB

The next meeting will be take place on 6 May 2015 as a teleconference. No further meetings are foreseen before the end of the mandate of this standing WG.

Scientific Committee

Minutes of the 15th meeting of the Standing Working Group on Guidance Review

Held on 4-5/03/2015

(Agreed on 27 March 2015)

Participants

- **Working Group Experts:**

Tony Hardy (chair), Michael Jeger, Sirpa Kärenlampi, Claude Lambré*, Robert Luttik**, Hans-Herman Thulke** and Chris Hogstrand**

- **EFSA:**

Daniela Maurici and Tilemachos Goumperis (SCER Unit), Djien Liem** (AFSCO Unit), Roy Kirby (RASA Department)***

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Diane Benford, Josef Schlatter and Hans Verhagen.

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², 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 were identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

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

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

*participated on 5 March by teleconference

** participated on 4 March

*** Participated on 4 March a.m.

4. Draft opinion on lifecycle (lifespan analysis) of EFSA's cross cutting guidance documents

The last draft of the opinion was tabled at the 71st Scientific Committee (SC) plenary on 18-19 February 2015 for discussion and possible adoption. The WG revised the document taking into consideration the comments received at the SC plenary. In particular:

- a new section on the implementation of cross-cutting guidance documents was added;
- prioritisation criteria for updating or revising the guidance documents were further refined;
- the effective management of the documents through their life cycle including status and version control was considered important;
- some recommendations were reinforced, e.g. the latest version of the documents should be easily retrievable for internal and external audiences.

A final draft will be circulated to the WG for last comments. Then, the document will be shared with the Scientific Committee members for approval by written procedure.

5. Possible workplan for 2015-2016 considering also the renewal of the Scientific Committee

The group discussed possible Terms of Reference for the renewal of the standing WG on Guidance Review under the new Scientific Committee. This issue will be further discussed at the next meeting.

6. Revision plan

The WG discussed which cross-cutting guidance documents may need revision. This topic will be further discussed at the next meeting with a view to provide a draft list for final endorsement at the Scientific Committee plenary in June 2015.

7. AOB

Meeting dates in 2015 have been confirmed:

- 20-21 April 2015, from lunch to lunch on the following day, Parma
- 28 May 2015, one day meeting, probably in Brussels or Amsterdam. If needed, to be transformed in teleconference.

Scientific Committee

Minutes of the 14th meeting of the Standing Working Group on Guidance Review

Held as teleconference on 9/01/2015, from 10.00 to 11.30 h.

(Agreed on 28 January 2015)

Participants

- **Working Group Experts:**

Tony Hardy (chair), Diane Benford, Chris Hogstrand, Michael Jeger, Sirpa Kärenlampi, Claude Lambré, Robert Luttik, Josef Schlatter and Hans Verhagen

- **EFSA:**

Daniela Maurici and Tilemachos Goumperis (SCER Unit)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Hans Herman Thulke.

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², 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. Draft opinion on lifecycle (lifespan analysis) of EFSA's cross cutting guidance documents (EFSA/SC/GR/1723 revision 6)

The WG discussed an advance draft of the opinion that has been compiled with the latest contributions from the WG members. A final draft will be circulated for last comments to the

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

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

WG before sending the document to the Scientific Committee for possible adoption at the February plenary.

5. AOB

Meeting dates in 2015 have been confirmed:

- 4-5 March 2015, from morning of the first day to lunch time of the second day, Parma
- 20-21 April 2015, from lunch time to about 16.00 h on the following day, Parma
- 28 May 2015, 1 day meeting, probably Brussels or Amsterdam. If needed, to be transformed in teleconference.

Scientific Committee

Minutes of the 13th meeting of the Standing Working Group on Guidance Review

Held on 11-12/12/2014, EFSA, Parma, Italy

(Agreed on 28 January 2015)

Participants

- **Working Group Experts:**

Tony Hardy (chair), Diane Benford*, Chris Hogstrand*, Sirpa Kärenlampi, Claude Lambré, Robert Luttik, Josef Schlatter and Hans Verhagen*

- **EFSA:**

Daniela Maurici (SCER Unit)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Hans Herman Thulke and Michael Jeger.

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², 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.

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

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

* participated via teleconference

4. Draft opinion on lifecycle (lifespan analysis) of EFSA's cross cutting guidance documents (EFSA/SC/GR/1723 revision 4)

The WG discussed the preliminary text of the opinion that has been prepared by some of the experts of the WG. Main discussion focussed on the analysis of the general cross cutting guidance, on the level of obligation for EFSA panels and other target audiences to follow and apply cross cutting guidance, and on the process and periodicity for reviewing/updating cross cutting guidance documents. Progress was made in the compilation of recommendations to be included in the conclusive chapter. A more advance document is going to be prepared for the next meeting, probably to be held as a teleconference, in order to have a final draft to be presented for possible adoption at the Scientific Committee plenary meeting in February 2015.

5. Discussion on possible workplan 2015-2016

The WG discussed the possibility to renew the mandate of the standing WG on Guidance Review under the next Scientific Committee, that will be renewed in July 2015.

6. AOB

Meeting dates in 2015 have been agreed:

- 4-5 March 2015, from morning of the first day to lunch time of the second day, Parma
- 20-21 April 2015, from lunch time to about 16.00 h of the following day, Parma
- 28 May 2015, 1 day meeting, probably Brussels or Amsterdam. If needed, to be transformed in teleconference.

Scientific Committee

Minutes of the 12th meeting of the Standing Working Group on Guidance Review

Held on 16-17/10/2014, EFSA, Parma, Italy

(Agreed on 17 November 2014)

Participants

- **Working Group Experts:**

Tony Hardy (chair), Diane Benford, Michael Jeger*, Chris Hogstrand, Sirpa Kärenlampi, Claude Lambré, Robert Luttik, Josef Schlatter and Hans Verhagen.

- **EFSA:**

Daniela Maurici (SCER Unit), Djien Liem** (AFSCO Unit)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Hans Herman Thulke. The chair communicated to the WG that Metka Filipič has resigned from the WG for private reasons. The chair thanked Metka for the contributions she has given to the work of the WG during the last 2.5 years.

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², 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.

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

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

- * participated via teleconference
- ** participated on 16th October

4. Feedback from the editorial team on next steps for the template for opinions and implementation of the revised structure of opinions and statements

The editorial team presented the revised template for EFSA's outputs that will be implemented as from January 2015. This template makes use of the features of Windows 7 that is now installed on all EFSA's computers. The revised structure of opinions as adopted by the EFSA Scientific Committee during the July 2014 plenary is published and already applicable for opinions and statements and will be revisited, if needed, after a trial period of about 8 months.

5. Preliminary draft opinion on lifecycle (lifespan analysis) of EFSA's cross cutting guidance document (EFSA/SC/GR/1723 rev 2)

The WG discussed the draft table of content of the opinion that should cover, among others, the following points:

- The doc on guidance lifecycle should cover all the Guidance Docs (GDs) developed in EFSA and not only those of the Scientific Committee
- Any GDs should have an expiring date or revision should be foreseen after 5 years
- The mechanisms to revise GDs should be further discussed and defined

The WG also discussed:

- Level of obligation to follow GDs
- Reasons for updating GDs
- Criteria for prioritisation of the revision of existing GDs

Preliminary text will be prepared by some members of the WG for discussion at the next meeting. The WG foresees to present a draft opinion for adoption at the SC plenary meeting in February 2015.

6. Presentation of the Prometheus project

The colleagues from the Assessment and Methodological Unit (AMU) presented the Prometheus project (PROmoting Methods for Evidence Use in Science). The overall strategic objectives are the definition and guiding principles for evidence base assessment, the collection of available methods/tools to fulfil the principles and the identification of the gaps where specific methods/tools are needed. This project foresees 3 deliverables, one in 2015 and two in 2016. All three deliverables will be presented to the EFSA Scientific Committee for endorsement. This work is very relevant for the WG on guidance review and will be monitored very closely.

7. AOB

Meeting in 2014 have been confirmed:

11-12 December, Parma

Meeting dates in 2015 have been agreed:

- 19-20 February 2015, Parma
- 20-21 April 2015, Parma
- 28 May 2015, 1 day meeting, probably Bruxelles or Amsterdam. If needed, to be transformed in teleconference.

Scientific Committee

Minutes of the 11th meeting of the Standing Working Group on Guidance Review

Held on 9-10/7/2014, EFSA, Parma, Italy

(Agreed on 28 July 2014)

Participants

- **Working Group Experts:**

Tony Hardy (chair), Metka Filipič, Michael Jeger, Chris Hogstrand, Sirpa Kärenlampi, Claude Lambré, Robert Luttik, Josef Schlatter and Hans Verhagen*.

- **EFSA:**

Daniela Maurici (SCER Unit), Djien Liem (AFSCO Unit)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Diane Benford, Hans Herman Thulke and Hans Verhagen.

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², 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. Scientific topics for discussion

New template/structure of EFSA Opinions/Statements

The revised structure to be used for EFSA opinions/statements was discussed and endorsed at the 68th SC plenary (8-9 July). The document will be published as guidance of the

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

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

- * participated via teleconference on 10 July 2014

Scientific Committee. The WG suggested some minor editorial modifications on the approved doc.

The intention is to run a pilot phase that will last probably until May 2015. After this trial period, comments will be once again collected and an updated version of the guidance will be tabled for final adoption at the June 2015 SC plenary.

Proposal to draft a document on Scientific Committee guidance documents lifecycle

The chair presented the outline of the document. The WG walked through the doc assessing for each published guidance doc or opinion of the SC:

- a) Category: technical guidance or advice.
- b) Target audience: for applicants, for internal use and/or wider international dimension, for MS.
- c) Status: standing doc or revision needed/in progress.
- d) Obligation for EFSA: optional, conditional, to follow or not applicable.

It has been agreed to draft a chapter where it is explained the difference between guidance and guideline and also when and on which basis guidance docs need to be updated.

5. AOB

Meeting in 2014 have been confirmed:

- Teleconference in September, date to be defined
- 16-17 October, Parma, lunch time to lunch time
- 11-12 December, Parma, lunch time to lunch time

Meeting dates in 2015 have been agreed:

- 19-20 Febr 2015, from lunch to lunch, Parma
- 20-21 April 2015, from lunch time to about 16 p.m. of the following day, Parma
- 28 May 2015, 1 day meeting, probably Bruxelles or Amsterdam. If needed, to be transformed in teleconference.

Scientific Committee

Minutes of the 10th meeting of the Standing Working Group on Guidance Review Held as teleconference on 23 June 2014

(Agreed on 28 July 2014)

Participants

- **Working Group Experts:**
Tony Hardy (chair), Metka Filipič, Sirpa Kärenlampi, Robert Luttik, Hans Verhagen.
- **EFSA:**
Daniela Maurici (SCER Unit)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Apologies were received from Diane Benford, Michael Jeger, Chris Hogstrand, Claude Lambré, Hans Herman Thulke and Josef Schlatter.

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², 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. Scientific topics for discussion

New template/structure of EFSA Opinions/Statements

The revision of the structure to be used for EFSA opinions/statements was discussed in light of the comments received from the units after having checked the proposed structure with already published opinions. The units that participated to the exercise were: NDA (two opinions on health claims and one opinion on novel food), Contam, Biohaz, PLH, ANS. GMO and CEF provided their comments in writing.

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

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

In general the applicability of the revised structure was confirmed, even if additional modifications will be made to the proposed structure. The guidance proposing new structure for opinions and statement will be proposed for possible endorsement at the next SC plenary in July.

Preliminary draft document on Scientific Committee (SC) guidance documents lifecycle

The chair presented the outline of the document. The WG agreed to consider:

- a) the different types of cross-cutting documents developed by the Scientific Committee (SC);
- b) the process and periodicity for reviewing and updating them;
- c) the criteria for prioritisation of subjects for SC guidance document request for rapid action.
- d) Clear definition on what is the intended use (mandatory, on a case by case basis).

A brief summary of this document will be presented at the 68th SC plenary in July 2014.

5. AOB

Nothing to report.

6. Next meeting dates in 2014

9-10 July, Parma,

16-17 October, Parma

11-12 December, Parma

Scientific Committee
Minutes of the 9th meeting of the Standing Working Group on Guidance Review
Held on 6-7 05 2014, London, UK
(Agreed on 28 May 2014)

Participants

- **Working Group Experts:**

Tony Hardy (chair), Diane Benford, Metka Filipič, Chris Hogstrand, Michael Jeger, Claude Lambré, Sirpa Kärenlampi, Robert Luttik, Josef Schlatter.

- **EFSA:**

SCER Unit (Daniela Maurici)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Hans Herman Thulke and Hans Verhagen.

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², 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.

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

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

4. Scientific topics for discussion

New template/structure of EFSA Opinions/Statements

The revision of the template/structure to be used for EFSA opinions/statements was discussed and agreed at the last Scientific Committee plenary in April. The document has been circulated to EFSA Units with the request to test the new template/structure with an already published opinion/statement in order to identify possible problems. The feedback will be collected to finalise the document that will be presented in a form of a guidance document and tabled for possible adoption at the Scientific Committee plenary in July 2014.

Proposal to draft a document on Scientific Committee guidance documents lifecycle

The chair presented for discussion the proposal to draft a statement that explains the guidance documents lifecycle, e.g. the different types of cross-cutting documents developed; the process and periodicity for reviewing and updating them; the criteria for prioritisation of subjects for SC guidance document request for rapid action.

A table of content of this document will be prepared and discussed at the next meeting.

Amendment of the WG Guidance Review mandate to reflect changes in the work-programme.

The [mandate](#) has been amended to reflect the additional tasks that have been agreed.

Proposal to draft a technical report to explain reasons for different risk assessment outcomes on the same substance

The proposal has been briefly discussed. Due to the priority given to the development of the statement on the Scientific Committee guidance documents lifecycle, this task has been postponed to a later stage.

5. Any Other Business

No items to report.

6. Next meeting dates in 2014

9-10 July, Parma,

16-17 October, Parma

11-12 December, Parma

Scientific Committee
Minutes of the 8th meeting of the Standing Working Group on Guidance Review
Held on 06-07 03 2014, Parma, Italy
(Agreed on 26 03 2014)

Participants

- **Working Group Experts:**

Tony Hardy (chair), Diane Benford, Metka Filipič, Chris Hogstrand, Sirpa Kärenlampi, Robert Luttik, Josef Schlatter and Hans Verhagen.

Michael Jeger has participated via teleconference.

- **EFSA:**

SCER Unit (Daniela Maurici) and AMU Unit (Fulvio Barizzzone)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Claude Lambré and Hans Herman Thulke.

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², 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.

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

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

4. Scientific topics for discussion

Drafting of the new template/structure of EFSA Opinions

The WG discussed a draft document presenting a revision of the template/structure to be used for EFSA scientific opinions. The current template dates back to 2003 and on several occasions it has been proposed that the template be revised. The draft presented has the aim to have chapter headings that better reflect the different steps undertaken during the (risk) assessment process (e.g. data interpretation, methodology used etc).

The WG proposed to concentrate for the moment on revising the structure of opinions and statements, without including detailed guidance documents.

The revised proposal will be tabled for possible endorsement at the next Scientific Committee plenary in April 2014. If endorsed, the panels will test the approach proposed with one existing opinion and comments will be collected by the secretariat. The finalisation of the structure/template of opinions and statements may be possible at the Scientific Committee July plenary meeting. Then there would be a subsequent period of about one year for new opinions to be produced according to the revised template, with subsequent review of the suitability.

Proposal to draft a technical report to explain reasons for different risk assessment outcomes on the same substance

Due to time constraints, this item has been postponed to the next meeting.

5. Any Other Business

No items to report

6. Next meeting dates in 2014

6-7 May, London

9-10 July, Parma, probably as teleconference

16-17 October, Parma

Scientific Committee

Minutes of the 7th meeting of the Standing Working Group on Guidance Review

Held on 16-17 January 2014, London UK

(Agreed on 20 February 2014)

Participants

- **Working Group Experts:**

Tony Hardy (chair), Diane Benford, Chris Hogstrand, Sirpa Kärenlampi, Michael Jeger, Claude Lambré, Robert Luttik, Josef Schlatter, Hans Verhagen.

- **EFSA:**

Daniela Maurici (SCER Unit)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received Metka Filipič and Hans Herman Thulke.

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², 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. Scientific topics for discussion

Brainstorming on the second part of the mandate ([M-2013-0261](#))

At its last meeting, the WG discussed the reasons that may lead to different evaluation of the same substance/active ingredient. The WG proposed to draft a paper presenting and explaining the reasons, for example different protection goals for the assessment, different target, different exposure, different legislation/timeline, different data sets. The proposal was presented at the Scientific Committee plenary in December 2013. The Scientific Committee was in favour of such a paper, to be supported by an internal mapping document. Moreover, the WG discussed the possibility to set up a standing WG on genotoxicity to respond to *ad*

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

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

hoc questions when controversial evaluations on this endpoint are identified in parallel ongoing assessment in EFSA. This overarching WG could also serve as a platform to provide guidance on the interpretation of the genotoxicity testing guidance document published in 2011. The Scientific Committee welcomed the proposal. The WG discussed the possible terms of reference of this self task mandate.

Presentation of the activities of the EFSA Applications desk

Objectives of the presentation were: presentation of activities for the completeness check of application dossiers, in particular for food enzyme, additives and flavourings; for feed additives; for GMO. In the end, the Applications Desk plan 2014-2016 were presented.

5. Any Other Business

Nothing to be reported.

6. Next meeting dates in 2014

6-7 March, Parma

6-7 May, Parma

9-10 July Parma, probably as teleconference

16-17 October, Parma

Scientific Committee

Minutes of the 6th meeting of the Standing Working Group on Guidance Review

Held on 17-18 October 2013, Ljubljana, Slovenia

(Agreed on 15 November 2013)

Participants

- **Working Group Experts:**

Tony Hardy (chair), Diane Benford, Metka Filipič, Sirpa Kärenlampi, Claude Lambré, Robert Luttik, Josef Schlatter, Hans Verhagen.

- **EFSA:**

Daniela Maurici (SCER Unit)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Chris Hogstrand and his alternate Guido Rychen, Michael Jeger, Birgit Noerrung and her alternate John Sofos, Hans Herman Thulke.

The WG was informed that Catherine Leclercq resigned for personal reasons as from 11th June 2013. Birgit Noerrung has resigned for personal reasons as from 21st October 2013.

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², 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. Scientific topics for discussion

Follow up after adoption and publication of the Scientific Committee opinion "Priority for the development of guidance documents" ([EFSA-Q-2012-00785](#))

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

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

The draft opinion was adopted at the Scientific Committee plenary meeting in July and published in August. Prioritisation of the guidance documents to be developed was discussed as work-programme at the Scientific Committee plenary in September. The development of guidance documents on biological relevance for toxicology, use of weight of evidence approach for risk assessment and harmonisation of the assessment of human exposure were considered as high priority.

Development of the second part of the mandate on guidance review ([M-2013-0261](#))

The WG discussed how to address the second part of the mandate. The terms of reference asks for the identification of commonalities and differences in the legislative and data requirements for EFSA risk assessment. The WG proposed to draft a technical report where the issues leading to different assessment of the same substance are clearly presented and explained (e.g. different legal framework, different exposure etc..).

5. Any Other Business

Nothing to be reported.

6. Next meeting dates in 2014

16-17 January, London

6-7 March, Parma

6-7 May, Parma

9-10 July Parma, probably as teleconference

16-17 October, Parma

Scientific Committee
Minutes of the 5th meeting of the Standing Working Group on Guidance Review
Held on 23-24 May 2013, Parma
(Agreed on 24 June 2013)

Participants

- **Working Group Experts:**

Tony Hardy (chair), Diane Benford, Metka Filipič, Michael Jeger¹, Sirpa Kärenlampi, Claude Lambré, Robert Luttik, Josef Schlatter, Hans Herman Thulke, Hans Verhagen.

- **EFSA:**

Dijen Liem and Daniela Maurici (SCER Unit), Christina Ehlert (ApDesk Unit).

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Catherine Leclercq, Birgit Noerrung, John Sofos.

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 Processes² and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests³, 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. Scientific topics for discussion

Preliminary draft of the opinion "Priority for the development of guidance documents"
[\(EFSA-Q-2012-00785\)](#)

The draft opinion is presenting priority for the development of new guidance documents or for updating of existing ones. The WG discussed the contributions to the different chapters of

¹ Not present on 23rd in the morning

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

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

the opinion provided by the members of the working group. Some comments were made that will be considered in the next revision. The draft opinion will be proposed for adoption at the Scientific Committee plenary in July 2013.

5. Any Other Business

Anything to be reported.

6. Next meeting dates

24 June 2013, from 10.00 to 13.00 as teleconference,
17-18 October 2013, Ljubljana,
16-17 January 2014, London.

Scientific Committee

Minutes of the 4th meeting of the Standing Working Group on Guidance Review

Held on 24-25 April 2013, Parma

(Agreed on 14 May)

Participants

- **Working Group Experts:**

Tony Hardy (chair), Diane Benford, Metka Filipič¹, Christer Hogstrand, Sirpa Kärenlampi, Claude Lambré², Robert Luttik, Josef Schlatter, John Sofos, Hans Verhagen³.

- **EFSA:**

Juliane Kleiner, Djien Liem, Daniela Maurici (SCOM Unit), Christina Ehlert (AppDesk Unit).

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Michael Jeger, Catherine Leclercq, Hans Herman Thulke.

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 Processes⁴ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests⁵, 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. Scientific topics for discussion

Preliminary draft of the opinion "Priority for the development of guidance documents"
[\(EFSA-Q-2012-00785\)](#)

¹ Present on 24th April afternoon and 25th April

² Present on 24th April afternoon and 25th April

³ Present on 24th April

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

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

The draft opinion is presenting priority for the development of new guidance documents or for updating of existing ones. The WG discussed the contributions to the different chapters of the opinion provided by the members of the working group. Some comments were made that will be considered in the next revision. The draft opinion will be probably proposed for adoption at the Scientific Committee plenary in July 2013.

5. Feedback on the questionnaire sent to Units/Panels on the use of guidance documents developed by the EFSA Scientific Committee

A questionnaire was prepared by the secretariat and sent to the Units/panels to investigate the use of existing guidance documents developed by the Scientific Committee. Questions were also made in relation to topics where the development of new guidance documents would be beneficial. 25 responses were received and summarised in a document that was analysed and discussed by the WG. The comments made by the Units/panels have been discussed and will be considered in the finalisation of the draft opinion.

6. Any Other Business

Anything to be reported.

7. Next meeting dates

23-24 May 2013, Parma
25 June 2013, from 10.00 to 13.00 as teleconference
17-18 October 2013, Ljubljana
16-17 January 2014, London.

Scientific Committee
Minutes of the 3rd meeting of the Standing Working Group on Guidance Review
Held on 7-8 March 2013, Parma

(Agreed on 4 April)

Participants

- **Working Group Experts:**

Tony Hardy (chair), Diane Benford, Metka Filipič¹, Christer Hogstrand², Michael Jeger, Sirpa Kärenlampi, Claude Lambré, Robert Luttik, Hans Herman Thulke, Hans Verhagen.

- **EFSA:**

Dijen Liem, Daniela Maurici (SCOM Unit), Christina Ehlert (AppDesk Unit), Carola Sondermann³ (AFSCO)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Catherine Leclercq, Josef Schlatter, Birgit Noerrung and her alternate John Sofos. Christina Ehlert will, from now on, replace Carla Martino as representative of the EFSA Application Desk.

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 Processes⁴ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests⁵, 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.

¹ Present on 7th March afternoon and 8th March

² Present on 7th March

³ For agenda item 5.1

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

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

4. Scientific topics for discussion

Preliminary draft of the opinion “Priority for the development of guidance documents” ([EFSA-Q-2012-00785](#))

At the last meeting, the WG identified a series of subjects for which the development of new guidance documents, or update of existing ones, would be beneficial. Some contributions were provided by WG members and included in a preliminary draft opinion. The WG discussed chapter by chapter the contributions received and made some comments that will be taken on board in the next revision.

The WG is expected to deliver an opinion in summer 2013.

5. Any Other Business

5.1. EFSA Thesaurus project

Carola Sondermann from the AFSCO Unit presented briefly the Thesaurus project. Preliminary work has been done to map existing Thesauri in the area of food and feed. The internal task force on the thesaurus project will meet regularly to discuss the information gathered and to agree on the next steps and timelines.

5.2. Possible revision of the SC genotoxicity testing strategies opinion

The WG was informed about the ongoing evaluations of Allura Red as food colorant by the ANS Panel and as feed colorant by the FEEDAP Panel. The genotoxicity working groups of the two Panels have met to discuss in particular the evaluation of the genotoxicity data and suggested to consider whether the Scientific Committee opinion on genotoxicity testing strategy (as published in 2011) would need to be updated. The issue was discussed and the WG came to the conclusion that there is no need for the moment to update the SC opinion on genotoxicity testing strategies.

6. Next meeting dates

24-25 April 2013, Parma
23-24 May 2013, Parma
25 June 2013, from 10.00 to 13.00 as teleconference
17-18 October 2013, Ljubljana
16-17 January 2014, London.

Scientific Committee
Minutes of the 2nd meeting of the Standing Working Group on Guidance Review
Held on 31 January-1 February 2013, Parma
(Agreed on 27 March 2013)

Participants

- **Working Group Experts:**

Tony Hardy (chair), Diane Benford, Metka Filipič, Sirpa Kärenlampi, Catherine Leclercq, Claude Lambré, Robert Luttik, Josef Schlatter, John Sofos, Hans Verhagen.

- **EFSA:**

Djien Liem, Daniela Maurici (SCOM Unit), Andrea Altieri (EMRISK Unit), Carla Martino (AppDESK Unit).

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received Christer Hogstrand, Hans Herman Thulke, Birgit Nörrung, Pasquale Mosesso.

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², 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. Scientific topics for discussion

Internal report "Mapping legislation and EFSA guidance documents in relation to regulatory data requirements for risk assessment in the food chain ([EFSA-Q-2012-007100](#))

The draft internal report was revised taking into consideration the discussion held at the kick off meeting on 5th December 2012. The internal report is now finalised and will be used, to

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

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

the extent necessary and possible, by the Working Group to address the Terms of Reference as requested in the mandate.

Table of content of the draft opinion on “Priority for the development of guidance documents” ([EFSA-Q-2012-00785](#))

The first task of the Working Group will be to prepare a draft opinion, to be submitted to the Scientific Committee for possible adoption, covering the following points of the Terms of Reference.

- to provide recommendations and set priorities for the review of existing guidance documents, or for the preparation of new EFSA guidance documents. This task will be conducted also considering advices from the Legal and Regulatory Affairs Unit when needed or considered appropriate;
- to assist the implementation and use of EFSA guidance documents across EFSA.

The WG is expected to deliver an opinion in summer 2013, making use and analysing the internal report mentioned above. The opinion will provide recommendations for the review of existing guidance documents and for the preparation of new ones. The WG discussed possible topics to be considered for guidance development and agreed on considering guidance on general principles and guidance on specific principles. For the moment, only the general principles, both scientific and technical, will be considered.

5. Next meetings in 2013

7-8 March, 24-25 April, 23-24 May.

Scientific Committee
Minutes of the 1st meeting of the Working Group on Guidance Review
Held on 5/12/2012, Parma
(Agreed on 8/03/2013)

Participants

- **Working Group Experts:**

Tony Hardy (chair), Diane Benford, Metka Filipic, Sirpa Karenlampi, Catherine Leclercq, Robert Luttik, Josef Schlatter, Hans Herman Thulke, Hans Verhagen

- **EFSA:**

- Daniela Maurici (SCOM Unit), Andrea Altieri (EMRISK Unit), Carla Martino (APDESK Unit)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Claude Lambre and Birgit Noerrung, and from their alternate Pasquale Mosesso and John Sofos.

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², 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. Presentation of the mandate of the standing WG on guidance review
[\(EFSA-Q-2012-00785\)](#)

The participants were presented with the internal EFSA mandate for the Standing WG on guidance review as signed by the EFSA's Executive Director on 22 November 2012. The development of the guidance review framework is part of the EFSA Science Strategy 2012-2013³. The objectives of the standing WG on guidance review are to perform the following tasks, as listed in the Terms of Reference of the mandate:

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

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

³ <http://www.efsa.europa.eu/en/corporate/pub/sciencestrategy12.htm>

- ✓ to provide recommendations and set priorities for the review of existing guidance documents, or for the preparation of new EFSA guidance documents. This task will be conducted also considering advices from the LRA Unit when needed or considered appropriate;
- ✓ to serve as an expert judgment platform by assisting EFSA in identifying commonalities and differences between guidance documents of different Panels/Risk Assessment bodies;
- ✓ to assist the implementation and use of EFSA guidance documents across EFSA;
- ✓ to assist in the development and implementation of advanced scientific training programmes for experts of the Scientific Committee, Scientific Panels and EFSA's scientific Units.

5. Presentation of the internal report “Mapping legislation and EFSA guidance documents in relation to regulatory data requirements for risk assessment in the food chain

EFSA has recently put forward an umbrella framework for the implementation of activities in relation to the development and harmonisation of risk assessment approaches. A task force of staff members compiled a comprehensive overview of all data requirements currently detailed by the EU legislation and EFSA guidance documents for regulated and non-regulated products for pre- and post-market monitoring in the areas covered by EFSA's mandate. The focus has been on information to be provided within the various activities of each Unit or Panel, mandatory or on a case by case basis. This report will be used by the SC WG on Guidance Review to address the Terms of reference as requested in the mandate.

6. Discussion on the work-plan and table of content of the opinion

The WG is expected to deliver an opinion in summer 2013, to make use and analyse the internal report mentioned above. The opinion will provide recommendations for the review of existing guidance documents and for the preparation of new ones.

7. Any Other Business

Carla Martino (EFSA Application Desk Unit) presented tables compiled by the Application Desk and published on the website, summarising the legislative frameworks, the scientific and the technical guidance documents developed by EFSA in relation to authorisation of regulated products (link below):

<http://www.efsa.europa.eu/en/apdesk/docs/apdeskhow.pdf>

8. Next meetings in 2013

31st Jan-1st February, 7-8 March, 24-25 April, 23-24 May.