

Scientific Panel on Biological Hazards

BIOCONTAM Unit

Minutes of the 10th meeting of the Working Group on Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs

Held by web conference on 4 May 2016

(Agreed on 13 May 2016)

Participants

- **Working Group Members:**

Ana Allende, Monika Ehling-Schulz, Niels Bohse Hendriksen, Anne-Brit Kolstø, Jacques Mahillon, Antonia Ricci (Chair) and Vincent Sanchis

- **EFSA:**

BIOCONTAM Unit: Maria Teresa Da Silva Felicio, Giusi Amore

PRAS Unit: Laszlo Bura, Frederique Istace

- **European Commission (DG SANTE):**

Unit E3: Sofie Hofkens

Unit G4: Pamina Mika-Suzuki

1. Welcome and apologies for absence

The Chair opened the meeting and welcomed the members of the working group (WG).

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the WG members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 9th Working Group meeting held on 15 April 2016.

The minutes of the 9th Working Group meeting held on 15 April 2016 were agreed.³

5. Scientific topic(s) for discussion

5.1. Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs⁴

The WG discussed the feedback from the BIOHAZ Panel on the draft opinion as well as the comments received from Ingvar Sundh who was nominated by PRAs Unit to review this draft opinion. All contributions received since the previous meeting were reviewed carefully.

Tasks were allocated to EFSA staff and the WG Members.

6. Next meeting

No additional meetings are foreseen.

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

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

³ <http://www.efsa.europa.eu/sites/default/files/biohazbacilluswgs.pdf>

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00254>

Annex

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

CONFLICT OF INTEREST: In the ADoI or in the SDoI filled for the present meeting Dr. Vincent Sanchis declared the following interest: expert in the ISO WG 20 differentiation between *B. thuringiensis* and *B. cereus*' (comité technique ISO/TC34 'food products', souscomité SC9 'Microbiology'). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁵ and the Decision of the Executive Director on Declarations of Interest⁶, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of item 'ISO WG differentiation between *B. thuringiensis* and *B. cereus*' by the concerned scientific group.

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

⁶ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

BIOCONTAM Unit

Minutes of the 9th meeting of the Working Group
on Risks for public health related to the presence
of *Bacillus cereus* and other *Bacillus* spp.
including *Bacillus thuringiensis* in foodstuffs

Held by web conference on 15 April 2016

(Agreed on 15 April 2016)

Participants

- **Working Group Members:**

Ana Allende, Antonia Ricci (Chair)

- **EFSA:**

BIOCONTAM Unit: Maria Teresa Da Silva Felicio, Giusi Amore, Mirena Ivanova

AMU Unit: Laura Martino

1. Welcome and apologies for absence

The Chair opened the meeting and welcomed the participants to this sub WG meeting organised with a selected number of WG members.

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the WG members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 8th Working Group meeting held on 8 April 2016.

The minutes of the 8th Working Group meeting were agreed by written procedure on 20 March 2016.³

5. Scientific topic(s) for discussion

5.1. Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs⁴

The subWG discussed thoroughly the section 2.2. on Methodologies of the draft opinion as well as the protocol for the extensive literature review on occurrence and levels of *B. thuringiensis* (Appendix G).

Tasks were allocated to EFSA staff and the WG Members.

6. Next meeting

The next meeting will take place on 4 May (as a web conference) from 14:00 to 17:00 (Parma time).

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

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

³ <http://www.efsa.europa.eu/sites/default/files/biohazbacilluswgs.pdf>

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00254>

Annex

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This results in the exclusion of the expert from any discussion, voting or other processing of item 'ISO WG differentiation between *B. thuringiensis* and *B. cereus*' by the concerned scientific group.

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

⁶ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

BIOCONTAM Unit

Minutes of the 8th meeting of the Working Group on Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs

Held on 8 April 2016, Parma (Italy)

(Agreed on 20 April 2016)

Participants

- **Working Group Members:**

Ana Allende (until 15:30), Monika Ehling-Schulz (until 16:00), Niels Bohse Hendriksen, Anne-Brit Kolstø, Jacques Mahillon (until 15:00), Antonia Ricci (Chair) and Vincent Sanchis (until 15:15)

- **EFSA:**

BIOCONTAM Unit: Maria Teresa Da Silva Felicio, Giusi Amore

PRAS Unit: Laszlo Bura, Frederique Istace

- **European Commission (DG SANTE):**

Unit E3: Sofie Hofkens (until 15:00)

1. Welcome and apologies for absence

The Chair opened the meeting and welcomed the members of the working group (WG). Apologies were received from Pamina Mika-Suzuki, Frederique Istace and Laszlo Bura.

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the WG members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 7th Working Group meeting held on 4 March 2016.

The minutes of the 7th Working Group meeting were agreed by written procedure on 16 March 2016.³

5. Scientific topic(s) for discussion

5.1. Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs⁴

The WG discussed the feedback from the BIOHAZ Panel on the draft opinion and reviewed carefully all contributions received since the previous meeting.

The WG also reviewed carefully all conclusions provided as answers to each ToR as well as the recommendations.

It was agreed to: (i) cite the contents of the Appendix F only when considered relevant by the WG, (ii) add a disclaimer to the draft opinion underlining that the information included in Appendix F represents solely the views of the IBMA and does not represent the views of this WG, and (iii) organise a teleconference to discuss with Pamina (DG SANTE) how to integrate/show the results from the survey to MSs on microbiological criteria or guideline microbiological limits for *B. cereus* or *Bacillus* spp.

Tasks were allocated to the WG Members.

6. Next meeting

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

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

³ <http://www.efsa.europa.eu/sites/default/files/biohazbacilluswgs.pdf>

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00254>

The next meeting will take place on 4 May (as a web conference) from 14:00 to 17:00 (Parma time).

Annex

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

CONFLICT OF INTEREST: In the ADoI or in the SDoI filled for the present meeting Dr. Vincent Sanchis declared the following interest: expert in the ISO WG 20 differentiation between *B. thuringiensis* and *B. cereus*' (comité technique ISO/TC34 'food products', souscomité SC9 'Microbiology'). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁵ and the Decision of the Executive Director on Declarations of Interest⁶, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of item 'ISO WG differentiation between *B. thuringiensis* and *B. cereus*' by the concerned scientific group.

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

⁶ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

BIOCONTAM Unit

Minutes of the 7th meeting of the Working Group on Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs

Held on 4 March 2016, Parma (Italy)

(Agreed on 16 March 2016)

Participants

- **Working Group Members:**

Ana Allende, Monika Ehling-Schulz, Niels Bohse Hendriksen, Anne-Brit Kolstø, Jacques Mahillon, Antonia Ricci (Chair) and Vincent Sanchis

- **EFSA:**

BIOCONTAM Unit: Maria Teresa Da Silva Felicio, Giusi Amore

PRAS Unit: Laszlo Bura, Frederique Istace

1. Welcome and apologies for absence

The Chair opened the meeting and welcomed the members of the working group (WG). Apologies were received from Pamina Mika-Suzuki and Sofie Hofkens.

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 6th Working Group meeting held on 18-19 January 2016.

The minutes of the 6th Working Group meeting were agreed by written procedure on 29 January 2016.³

5. Scientific topic(s) for discussion

5.1. Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs⁴

The Working Group discussed in detail the pending actions, feedback from the BIOHAZ Panel on the draft opinion and reviewed carefully all contributions received on the draft opinion since the previous meeting.

The WG also discussed carefully the content of the Appendix F showing the non-confidential information provided by IBMA representatives during the technical consultation.

Tasks were allocated to the Working group Members.

6. Next meeting

The dates for the next meetings of the Working Group are:

- 8 April (physical meeting in Parma) from 8:30 to 17:30 and
- 4 May (web conference) from 14:00 to 17:00 (Parma time).

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

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

³ <http://www.efsa.europa.eu/sites/default/files/biohazbacilluswgs.pdf>

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00254>

Annex

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

CONFLICT OF INTEREST: In the ADoI or in the SDoI filled for the present meeting Dr. Vincent Sanchis declared the following interest: expert in the ISO WG 20 differentiation between *B. thuringiensis* and *B. cereus*' (comité technique ISO/TC34 'food products', souscomité SC9 'Microbiology'). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁵ and the Decision of the Executive Director on Declarations of Interest⁶, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of item 'ISO WG differentiation between *B. thuringiensis* and *B. cereus*' by the concerned scientific group.

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

⁶ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

BIOCONTAM Unit

Minutes of the 6th meeting of the Working Group on Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs

Held on 18 January to 19 January 2016, Parma (Italy)

(Agreed on 29 January 2016)

Participants

- **Working Group Members:**

Ana Allende, Monika Ehling-Schulz, Niels Bohse Hendriksen, Anne-Brit Kolstø, Jacques Mahillon, Antonia Ricci (Chair) and Vincent Sanchis

- **Hearing Experts¹:**

Denise Munday (SCAE-Valent BioSciences Sàrl, Switzerland), Maria Pilar Herrero (Valent BioSciences Corp., USA), Jacqueline Süß (GAB Consulting GmbH, Germany), Sergio Franceschini (CBC (Europe) S.r.l., Divisione BIOGARD, Italy) and Jacob Eyal (Certis U.S.A., LLC, USA)

- **European Commission (DG SANTE):**

Unit E3: Sofie Hofkens

Unit G4: Pamina Mika Suzuki (only 19 January from 15:00 to 16:30)

- **EFSA:**

BIOCONTAM Unit: Maria Teresa Da Silva Felicio, Giusi Amore

PRAS Unit: Laszlo Bura, Frederique Istace

1. Welcome and apologies for absence

¹ 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>.

The Chair welcomed the participants including this time all nominated representatives of the International Biocontrol Manufacturers Association (IBMA) which were invited as hearing experts for the technical consultation. A round of presentations took place to introduce all participants at the meeting.

2. Adoption of agenda

The agenda for the first day of the meeting (technical consultation) was adopted with the following changes: a joint session with all nominated IBMA representatives followed by two separate sessions with the representatives of SCAE-Valent BioSciences Sàrl/Valent BioSciences Corp. and CBC (Europe) S.r.l./Certis U.S.A./GAB Consulting GmbH, respectively. The technical consultation was finalised with a joint session with all IBMA representative for the final discussion, agreement of tasks and deadlines. The agenda for the second day of the meeting was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 5th Working Group meeting held on 9 December 2015.

The minutes of the 5th Working Group meeting were agreed by written procedure on 23 December 2015.⁴

5. Scientific topic(s) for discussion

5.1. Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs⁵

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

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

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

A technical consultation with hearing experts nominated by the International Biocontrol Manufacturers Association) took place during the first day of this WG meeting. These hearing experts answered all questions previously shared by the WG.

The Working Group discussed in detail the pending actions, the approaches to answer some of the ToRs and reviewed carefully all contributions received on the draft opinion since the previous meeting.

Tasks were allocated to the Working group Members as well as to the hearing experts from industry participating at the technical consultation.

6. Next meeting

The dates for the next meetings of the Working Group are:

- 4 March (web conference) from 14:00 to 17:00 (Parma time),
- 8 April (physical meeting in Parma) from 8:30 to 17:30 and
- 4 May (web conference) from 14:00 to 17:00 (Parma time).

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00254>

Annex

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

CONFLICT OF INTEREST: In the ADoI or in the SDoI filled for the present meeting Dr. Vincent Sanchis declared the following interest: expert in the ISO WG 20 differentiation between *B. thuringiensis* and *B. cereus*' (comité technique ISO/TC34 'food products', souscomité SC9 'Microbiology'). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁶ and the Decision of the Executive Director on Declarations of Interest⁷, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of item 'ISO WG differentiation between *B. thuringiensis* and *B. cereus*' by the concerned scientific group.

⁶ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁷ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

BIOCONTAM Unit

Minutes of the 5th meeting of the Working Group on Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs

Held on 9 December 2015, webconference

(Agreed on 23 December 2015)

Participants

- **Working Group Members:**

Ana Allende, Monika Ehling-Schulz, Niels Bohse Hendriksen, Jacques Mahillon (until 10:15), Antonia Ricci (Chair), Vincent Sanchis

- **European Commission (DG SANTE):**

Unit E3: Pamina Mika Suzuki (until 10:30 and from 11:30 onwards)

- **EFSA:**

BIOCONTAM Unit: Maria Teresa Da Silva Felicio

PRAS Unit: Laszlo Bura, Frederique Istace

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Sofie Hofkens and Anne-Brit Kolstø.

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 4th Working Group meeting held on 24 November 2015.

The minutes of the 4th Working Group meeting were agreed by written procedure on 30 November 2015.³

5. Scientific topic(s) for discussion

5.1. Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs⁴

The Working Group discussed in detail the pending actions, feedback from the BIOHAZ Panel on the draft opinion and reviewed carefully some contributions received on the draft opinion since the previous meeting.

Decisions were taken regarding the search strategy for the literature review on the presence/levels of *B. thuringiensis* in foods. Tasks were allocated to the Working group Members.

6. Next meeting

The next meeting of the Working Group is on 18 January (14:00 to 18:00) to 19 January (9:00 to 17:00), Parma).

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

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

³ <http://www.efsa.europa.eu/sites/default/files/biohazbacilluswgs.pdf>

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00254>

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This results in the exclusion of the expert from any discussion, voting or other processing of item 'ISO WG differentiation between *B. thuringiensis* and *B. cereus*' by the concerned scientific group.

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

⁶ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

BIOCONTAM Unit

Minutes of the 4th meeting of the Working Group on Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs

Held on 24 November 2015, webconference

(Agreed on 30 November 2015)

Participants

- **Working Group Members:**

Ana Allende, Monika Ehling-Schulz, Niels Bohse Hendriksen, Anne-Brit Kolstø, Jacques Mahillon, Antonia Ricci (Chair), Vincent Sanchis

- **European Commission (DG SANTE):**

Unit E3: Sophie Hofkens

- **EFSA:**

BIOCONTAM Unit: Maria Teresa Da Silva Felicio, Giusi Amore

PRAS Unit: Laszlo Bura, Frederique Istace

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Pamina Mika Suzuki.

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 3rd Working Group meeting held on 18 November 2015.

The minutes of the 3rd Working Group meeting were agreed by written procedure on 25 November 2015.³

5. Scientific topic(s) for discussion

5.1. Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs⁴

The Working Group discussed in detail the pending actions, feedback from the BIOHAZ Panel on the draft opinion and reviewed carefully some contributions received on the draft opinion since the previous meeting.

The WG was updated on the organisation of the consultations with representatives of the International Biocontrol Manufacturers Association (IBMA) as well as on the Member State consultations via PSN network (PRAS Unit) and DG SANTE.

Decisions were taken regarding the inclusion criteria and search strategy for the literature review on the presence/levels of *B. thuringiensis* in foods. Tasks were allocated to the Working group Members.

6. Next meeting

The next meetings of the Working Group are:

- 9 December (web conference, 9:00 to 11:00) and
- 18 January (14:00 to 18:00) to 19 January (9:00 to 17:00), Parma).

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

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

³ <http://www.efsa.europa.eu/sites/default/files/biohazbacilluswgs.pdf>

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00254>

Annex

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This results in the exclusion of the expert from any discussion, voting or other processing of item 'ISO WG differentiation between *B. thuringiensis* and *B. cereus*' by the concerned scientific group.

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

⁶ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

BIOCONTAM Unit

Minutes of the 3rd meeting of the Working Group
on Risks for public health related to the presence
of *Bacillus cereus* and other *Bacillus* spp.
including *Bacillus thuringiensis* in foodstuffs

Held on 18 November 2015, webconference, 10:00-13:00

(Agreed on 25 November 2015)

Participants

- **Working Group Members:**

Ana Allende, Antonia Ricci (Chair)

- **European Commission (DG SANTE):**

Unit G4: Pamina Mika Suzuki (until 12:00)

- **EFSA:**

BIOCONTAM Unit: Maria Teresa Da Silva Felicio, Giusi Amore

PRAS Unit: Frederique Istace

AMU Unit: Laura Martino

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Sofie Hofkens.

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 2nd Working Group meeting held on 29-30 October 2015

The minutes of the 2nd Working Group meeting were agreed by written procedure on 23 October 2015.³

5. Scientific topic(s) for discussion

5.1. Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs⁴

The WG explored further together with the AMU colleague the possibility of doing a systematic literature review (SLR) on the presence/levels of *B. thuringiensis* in foods in the scope of this mandate. A preliminary proposal for the adequate search strategy (string, selected databases) was discussed and the practical feasibility of doing a systematic literature review was questioned. It was agreed that:

- (i) it will not be possible to do a systematic literature review due to the limited timelines of this mandate and available resources;
- (ii) efforts will be made to follow a structured approach to still perform an extensive literature search;
- (iii) the relevant search string will be refined and a draft protocol prepared defining eligibility criteria for the screening phase ;
- (iv) the AMU Unit will assist the *Bacillus* WG allocating the needed Distiller licenses to the WG members performing the literature search, training these on the use of the tool and guiding them when necessary on the followed approach.

Tasks were agreed among the participating WG members and EFSA staff.

6. Next meeting

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

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

³ <http://www.efsa.europa.eu/sites/default/files/biohazbacilluswgs.pdf>

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00254>

The next meetings of the Working Group are:

- 24 November (web conference, 9:00 to 11:00, Parma time),
- 9 December (9:00 to 12:00, Parma time)
- 18 January (14:00 to 18:00) to 19 January (9:00 to 17:00), Parma).

Annex

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

CONFLICT OF INTEREST: In the ADoI or in the SDoI filled for the present meeting Dr. Vincent Sanchis declared the following interest: expert in the ISO WG 20 differentiation between *B. thuringiensis* and *B. cereus*' (comité technique ISO/TC34 'food products', souscomité SC9 'Microbiology'). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁵ and the Decision of the Executive Director on Declarations of Interest⁶, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of item 'ISO WG differentiation between *B. thuringiensis* and *B. cereus*' by the concerned scientific group.

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

⁶ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

BIOCONTAM Unit

Minutes of the 2nd meeting of the Working Group on Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs

Held on 29-30 September 2015, Brussels (Belgium)

(Agreed on 23 October 2015)

Participants

- **Working Group Members:**

Ana Allende, Monika Ehling-Schulz, Niels Bohse Hendriksen, Anne-Brit Kolstø, Jacques Mahillon, Antonia Ricci (Chair), Vincent Sanchis

- **European Commission (DG SANTE):**

Unit E3: Sophie Hofkens

Unit G4: Pamina Mika Suzuki

- **EFSA:**

BIOCONTAM Unit: Maria Teresa Da Silva Felicio, Giusi Amore (participated via videoconference)

PRAS Unit: Laszlo Bura, Frederique Istace, Jeff Pim (all participated via video conference)

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 1st Working Group meeting held on 23 July 2015.

The minutes of the 1st Working Group meeting were agreed by written procedure on 5 August 2015.³

5. Scientific topic(s) for discussion

5.1. Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs⁴

The PRAS Unit presented their outsourced literature reviews in this area as well as the structure of the Draft Assessment Reports (DARs) provided for previous evaluation of *B. thuringiensis* plant protection products in EFSA in the context of the Pesticides' peer-review process. It was agreed to: (i) share one DAR with the WG to identify possible relevant sections that could be also checked in the other DARs; (ii) organise a technical consultation with representatives of the International Biocontrol Manufacturers Association (IBMA) and the questionnaire drafted by EFSA for this purpose was carefully reviewed, (iii) complement this technical consultation with the consultation of the Member States via PRAs network using a similar questionnaire.

The Working Group discussed thoroughly the terms of reference with the European Commission and agreed on approaches to answer these. It will not be possible to do a quantitative evaluation of the risk to public health

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² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

³ <http://www.efsa.europa.eu/sites/default/files/biohazbacilluswgs.pdf>

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00254>

arising from the presence of BT in food. Therefore only a qualitative evaluation will be done considering both the relevant scientific literature and the information from the background documents provided by the EC describing the specific cases in the alleged food poisoning due to *B. thuringiensis* in the EU. DG SANTE agreed to consult the Member States regarding possible national microbiological criteria or defined thresholds on *B. cereus* group in different types of food. The WG will explore further the possibility of doing a systematic literature review (SLR) on the presence/levels of *B. thuringiensis* in foods in the scope of this mandate. Tasks were allocated to the Working group Members.

6. Next meeting

The next meetings of the Working Group are:

- 24 November (web conference, 9:00 to 13:00, Parma times),
- if needed one web conference in December (date and time to be agreed) and
- 18 January (14:00 to 18:00) to 19 January (9:00 to 17:00), Parma).

Annex

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

CONFLICT OF INTEREST: In the ADoI or in the SDoI filled for the present meeting Dr. Vincent Sanchis declared the following interest: expert in the ISO WG 20 differentiation between *B. thuringiensis* and *B. cereus*' (comité technique ISO/TC34 'food products', souscomité SC9 'Microbiology'). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁵ and the Decision of the Executive Director on Declarations of Interest⁶, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

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Scientific Panel on Biological Hazards

BIOCONTAM Unit

Minutes of the 1st meeting of the Working Group on Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs

Held on 23 July 2015, Parma, Italy

(Agreed on 5 August 2015)

Participants

- **Working Group Members:**

Ana Allende, Monika Ehling-Schulz, Niels Bohse Hendriksen, Anne-Brit Kolstø, Jacques Mahillon, Antonia Ricci (Chair), Vincent Sanchis

- **European Commission (DG SANTE):**

Unit E3: Sophie Hofkens

Unit G4: Marina Marini, Pamina Mika Suzuki

- **EFSA:**

BIOCONTAM Unit: Maria Teresa Da Silva Felicio, Emmanouil Chantzis

PRAS Unit: Benedikte Vagenende, Jeff Pim

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Niels Bohse Hendriksen (WG Member).

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Scientific topic(s) for discussion

4.1. Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs³

The Working Group discussed the mandate received from the European Commission and its terms of reference. Data needs and the approach to answer the terms of reference were discussed. The table of contents of the draft scientific opinion were agreed and tasks were allocated to the Working group Members. The Working Group also discussed the opportunity to hold a technical consultation with stakeholders to gather data and information useful for the development of the Scientific Opinion. A repository in EFSA's document management system for relevant scientific documents was presented.

5. Next meeting

The next meetings of the Working Group are:

- 29 (afternoon) to 30 September (full day). This is still to be confirmed (including location).
- 4 November (web conference, 13:30-17:30, Parma times).

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

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

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Annex

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