

Scientific Panel on Biological Hazards

Minutes of the 16th meeting of the Working Group on QPS

Held on 6 and 7 October 2016, Madrid (Spain)

(Agreed on 9 November 2016)

Participants

- **Working Group Members:**

Pablo S. Fernandez Escamez

Amparo Querol

Günter Klein

Ingvar Sundh

Juan E. Suarez

Just Vlak

Lieve Herman

Luisa Peixe

Miguel Prieto Maradona

Pier Sandro Cocconcelli

- **Hearing Experts¹:**

Not Applicable

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

Not Applicable

- **EFSA:**

BIOCONTAM Unit: Sandra Correia

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>.

AMU Unit: Fulvio Barizzone

Pesticides Unit: Frederique Istace, Christopher Lythgo

FIP Unit: Margarita Aguilera-Gomez

These last 3 Units have participated via teleconference, in agenda point 5.1.

- **Others:**

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Leng Heng (Nutrition Unit) and Rosella Brozzi (FEED Unit).

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 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 15th Working Group meeting held on 20 June 2016, WEB/TELE-conference.

The minutes of the 15th Working Group meeting were agreed by written procedure on 30 June 2016.⁴

5. Scientific topics for discussion

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/assets/gps2014.pdf>

5.1. Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA⁵

Feedback from the previous BIOHAZ plenary (September) on the current draft opinion was provided by the chair to the WG. In reply to the suggestions received, some clarifications were included in the background of the document (for instance, on the purpose of the QPS exercise which is only intended for regulated products and for internal use by some EFSA Units). The experts went through the draft opinion and initially discussed the "Introduction" and "Data and methodology" chapters. The four EFSA Units for which the QPS assessment is done (Feed, FIP, Pesticides and Nutrition) were also invited to participate in the discussion in a dedicated point of the meeting Agenda to clarify some pending issues with the experts related to the QPS assessment. The "Assessment" chapter where the evaluations of the previous QPS recommendations and respective qualifications are included was thoroughly discussed. The structure of the different aspects considered for each specific assessment was revised and harmonised. The draft conclusions were also discussed by the experts. Some small pending issues will be sorted out by email after the meeting but in general the WG is satisfied with the current version.

Lessons were discussed and extracted from the extensive literature search (ELS) exercise run during this QPS mandate that will be compiled for the improvement of future exercises for the same purpose.

This Opinion will be presented to the BIOHAZ Panel for thorough reading at the plenary in October and for possible adoption at the plenary in December of 2016.

5.2. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 5: Suitability of taxonomic units notified to EFSA until March 2016⁶

The list of microorganisms notified to the four EFSA Units (Feed, FIP, Pesticides and Nutrition) has been again updated. From all notifications received since March 2016 until the beginning of September, three microorganisms were evaluated for a possible QPS recommendation. The evaluation of the respective taxonomic units was finalised by the experts. Some small pending issues will be sorted out by email after the meeting but in general the WG is satisfied with the current version.

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00018>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00697>

This Statement will be presented to the BIOHAZ Panel for thorough reading at the plenary in October and for possible adoption at the plenary in December of 2016.

6. Any Other Business

Not Applicable

7. Next meeting

None

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 Dr. Günter Klein declared the following interest: under "Occasional consultancy", participation in a meeting at EFSA in June 2014 concerning regulatory review of a dossier (*Bacillus toyonensis* as feed additive) as an *ad hoc* expert invited by a private company. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁷ and the Decision of the Executive Director on Declarations of Interest⁸, and taking into account the specific matters discussed at the meeting in question, a conflict of a specific nature has been identified in relation to the expert past consultancy activity for this company. The expert will be excluded from appraising his own work in the area of this *ad hoc* consultancy.

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

⁸ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

Minutes of the 15th meeting of the Working Group on QPS

Held on 20 June 2016, by WEB/TELE-conference

(Agreed on 30 June 2016)

Participants

- **Working Group Members:**

Pablo S. Fernandez Escamez

Pier Sandro Cocconcelli

Lieve Herman

Günter Klein

Miguel Prieto Maradona

Luisa Peixe

Amparo Querol

Ingvar Sundh

Just Vlak

- **Hearing Experts¹:**

Not Applicable

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

Not Applicable

- **EFSA:**

BIOCONTAM Unit: Sandra Correia, Mirena Ivanova

AMU Unit: Fulvio Barizzone, Andrea Bau

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>.

Pesticides Unit: Frederique Istace, Christopher Lythgo

FEED Unit: Rosella Brozzi

FIP Unit: Margarita Aguilera-Gomez

- **Others:**

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Juan E. Suarez and Leng Heng (Nutrition Unit).

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 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 14th Working Group meeting held on 20 April 2016, WEB/TELE-conference.

The minutes of the 14th Working Group meeting were agreed by written procedure on 29 April 2016.⁴

5. Scientific topics for discussion

5.1. Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA⁵

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/assets/qps2014.pdf>

The experts further improved the current draft opinion with focus on the introduction and methodology chapters. The four EFSA Units for which the QPS assessment is done (Feed, FIP, Pesticides and Nutrition) also revised those chapters and were invited to participate in a dedicated point of the meeting Agenda in order to discuss some pending issues with the experts related to the QPS assessment.

The workplan for the follow-up ELS was presented as well as the plan for the finalisation of the revision of the QPS list and of the scientific Opinion itself. Experts are starting to revise the previous recommendations for the QPS status and respective qualifications.

This Opinion will be presented to the BIOHAZ Panel for thorough reading at the plenary in October and for possible adoption at the plenary in December of 2016.

5.2. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 5: Suitability of taxonomic units notified to EFSA until March 2016⁶

The list of microorganisms notified to the four EFSA Units (Feed, FIP, Pesticides and Nutrition) has been updated. From all notifications received since March 2016 until the beginning of June, two microorganisms will go through the QPS assessment process. The evaluation of the respective taxonomic units was initialised by the experts. Units will be asked to further update the notifications list until September of 2016.

This Statement will be presented to the BIOHAZ Panel for thorough reading at the plenary in October and for possible adoption at the plenary in December of 2016.

6. Any Other Business

Not Applicable

7. Next meeting

- 16th WG meeting (6 October 2016) (physical meeting)

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00018>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00697>

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 Dr. Günter Klein declared the following interest: participation in a meeting at EFSA in June 2014 concerning regulatory review of a dossier (*Bacillus toyonensis* as feed additive) organised by EFSA as an ad hoc expert invited by the company. The invitation to the meeting was arranged on short term due to unavailability of the original expert of the same Institute and is on behalf of representing the original expert in the meeting. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁷ and the Decision of the Executive Director on Declarations of Interest⁸, 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 *Bacillus toyonensis* by the concerned scientific group.

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

⁸ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

Minutes of the 14th meeting of the Working Group on QPS

Held on 20 April 2016, by WEB/TELE-conference

(Agreed on 29 April 2016)

Participants

- **Working Group Members:**

Pablo S. Fernandez Escamez

Pier Sandro Cocconcelli

Lieve Herman

Günter Klein

Miguel Prieto Maradona

Luisa Peixe

Amparo Querol

Juan E. Suarez

Ingvar Sundh

Just Vlak

- **Hearing Experts¹:**

Not Applicable

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

Not Applicable

- **EFSA:**

BIOCONTAM Unit: Sandra Correia

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>.

AMU Unit: Fulvio Barizzone

Pesticides Unit: Frederique Istace, Christopher Lythgo

- **Others:**

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Andrea Bau (AMU).

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 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 13th Working Group meeting held on 2 and 10 March 2016, WEB/TELE-conference.

The minutes of the 13th Working Group meeting were agreed by written procedure on 4 April 2016.⁴

5. Scientific topics for discussion

5.1. Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA⁵

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/assets/qps2014.pdf>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00189>

The experts went through the current draft opinion and further improved the introduction and methodology chapters. The four EFSA Units for which the QPS assessment is done (Feed, FIP, Pesticides and Nutrition) have been once more asked to also revise those chapters. Pesticides Unit participated in a dedicated point of the meeting Agenda in order to discuss some pending issues with the experts related to the pesticides regulatory framework and the QPS assessment. The Units will be asked again to revise the draft opinion, on the aspects linked to the specific regulatory frameworks, the type of assessments developed and the usefulness or limitations of the QPS assessment.

The state of the art of the ELS process was presented. The article evaluation phase is almost finished and only a few conflicts are to be settled. The plan for the follow up ELS was presented by AMU to the experts. Experts will start revising the previous recommendations for the QPS status and respective qualifications.

5.2. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 4: Suitability of taxonomic units notified to EFSA until March 2016⁶

The list of microorganisms notified to the four EFSA Units (Feed, FIP, Pesticides and Nutrition) has been updated. From all notifications received since September 2015 until the end of March, twelve microorganisms in total will go through the QPS assessment process. The evaluation of the respective new taxonomic units was initialised by the experts. The two taxonomic units that have been already initialised wave been finalised.

This Statement will be presented to the BIOHAZ Panel for thorough reading at the plenary in April and for possible adoption at the plenary in June of 2016.

6. Any Other Business

Not Applicable

7. Next meeting

- 15th WG meeting (20 June pm) (web conference)
- 16th WG meeting (6 October 2016) (physical meeting)

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00697>

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 Dr. Günter Klein declared the following interest: participation in a meeting at EFSA in June 2014 concerning regulatory review of a dossier (*Bacillus toyonensis* as feed additive) organised by EFSA as an ad hoc expert invited by the company. The invitation to the meeting was arranged on short term due to unavailability of the original expert of the same Institute and is on behalf of representing the original expert in the meeting. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁷ and the Decision of the Executive Director on Declarations of Interest⁸, 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 *Bacillus toyonensis* by the concerned scientific group.

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

⁸ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

Minutes of the 13th meeting of the Working Group on QPS

Held on 2 and 10 March 2016, by WEB/TELE-conference

(Agreed on 4 April 2016)

Participants

- **Working Group Members:**

Pablo S. Fernandez Escamez^{1,2}

Pier Sandro Cocconcelli²

Lieve Herman¹

Günter Klein¹

Miguel Prieto Maradona¹

Luisa Peixe¹

Amparo Querol¹

Juan E. Suarez²

Ingvar Sundh²

Just Vlak¹

- **Hearing Experts³:**

Not Applicable

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

Not Applicable

¹ Participated on 2 March

² Participated on 10 March

³ 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>.

- **EFSA:**
BIOCONTAM Unit: Sandra Correia, Mirena Ivanova
AMU Unit: Fulvio Barizzone, Andrea Bau
- **Others:**
Not Applicable

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 Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, 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 12th Working Group meeting held on 9 February 2016 in Parma.

The minutes of the 12th Working Group meeting were agreed by written procedure on 19 February 2016.⁶

5. Scientific topics for discussion

5.1. Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA⁷

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

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁶ <http://www.efsa.europa.eu/sites/default/files/assets/qps2014.pdf>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00189>

During the two web conference meeting, experts were informed of the state of the art of the ELS exercise for each taxonomic unit group and doubts about the procedure for the article evaluation phase were clarified. The on-going discrepancies identified by Distiller were presented and a procedure to discuss and solve those discrepancies was established.

6. Any Other Business

Not Applicable

7. Next meeting

- 14th WG meeting (20 April pm) (web conference)
- 15th WG meeting (20 June pm) (web conference)
- 16th WG meeting (5 or 6 October 2016) (physical meeting)

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 Dr. Günter Klein declared the following interest: participation in a meeting at EFSA in June 2014 concerning regulatory review of a dossier (*Bacillus toyonensis* as feed additive) organised by EFSA as an ad hoc expert invited by the company. The invitation to the meeting was arranged on short term due to unavailability of the original expert of the same Institute and is on behalf of representing the original expert in the meeting. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁸ and the Decision of the Executive Director on Declarations of Interest⁹, 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 *Bacillus toyonensis* by the concerned scientific group.

⁸ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁹ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

Minutes of the 12th meeting of the Working Group on QPS

Held on 9 February 2016, Parma (Italy)

(Agreed on 19 February 2016)

Participants

- **Working Group Members:**

Pablo S. Fernandez Escamez

Pier Sandro Cocconcelli

Lieve Herman

Günter Klein

Miguel Prieto Maradona

Luisa Peixe

Amparo Querol

Juan E. Suarez

Ingvar Sundh

Just Vlak

- **Hearing Experts¹:**

Not Applicable

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

Not Applicable

- **EFSA:**

BIOCONTAM Unit: Sandra Correia, Mirena Ivanova

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>.

AMU Unit: Fulvio Barizzone
FIP Unit: Margarita Aguilera-Gomez
Pesticides Unit: Frederique Istace

- **Others:**
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Andrea Bau (AMU), Rosella Brozzi (Feed Unit) and Leng Heng (Nutrition Unit).

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 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 11th Working Group meeting held on 25 September 2015, WEB/TELE-conference.

The minutes of the 11th Working Group meeting were agreed by written procedure on 5 October 2015.⁴

5. Scientific topics for discussion

5.1. Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA⁵

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/assets/qps2014.pdf>

The experts went through the current draft opinion and kept improving the introduction and methodology sections.

The four EFSA Units for which the QPS assessment is done (Feed, FIP, Pesticides and Nutrition) have been previously asked to revise the introduction and methodology sections, to provide input and also to participate in a dedicated point of the meeting Agenda. They will be further asked to revise the introduction and methodology sections on the aspects linked to the specific Regulatory frameworks, the type of assessments developed and the usefulness or limitations of the QPS assessment.

The state of art of the ELS process was presented by AMU. The screening phase is almost finished and the 2nd phase - article evaluation, is starting. Doubts, concerns and limitations found during this process were presented and discussed.

5.2. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 4: Suitability of taxonomic units notified to EFSA until March 2016⁶

The list of microorganisms notified to the four EFSA Units (Feed, FIP, Pesticides and Nutrition) has been updated. From all notifications received since September 2015, two microorganisms will go through the QPS assessment process. The evaluation of the respective taxonomic units was initialised by the experts.

6. Any Other Business

Not Applicable

7. Next meeting

- 13th WG meeting (2 and 10 March) (web conference)
- 14th WG meeting (20 April pm) (web conference)
- 15th WG meeting (20 June pm) (web conference)
- 16th WG meeting (5 or 6 October 2016) (physical meeting)

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00189>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00697>

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 Dr. Günter Klein declared the following interest: participation in a meeting at EFSA in June 2014 concerning regulatory review of a dossier (*Bacillus toyonensis* as feed additive) organised by EFSA as an ad hoc expert invited by the company. The invitation to the meeting was arranged on short term due to unavailability of the original expert of the same Institute and is on behalf of representing the original expert in the meeting. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁷ and the Decision of the Executive Director on Declarations of Interest⁸, 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 *Bacillus toyonensis* by the concerned scientific group.

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

⁸ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

Minutes of the 11th meeting of the Working Group on QPS

Held on 25 September 2015, by WEB/TELE-conference

(Agreed on 1 October 2015)

Participants

- **Working Group Members:**

Pablo S. Fernandez Escamez

Lieve Herman

Miguel Prieto Maradona

Luisa Peixe

Güenter Klein

Juan E. Suarez

Just Vlak

Ingvar Sundh via teleconference (participated from 13-16h)

- **Hearing Experts¹:**

Not Applicable

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

Not Applicable

- **EFSA:**

BIOCONTAM Unit: Sandra Correia

AMU Unit: Fulvio Barizzone, Andrea Bau

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>.

- **Others:**

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Amparo Querol and Pier Sandro Cocconcelli.

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 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 10th Working Group meeting held between 29 June and 28 July 2015, WEB/TELE-conference.

The minutes of the 10th Working Group meeting were agreed by written procedure on 23 September 2015.⁴

5. Scientific topics for discussion

5.1. Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA⁵

The experts went through the current draft opinion and further revised the introduction and methodology sections. The four EFSA Units for which the QPS assessment is done (Feed, FIP, Pesticides and Nutrition) will be asked again to revise the introduction and methodology sections on the aspects linked to the specific Regulatory framework, the type of

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

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

⁴ <http://www.efsa.europa.eu/en/biohazwqs/docs/qps2014.pdf>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00189>

assessments developed and the usefulness or limitations of the QPS assessment.

AMU Unit presented the revised ELS strategies, specific to groups of taxonomic units, which were improved to facilitate the literature searches and to minimise the efforts during the screening/ study selection phases. AMU will finalise the specific ELS strategies according to the input received during the meeting and will share it again with the WG for final approval.

5.2. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 3: Suitability of taxonomic units notified to EFSA until September 2015⁶

The list of microorganisms notified to the four EFSA Units (Feed, FIP, Pesticides and Nutrition) has been updated. From all notifications received since March 2015, three further microorganisms will go through the QPS assessment process. The evaluation of those taxonomic units was discussed by the experts.

6. Any Other Business

Not Applicable

7. Next meeting

- 12th WG meeting (end January - beginning February 2016) (physical meeting) - date to be confirmed

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00696>

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 Dr Günter Klein declared the following interest: participation in a meeting at EFSA in June 2014 concerning regulatory review of a dossier (*Bacillus toyonensis* as feed additive) organised by EFSA as an ad hoc expert invited by the company. The invitation to the meeting was arranged on short term due to unavailability of the original expert of the same Institute and is on behalf of representing the original expert in the meeting. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁷ and the Decision of the Executive Director on Declarations of Interest⁸, 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 *Bacillus toyonensis* by the concerned scientific group.

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

⁸ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

Minutes of the 10th meeting of the Working Group on QPS

Held by WEB/TELE-conference between 29 June and 28 July 2015

(Agreed on 23 September 2015)

Participants

- **Working Group Members:**

Ingvar Sundh¹
Günter Klein²
Pablo S. Fernandez Escamez³
Amparo Querol⁴
Miguel Prieto Maradona⁵
Juan E. Suarez⁵
Luisa Peixe⁶
Pier Sandro Cocconcelli⁷
Just Vlak⁸

- **Hearing Experts:⁹**

Not Applicable

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

Not Applicable

¹ Participated on 29 June 2015.

² Participated on 2 July 2015.

³ Participated on 6 July 2015.

⁴ Participated on 8 July 2015.

⁵ Participated on 9 July 2015.

⁶ Participated on 15 July 2015.

⁷ Participated on 22 July 2015.

⁸ Participated on 29 July 2015.

⁹ 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>.

- **EFSA:**
AMU Unit: Lara Congiu
BIOCONTAM Unit: Sandra Correia
- **Others:**
Not Applicable

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 Processes¹⁰ and the Decision of the Executive Director on Declarations of Interest,¹¹ 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 9th Working Group meeting held on 2 July 2015, WEB/TELE-conference

The minutes of the 9th Working Group meeting were agreed by written procedure on 10 July 2015.¹²

5. Scientific topics for discussion

5.1. Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA¹³

During the individual teleconferences, held between 29 June and 28 July 2015, the AMU Unit liaised with each WG expert in order to get focussed

¹⁰ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

¹¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

¹² <http://www.efsa.europa.eu/en/biohazwqs/docs/qps2014.pdf>

¹³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00189>

and definitive feed-backs on the search strings to be used. Based on their specific expertise, AMU led the experts to tailor search strings in the most effective and appropriate way so as to reach an effective agreement and provide the relevant references needed. The main points discussed during each of the individual teleconferences were: taxonomic units and specific outcome search strings, timespan, databases and search field to be used.

6. Any Other Business

Not Applicable

7. Next meeting

11th WG meeting: 25 September 2015, web/teleconference

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 Dr Günter Klein declared the following interest: participation in a meeting at EFSA in June 2014 concerning regulatory review of a dossier (*Bacillus toyonensis* as feed additive) organised by EFSA as an ad hoc expert invited by the company. The invitation to the meeting was arranged on short term due to unavailability of the original expert of the same Institute and is on behalf of representing the original expert in the meeting. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹⁴ and the Decision of the Executive Director on Declarations of Interest,¹⁵ 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 *Bacillus toyonensis* by the concerned scientific group.

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

¹⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

Minutes of the 9th meeting of the Working Group on QPS

Held on 2 July 2015, Parma (Italy)

(Agreed on 8 July 2015)

Participants

- **Working Group Members:**

Pablo S. Fernandez Escamez

Miguel Prieto Maradona

Luisa Peixe

Pier Sandro Cocconcelli

Günter Klein

Juan E. Suarez

Just Vlak

Ingvar Sundh via teleconference (participated from 13.00 to 16.00)

- **Hearing Experts:¹**

Not Applicable

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

Not Applicable

- **EFSA:**

BIOCONTAM Unit: Sandra Correia

AMU Unit: Laura Ciccolallo

Feed Unit: Rosella Brozzi

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>.

FIP Unit: Margarita Aguilera-Gomez, Anne Theobald

Pesticides Unit: Christopher Lythgo

Nutrition Unit: Wolfgang Gelbmann

- **Others:**

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Amparo Querol.

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 Processes² and the Decision of the Executive Director on Declarations of Interest,³ 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 8th Working Group meeting held on 16 April 2015, WEB/TELE-conference

The minutes of the 8th Working Group meeting were agreed by written procedure on 21 April 2015.⁴

5. Scientific topics for discussion

5.1. Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA⁵

The experts went through the current draft opinion and revised thoroughly the introduction and methodology sections. The four EFSA

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

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

⁴ <http://www.efsa.europa.eu/en/biohazwqs/docs/qps2014.pdf>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00189>

Units for which the QPS assessment is done (Feed, FIP, Pesticides and Nutrition) have been previously asked to revised the introduction and methodology sections, to provide input and also to participate in a dedicated point of the meeting Agenda.

5.2. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 3: Suitability of taxonomic units notified to EFSA until July 2015⁶

The list of microorganisms notified to the four EFSA Units (Feed, FIP, Pesticides and Nutrition) has been updated. From all notifications received since October 2014, one microorganism will go through the QPS assessment process. The initial evaluation was discussed by the experts.

6. Any Other Business

Not Applicable

7. Next meeting

10th WG meeting: between 29 June and 28 July, bilateral web/teleconferences with each expert

11th WG meeting: 25 September 2015, web/teleconference

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00696>

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 Dr Günter Klein declared the following interest: participation in a meeting at EFSA in June 2014 concerning regulatory review of a dossier (*Bacillus toyonensis* as feed additive) organised by EFSA as an ad hoc expert invited by the company. The invitation to the meeting was arranged on short term due to unavailability of the original expert of the same Institute and is on behalf of representing the original expert in the meeting. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁷ and the Decision of the Executive Director on Declarations of Interest,⁸ 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 *Bacillus toyonensis* by the concerned scientific group.

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

⁸ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards
Minutes of the 8th meeting of the Working Group on QPS
WEB-conference, 16 April 2015
(Agreed on 21 April 2015)

Participants

- **Working Group Experts:**
 - Miguel Prieto Maradona (Chair)
 - Pablo S. Fernandez Escamez
 - Pier Sandro Cocconcelli (until 15:30h)
 - Güenter Klein
 - Juan E. Suarez

- **Hearing Experts¹:**
 - Not Applicable

- **European Commission and/or Member States representatives:**
 - Not Applicable

- **EFSA:**
 - BIOCONTAM Unit (Sandra Correia, Emmanouil Chantzis)

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.

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>.

3. Declarations of interest

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 6th Working Group meeting held on 23 March 2015 by web conference.

The minutes of the 6th Working Group meeting were agreed by written procedure on 15 April 2015⁴.

5. Scientific topics for discussion

5.1. Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA⁵

The list of microorganisms recommended for the QPS list in 2013 and their qualifications will be revised according to new scientific knowledge through an Extensive literature Search (ELS) being developed by the WG with the support of Assessment and Methodological Support Unit (AMU). The revised list will be included in the scientific opinion to be finalised by December of 2016. AMU presented the summary of the pilot test exercise run during the month of March.

6. Any Other Business

6.1. Not applicable

7. Next meetings

9th WG meeting – 2 July (Parma)

10th WG meeting – 25 September (web-conference)

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

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

⁴ <http://www.efsa.europa.eu/cs/BlobServer/en/biohazwgs/docs/WgQPS2014.pdf>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00189>

Annex

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

- a) **CONFLICT OF INTEREST:** In the ADoI and SDoI filled for the present meeting **DR. GÜNTER KLEIN** declared the following interest: participation in a meeting at EFSA in June 2014 concerning regulatory review of a dossier (*Bacillus toyonensis* as feed additive) organised by EFSA as an *ad hoc* expert invited by the company. The invitation to the meeting was arranged on short term due to unavailability of the original expert of the same Institute and is on behalf of representing the original expert in the meeting. 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 *Bacillus toyonensis* by the concerned scientific group.

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

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

Biocontaminants (BIOCONTAM) Unit

Scientific Panel on Biological Hazards
Minutes of the 7th meeting of the Working Group on QPS
WEB-conference, 31 March 2015
(Agreed on 21 April 2015)

Participants

- **Working Group Experts:**
 - Miguel Prieto Maradona (Chair)
 - Amparo Querol
 - Luisa Peixe
 - Ingvar Sundh

- **Hearing Experts¹:**
 - Not Applicable

- **European Commission and/or Member States representatives:**
 - Not Applicable

- **EFSA:**
 - BIOCONTAM Unit (Sandra Correia, Emmanouil Chantzis)

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

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

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>.

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 23 March 2015 by web conference.

The minutes of the 6th Working Group meeting were agreed by written procedure on 15 April 2015⁴.

5. Scientific topics for discussion

5.1. Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA⁵

The list of microorganisms recommended for the QPS list in 2013 and their qualifications will be revised according to new scientific knowledge through an Extensive literature Search (ELS) being developed by the WG with the support of Assessment and Methodological Support Unit (AMU). The revised list will be included in the scientific opinion to be finalised by December of 2016. AMU presented the summary of the pilot test exercise run during the month of March.

6. Any Other Business

6.1. Not applicable

7. Next meetings

8th WG meeting – 16 April (web-conference)

9th WG meeting – 2 July (Parma)

10th WG meeting – 25 September (web-conference)

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

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

⁴ <http://www.efsa.europa.eu/cs/BlobServer/en/biohazwgs/docs/WgQPS2014.pdf>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00189>

Annex

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

- a) **CONFLICT OF INTEREST:** In the ADoI and SDoI filled for the present meeting **DR. GÜNTER KLEIN** declared the following interest: participation in a meeting at EFSA in June 2014 concerning regulatory review of a dossier (*Bacillus toyonensis* as feed additive) organised by EFSA as an *ad hoc* expert invited by the company. The invitation to the meeting was arranged on short term due to unavailability of the original expert of the same Institute and is on behalf of representing the original expert in the meeting. 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 *Bacillus toyonensis* by the concerned scientific group.

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

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

Biocontaminants (BIOCONTAM) Unit

Scientific Panel on Biological Hazards
Minutes of the 6th meeting of the Working Group on QPS
WEB-conference, 23 March 2015
(Agreed on 31 March 2015)

Participants

- **Working Group Experts:**
 - Miguel Prieto Maradona (Chair)
 - Christophe Nguyen-the (participated from 10-11h)
 - Luisa Peixe
 - Pablo S. Fernandez Escamez
 - Pier Sandro Cocconcelli
 - Güenter Klein (participated from 10-13h)
 - Juan E. Suarez

- **Hearing Experts¹:**
 - Not Applicable

- **European Commission and/or Member States representatives:**
 - Not Applicable

- **EFSA:**
 - BIOCONTAM Unit (Sandra Correia, Emmanouil Chantzis)

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>.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received by Ingvar Sundh, Just Vlak, and Amparo Querol.

2. Adoption of agenda

The agenda was adopted with only one change. An extra bullet was added to the end to discuss the on-going situation of the ELS pilot search.

3. Declarations of interest

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 3 February 2015 in Valencia, Spain.

The minutes of the 5th Working Group meeting were agreed by written procedure on 26 February 2015⁴

5. Scientific topics for discussion

5.1. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 2: Suitability of taxonomic units notified to EFSA until January 2015⁵

The assessment according to the QPS approach of the microorganisms that have been notified to date and which are not currently present in the QPS list, was finalised by the experts. These evaluations, included in the Panel Statement, will be presented for possible adoption at the BIOHAZ Panel meeting in June of 2015.

5.2. Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA⁶

The revision of the list of microorganisms recommended for the QPS list in 2013 and their qualifications will be revised according to new scientific knowledge through an Extensive literature Search (ELS) being developed by the Assessment and Methodological Support Unit (AMU) and in close collaboration with the WG. The revised list will be included in the scientific opinion to be finalised by December of 2016. Experts revised the current draft opinion with special attention to the introductory parts.

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

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

⁴ <http://www.efsa.europa.eu/cs/BlobServer/en/biohazwgs/docs/WgQPS2014.pdf>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00695>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00189>

6. Any Other Business

6.1. Not applicable

7. Next meetings

7th WG meeting – 31 March (web-conference)

8th WG meeting – 16 April (web-conference)

Annex

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

- a) **CONFLICT OF INTEREST:** In the ADoI and SDoI filled for the present meeting **DR. GÜNTER KLEIN** declared the following interest: participation in a meeting at EFSA in June 2014 concerning regulatory review of a dossier (*Bacillus toyonensis* as feed additive) organised by EFSA as an *ad hoc* expert invited by the company. The invitation to the meeting was arranged on short term due to unavailability of the original expert of the same Institute and is on behalf of representing the original expert in the meeting. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁷ and the Decision of the Executive Director on Declarations of Interest⁸, 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 *Bacillus toyonensis* by the concerned scientific group.

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

⁸ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Biocontaminants (BIOCONTAM) Unit

Scientific Panel on Biological Hazards
Minutes of the 5th meeting of the Working Group on QPS
Held on 3 February 2015, Valencia (Spain)
with a VIDEO/WEB-conference (afternoon)
(Agreed on 26 February 2015)

Participants

- **Working Group Experts:**
 - Miguel Prieto Maradona (Chair)
 - Amparo Querol
 - Christophe Nguyen-the
 - Luisa Peixe
 - Pablo S. Fernandez Escamez
 - Pier Sandro Cocconcelli

- **Hearing Experts¹:**
 - Not Applicable

- **European Commission and/or Member States representatives:**
 - Not Applicable

- **EFSA:**
 - BIOCONTAM Unit (Sandra Correia)
 - AMU Unit (Andrea Baù; Laura Ciccolallo and Lara Congiu by Video-conference)

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>.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Günter Klein, Ingvar Sundh, Juan E. Suarez and Just Vlak.

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 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 4th Working Group meeting held on 12 and 13 November 2014, WEB/TELE-conference.

The minutes of the 4th Working Group meeting were agreed by written procedure on 24 November 2014⁴

5. Scientific topics for discussion

5.1. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 2: Suitability of taxonomic units notified to EFSA until January 2015⁵

The current state of the work plan was updated to the WG. The assessment according to the QPS approach of the microorganisms that have been recently notified and which are not currently present in the QPS list, was initialised by the experts. These evaluations will be included in the Panel Statement that will be presented for possible adoption at the BIOHAZ Panel meeting in June of 2015.

5.2. Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA⁶

The revision of the list of microorganisms recommended for the QPS list in 2013 and their qualifications will be revised according to new scientific knowledge through an Extensive literature Search (ELS) being developed by the Assessment and Methodological Support Unit (AMU) and in close collaboration with the WG. The protocol and work plan to follow were discussed. The revised list will be included in the scientific opinion to be finalised by December of 2016.

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

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

⁴ <http://www.efsa.europa.eu/en/biohazwgs/docs/qps2014.pdf>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00695>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00189>

6. Any Other Business

6.1. Not applicable

7. Next meeting

6th WG meeting – middle/ end of March (date to be defined)

Annex

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

- a) **CONFLICT OF INTEREST:** In the ADoI and SDoI filled for the present meeting **DR. GÜNTER KLEIN** declared the following interest: participation in a meeting at EFSA in June 2014 concerning regulatory review of a dossier (*Bacillus toyonensis* as feed additive) organised by EFSA as an *ad hoc* expert invited by the company. The invitation to the meeting was arranged on short term due to unavailability of the original expert of the same Institute and is on behalf of representing the original expert in the meeting. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁷ and the Decision of the Executive Director on Declarations of Interest⁸, 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 *Bacillus toyonensis* by the concerned scientific group.

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

⁸ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on BIOHAZ
Minutes of the 4th meeting of the Working Group on QPS
VIDEO/WEB-conference, 12 11 2014 (afternoon) and 13 11 2014 (morning)
(Agreed on 24 11 2014)

Participants

- **Working Group Experts:**
 - Miguel Prieto Maradona (Chair)
 - Amparo Querol
 - Christophe Nguyen-the
 - Günter Klein
 - Ingvar Sundh
 - Juan E. Suarez
 - Luisa Peixe
 - Pablo S. Fernandez Escamez
 - Pier Sandro Cocconcelli
 - Just Vlak

- **EFSA:**
 - BIOCONTAM Unit (Sandra Correia)
 - AMU Unit (Laura Ciccolallo, Andrea Baù)

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

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 (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the SDoI, please refer to Annex I.

4. **Agreement of the minutes of the 3rd Working Group meeting held on 21 10 2014, Madrid.** The minutes were agreed by written procedure on 5 11 2014 and published on the EFSA website 6 11 2014.

5. Scientific topic for discussion

5.1. Topic n°1 ([Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 1: Suitability of taxonomic units notified to EFSA until July 2014](#))

The current state of the work plan was described to the WG. The assessment according to the QPS approach of the microorganisms that have been notified and which are not currently present in the QPS list, was finalised by the experts. These evaluations will be included in the Panel Statement that will be presented for possible adoption at the BIOHAZ Panel meeting in December of 2014.

5.2. Topic n°2 ([Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA](#))

The revision of the list of microorganism recommended for the QPS list in 2013 and their qualifications will be revised according to new scientific knowledge through an Extensive literature Search (ELS) already being developed by the Assessment and Methodological Support Unit (AMU) and in close collaboration with the WG. The protocol and approach to follow were decided. The revised list will be included in a scientific opinion to be finalised by December of 2016.

6. Next meetings

5th WG meeting - end of January (date to be defined) - Valencia

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

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

Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)³

- a) **CONFLICT OF INTEREST:** In the SDoI filled for the present meeting **DR. GÜNTER KLEIN** declared the following interest: participation in a meeting at EFSA in June 2014 concerning regulatory review of a dossier (*Bacillus toyonensis* as feed additive) organised by EFSA as an *ad hoc* expert invited by the company. The invitation to the meeting was arranged on short term due to unavailability of the original expert of the same institute and is on behalf of representing the original expert in the meeting. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when that item of the meeting (evaluation of *Bacillus toyonensis*) is discussed, voted on or in any way processed by that concerned scientific group.

³ The Annual Declarations of Interests have been screened and approved before inviting the experts to the meeting, in accordance with the Decision of the Executive Director implementing the Policy on Independence regarding Declarations of Interests.

Scientific Panel on BIOHAZ
Minutes of the 3rd meeting of the Working Group on QPS
Held on 21 10 2014, Madrid
(Agreed on 05 11 2014)

Participants

- **Working Group Experts:**
 - Miguel Prieto Maradona (Chair)
 - Amparo Querol
 - Christophe Nguyen-the
 - Günter Klein
 - Ingvar Sundh
 - Juan E. Suarez
 - Luisa Peixe
 - Pablo S. Fernandez Escamez
 - Pier Sandro Cocconcelli
 - Just Vlak

- **EFSA:**
 - BIOCONTAM Unit (Sandra Correia)
 - AMU Unit (Laura Ciccolallo, Andrea Baù)

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

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 (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the SDoI, please refer to Annex I.

4. Agreement of the minutes of the 2nd Working Group meeting held on 17 09 2014, WEB/TELE-conference. The minutes were agreed by written procedure on 2 10 2014 and published on the EFSA website 3 10 2014.

5. Scientific topic for discussion

5.1. Topic n°1 ([Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 1: Suitability of taxonomic units notified to EFSA until July 2014](#))

The current state of the work plan was described to the WG. The microorganisms that have been notified and which are not currently present in the QPS list, were further assessed by the experts. These evaluations will be included in a Panel Statement that will be presented for possible adoption at the BIOHAZ Panel meeting in December of 2014.

5.2. Topic n°2 ([Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA](#))

The revision of the list of microorganism recommended for the QPS list in 2013 and their qualifications will be revised according to new scientific knowledge through an Extensive literature Search (ELS) already being developed by the Assessment and Methodological Support Unit (AMU) and in close collaboration with the WG. The protocol and approach to follow were further refined. The revised list will be included in a scientific opinion to be finalised by December of 2016.

6. Next meetings

4th WG meeting - 12/13 November - web conference

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

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

Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)³

- a) **CONFLICT OF INTEREST:** In the SDoI filled for the present meeting **DR. GÜNTER KLEIN** declared the following interest: participation in a meeting at EFSA in June 2014 concerning regulatory review of a dossier (*Bacillus toyonensis* as feed additive) organised by EFSA as an *ad hoc* expert invited by the company. The invitation to the meeting was arranged on short term due to unavailability of the original expert of the same institute and is on behalf of representing the original expert in the meeting. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when that item of the meeting (evaluation of *Bacillus toyonensis*) is discussed, voted on or in any way processed by that concerned scientific group.

³ The Annual Declarations of Interests have been screened and approved before inviting the experts to the meeting, in accordance with the Decision of the Executive Director implementing the Policy on Independence regarding Declarations of Interests.

Scientific Panel on BIOHAZ
Minutes of the 2nd meeting of the Working Group on QPS
WEB/ TELE-conference, 17 09 2014

(Agreed on 02 10 2014)

Participants

• **Working Group Experts:**

- Miguel Prieto Maradona (Chair)
- Amparo Querol
- Christophe Nguyen-the
- Güenter Klein
- Ingvar Sundh
- Juan E. Suarez
- Luisa Peixe
- Pablo S. Fernandez Escamez
- Pier Sandro Cocconcelli
- Just Vlæk

• **EFSA:**

- BIOCONTAM Unit (Sandra Correia)
- AMU Unit (Laura Ciccolallo, Lara Congiu, Andrea Baù)

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

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director implementing this Policy regarding

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

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.

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

4. Agreement of the minutes of the 1st Working Group meeting held on 04 06 2014 (afternoon) and 05 06 2014 (morning), Parma. The minutes were agreed by written procedure on 10 06 2014 and published on the EFSA website 12 06 2014.

5. Scientific topic for discussion

5.1. Topic n°1 ([Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 1: Suitability of taxonomic units notified to EFSA until July 2014](#))

The current state of the work plan was explained to the WG. The microorganism that have been notified and which are not currently present in the QPS list, are being assessed by the experts. These evaluations will be included in a Panel Statement that will be presented for possible adoption at the BIOHAZ Panel meeting in December of 2014.

5.2. Topic n°2 ([Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA](#))

The revision of the list of microorganism recommended for the QPS list in 2013 and their qualifications will be revised according to new scientific knowledge through an Extensive literature Search (ELS) already being developed by the Assessment and Methodological Support Unit (AMU) and in close collaboration with the WG. It will be included in a scientific opinion to be published by December of 2016.

6. Next meetings

- 3rd WG meeting - 21 October – Madrid
- 4th WG meeting - 12/13 November - web conference

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

Annex I

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

- a) **CONFLICT OF INTEREST:** With regard to this meeting **DR. GÜNTER KLEIN** declared the following interest: participation in a meeting at EFSA in June 2014 concerning regulatory review of a dossier (*Bacillus toyonensis* as feed additive) organised by EFSA as an ad hoc expert invited by the company. The invitation to the meeting was arranged on short term due to unavailability of the original expert of the same Institute and is on behalf of representing the original expert in the meeting. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when that item (evaluation of *Bacillus toyonensis*) is discussed, voted on or in anyway processed by that concerned scientific group.

BIOCONTAM UNIT

Scientific Panel on BIOHAZ

Minutes of the 1st meeting of the Working Group on QPS

Held on 04 06 2014 (afternoon) and 05 06 2014 (morning), Parma

(Agreed on 10 06 2014)

Participants

• **Working Group Experts:**

- Miguel Prieto Maradona (Chair)
- Amparo Querol
- Christophe Nguyen-the
- Günter Klein
- Ingvar Sundh
- Juan E. Suarez
- Luisa Peixe
- Pablo S. Fernandez Escamez
- Pier Sandro Cocconcelli
- Just Vlak has participated via teleconference

• **EFSA:**

- Sandra Correia, Winy Messens (BIOCONTAM), Aguilera-Gomez Margarita (FIP), Istace Frederique (PRAS)

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received. Just Vlak did not participate in agenda points 5 (first part), 6 and 7.

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 topic for discussion

5.1 Topic n°1 ([update of the list of QPS recommended biological agents intentionally added to food or feed as notified to EFSA](#))

The self-task mandate and its terms of reference were presented by the Chair to the experts. The proposal for the work plan was discussed and agreed. The updated list of microorganisms notified by the EFSA Units was presented to the experts. The deadline for adoption is December of 2016 but in the meantime, BIOHAZ Panel statements will be published according to the needs of the EFSA Units. Representatives of those Units were invited to the meeting in order to exchange some views with the experts on the work plan and explain specificities from each area. Finally, tasks were defined in accordance to the work plan and attributed to the working group experts. An extensive literature search will be developed in order to collect new scientific information for the review of the current list of QPS microorganisms and their qualifications.

5. Next meetings

- 2nd WG meeting - 17 September – web conference
- 3rd WG meeting - 21 October – Madrid
- 4th WG meeting - 12/13 November - web conference

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

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