

SCIENTIFIC PANEL ON BIOHAZ

MINUTES OF THE 12th MEETING OF THE WORKING GROUP ON QPS

Held on 21 and 22 October (9:00-13:00 and 14:00-18:00) in Parma

(Agreed on 12 November 2019)

Participants

■ Working Group Members:

Lieve Herman (chair)

Amparo Querol

Ingvar Sundh

Juan E. Suarez

Just Vlak

Luisa Peixe

Marianne Chemaly

Miguel Prieto Maradona

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: Fulvio Barizzzone (10:00–11:00) 21 October

Nutrition Unit: Annamaria Rossi (09:00–10:00) 21 October

Feed Unit: Rosella Brozzi (09:00–10:00) 22 October

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



FIP Unit: Jaime Aguilera (09:00–10:00) 21 October

Pesticides Unit: Frédérique Istace (09:00–10:00) 21 October

■ 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 Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 11th Working Group meeting held by web/tele conference on 9 September 2019.

The minutes of the 11th Working Group meeting held on 9 September 2019 were agreed by written procedure on 30 September 2019."⁴

5. Scientific topic(s) for discussion

5.1. Self-task mandate for Scientific opinion on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA ⁵

The screening and evaluation of possible safety concerns published in literature related to the taxonomic units included in the QPS list, for the period between January and June 2019, was finalised. The overall summary of the several ELS exercises run the current 3 years mandate was included in the Opinion. The deadline proposed for this mandate and this opinion is December of 2019.

5.2. Self-task mandate for a statement on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/sites/default/files/wqs/biological-hazards/qps2019.pdf>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684>



notified to EFSA. 11: Suitability of taxonomic units notified to EFSA until September 2019⁶

The 48 microorganisms from applications for market authorisation between April to September 2019 were included in the QPS notification list. Of these, 21 biological agents already had QPS status and did not require further evaluation in this Statement and 12 were not included because: 6 were notifications of filamentous fungi that were excluded from the QPS exercise; 5 were notifications of *Escherichia coli* that were excluded from further QPS evaluations within the current QPS mandate and *Sphingomonas paucimobilis* which was already evaluated in the previous Panel Statement. 15 new notifications were considered for the QPS assessment within this Statement: *Aurantiochytrium limacinum*, *Bacillus velezensis*, *Cupriavidus necator*, *Geobacillus thermoglucosidans*, *Hamamotoba singularis*, *Lactobacillus parafarraginis*, *Pantoea ananatis*, *Kodamaea ohmeri*, *Paenibacillus illinoisensis*, *Protaminobacter rubrum*, *Schizochytrium limacinum*, *Rhodococcus aetherovorans*, *Rhodococcus ruber*, *Tetraselmis chuii*, *Zygosaccharomyces rouxii*. The Panel Statement will be presented for possible adoption at the BIOHAZ Panel plenary in December 2019.

6. Any Other Business

Not Applicable

7. Next meetings

Not applicable

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00832>

SCIENTIFIC PANEL ON BIOHAZ

MINUTES OF THE 11th MEETING OF THE WORKING GROUP ON QPS

WEB/TELE-conference, 9 September

(Agreed on 30 September 2019)

Participants

■ Working Group Members:

Lieve Herman (chair)

Amparo Querol

Ingvar Sundh

Juan E. Suarez

Just Vlak

Luisa Peixe

Marianne Chemaly

Miguel Prieto Maradona

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: Fulvio Barizzzone (11:00–12:00)

Nutrition Unit: Patricia Romero (14:00–15:00)

Feed Unit: Rosella Brozzi (14:00–15:00)

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<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 Jaime Aguilera (FIP Unit) and Frédérique Istace (Pesticides 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 Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 10th Working Group meeting held on 21/22 May 2019, Valencia, Spain.

The minutes of the 11th Working Group meeting held on 21/22 May 2019 were agreed by written procedure on 7 June 2019."⁴

5. Scientific topic(s) for discussion

5.1. Self-task mandate for Scientific opinion on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA ⁵

The screening and evaluation of possible safety concerns published in literature related to the taxonomic units included in the QPS list, for the period between January and June 2019, was initiated in July and will be finalised in October. The overall summary of the several ELS exercises run the current 3 years mandate will be included in the Opinion. The deadline proposed for this mandate and this opinion is December of 2019.

5.2. Self-task mandate for a statement on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/qps2019.pdf>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684>



notified to EFSA. 11: Suitability of taxonomic units notified to EFSA until September 2019⁶

The draft Panel Statement was discussed by the WG. The QPS notification list was updated with 39 microorganisms from applications for market authorisation. Of these, 21 already had QPS status, 18 were excluded from the QPS exercise by the previous QPS mandate (4 filamentous fungi) or from further evaluations within the current mandate (6 notifications of *Escherichia coli*). *Bacillus velezensis*, *Geobacillus thermoglucosidans* (*Parageobacillus thermoglucosidasius*), *Hamamotoa singularis*, *Pantoea ananatis*, *Protaminobacter rubrum*, *Schizochytrium* sp. and *Tetraselmis chuii* were evaluated for the *first* time. New TUs may arrive and will be included until the end of September. The Panel Statement will be presented for possible adoption at the BIOHAZ Panel plenary in December 2019.

6. Any Other Business

Not Applicable

7. Next meetings

- 12th WG meeting: 21 - 22 October, Parma

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00832>

SCIENTIFIC PANEL ON BIOHAZ

MINUTES OF THE 10th MEETING OF THE WORKING GROUP ON QPS

21 and 22 May 2019, Valencia Spain

(Agreed on 7 June 2019)

Participants

■ Working Group Members:

Lieve Herman (chair)

Amparo Querol

Ingvar Sundh (only on 22 May)

Juan E. Suarez

Just Vlak

Luisa Peixe

Marianne Chemaly (by web conference)

Miguel Prieto Maradona

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

Nutrition Unit: Annemaria Rossi by web conference (21 May 14:00–15:00)

Feed Unit: Rosella Brozzi by web conference (21 May 14:00–15:00)

TS Unit: Marco Conterbia/ Ricardo Bonini by web conference (21 May 15:00–16:00)

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



AMU Unit: Fulvio Barizzzone by web conference (21 May 16:00–17:00)

- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jaime Aguilera (FIP Unit) and Frédérique Istace (Pesticides 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 Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 9th Working Group meeting held on 21 January 2019, Parma.

The minutes of the 9th Working Group meeting held on 21 January 2019 were agreed by written procedure on 11 February 2019."⁴

5. Scientific topic(s) for discussion

5.1. Self-task mandate for Scientific opinion on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA ⁵

The screening and evaluation of possible safety concerns published in literature related to the taxonomic units included in the QPS list, for the period between July and December 2018, was finalised. The overall summary of the several ELS exercises run the current 3 years mandate will be included in the Opinion. The deadline proposed for this mandate and this opinion is December of 2019.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/qps2019.pdf>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684>



5.2. Self-task mandate for a statement on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA. 10: Suitability of taxonomic units notified to EFSA until March 2019⁶

The discussion of the draft Panel Statement was finalised by the WG. The QPS notification list was updated with 45 microorganisms from applications for market authorisation. Of these, 19 already had QPS status, 18 were excluded from the QPS exercise by the previous QPS mandate (11 filamentous fungi) or from further evaluations within the current mandate (7 notifications of *Escherichia coli*). *Sphingomonas elodea*, *Gluconobacter frateurii*, *Corynebacterium ammoniagenes*, *Corynebacterium casei*, *Burkholderia ubonensis*, *Phaeodactylum tricornutum*, *Microbacterium foliorum* and *Euglena gracilis* were evaluated for the first time. The Panel Statement will be presented for possible adoption at the BIOHAZ Panel plenary in June 5 and 6.

6. Any Other Business

Not Applicable

7. Next meetings

- 11th WG meeting: 9 September, Web conference
- 12th WG meeting: 21 - 22 October, Parma

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00831>

SCIENTIFIC PANEL ON BIOHAZ

MINUTES OF THE 9TH MEETING OF THE WORKING GROUP ON QPS

WEB/TELE-conference, 21 January 2019

(Agreed on 11 February 2019)

Participants

■ Working Group Members:

Lieve Herman (chair)

Amparo Querol

Ingvar Sundh

Juan E. Suarez

Just Vlak

Luisa Peixe

Marianne Chemaly

Miguel Prieto Maradona

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: Fulvio Barizzzone (13:40 – 15:00 h)

■ Others:

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Wolfgang Gelbmann, Leng Heng (Nutrition Unit), Jaime Aguillera (FIP Unit), Rosella Brozzi (Feed Unit) and Frédérique Istace (Pesticides 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 Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 8th Working Group meeting held on 23 October 2018, Parma.

The minutes of the 8th Working Group meeting held on 23 October 2018 were agreed by written procedure on 5 November 2018.⁴

5. Scientific topic(s) for discussion

5.1. Self-task mandate for Scientific opinion on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA⁵

The initial chapters of the draft Opinion were finalised by the WG. The screening of possible safety concerns published in literature related to the taxonomic units included in the QPS list, for the period between July and December 2018, will be launched soon with the support of AMU Unit. The summary of the several ELS exercises run during these 3 years period will be included in the Opinion. The deadline proposed for this mandate and this opinion is December of 2019.

5.2. Self-task mandate for a statement on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/sites/default/files/wqs/biological-hazards/qps2019.pdf>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684>



notified to EFSA. 10: Suitability of taxonomic units notified to EFSA until March 2019⁶

The discussion of the draft Panel Statement was initialised by the WG. The QPS notification list was updated with 21 applications, received from October and December 2018 for market authorisation: 9 biological agents already had QPS status and 10 were excluded of the QPS exercise from the previous QPS mandate (6 filamentous fungi) or from further evaluations within the current mandate (four notifications of *Escherichia coli*). One taxonomic unit was (re)evaluated: *Sphingomonas elodea* and *Gluconobacter frateurii* will be evaluated for the first time. The deadline for this Panel Statement is June 2019.

6. Any Other Business

Not Applicable

7. Next meetings

- 10th WG meeting: 21- 22 May, Valencia
- 11th WG meeting: 9 September PM, Web conference
- 12th WG meeting: 21 - 22 October, Parma

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00831>

Scientific Panel on BIOHAZ

Minutes of the 8th meeting of the Working Group on QPS

Held on 23 October (09:00-17:00) in Parma

(Agreed on 5 November 2018)

Participants

- **Working Group Members:**

Lieve Herman (chair)
Amparo Querol
Ingvar Sundh
Juan E. Suarez
Just Vlak
Luisa Peixe
Marianne Chemaly
Miguel Prieto Maradona
Pablo S. Fernandez Escamez
Pier Sandro Cocconcelli

- **Hearing Experts¹:**

Not Applicable

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

Not Applicable

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>.

- **EFSA:**

BIOCONTAM Unit: Sandra Correia, Michaela Hempen

AMU Unit: Fulvio Barizzzone (10:00 – 13:00 h)

Nutrition Unit: Leng Heng (09:00-11:00 h)

Feed Unit: Rosella Brozzi (09:00-11:00 h)

- **Others:**

Not Applicable

1. Welcome and apologies for absence

The chair welcomed the participants. Apologies were received from Wolfgang Gelbmann (Nutrition Unit), Jaime Aguilera (FIP Unit) and Frédérique Istace (Pesticides 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 Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topics for discussion

4.1. Self-task mandate for Scientific opinion on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA⁴

The initial chapters of the draft Opinion were further discussed by the WG. The screening of possible safety concerns published in literature related to

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

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

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684>

the taxonomic units included in the QPS list, for the period between January and June 2018, is being finalised by experts supported by AMU Unit. The summary of the discussion on the revision of the current qualification on "*Absence of resistance to antimycotics used for medicinal treatment of yeast infections, in cases where viable cells are added to the food or feed chain*" was finalised. The deadline proposed for this mandate and this opinion is December of 2019.

4.2. Self-task mandate for a statement on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA. 9: Suitability of taxonomic units notified to EFSA until September 2018⁵

The draft Panel Statement was finalised by the WG. The QPS notification list was updated with 59 applications, received from April and September 2018 for market authorisation: 39 biological agents already had QPS status and 16 were excluded of the QPS exercise from the previous QPS mandate (6 filamentous fungi) or from further evaluations within the current mandate (three notification of *Enterococcus faecium* and seven of *Escherichia coli*). One taxonomic unit was (re)evaluated: *Pseudomonas fluorescens* had been previously evaluated in 2016, and was now re-evaluated within this mandate, and *Mycobacterium setense* and *Komagataeibacter sucrofermentans* were evaluated for the first time. The deadline for this Panel Statement is December 2018.

5. Any Other Business

Not Applicable

6. Next meeting

- Meeting dates for 2019 to be defined.

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00830>

Scientific Panel on BIOHAZ

Minutes of the 7th meeting of the Working Group on QPS

Held on 17 September (13:00-17:00) by WEB/TELE-conference

(Agreed on 24 September 2017)

Participants

- **Working Group Members:**

Lieve Herman (chair)
Pablo S. Fernandez Escamez
Pier Sandro Cocconcelli
Miguel Prieto Maradona
Luisa Peixe
Amparo Querol
Ingvar Sundh
Juan E. Suarez
Marianne Chemaly
Just Vlak

- **Hearing Experts¹:**

Malcolm Richardson

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

Not Applicable

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>.

- **EFSA:**

BIOCONTAM Unit: Sandra Correia

AMU Unit: Fulvio Barizzzone (14:30 – 15:30 h)

FIP Unit: Jaime Aguilera (15:15-16:15 h)

Nutrition Unit: Wolfgang Gelbmann (13:15-16:15 h)

- **Others:**

Not Applicable

1. Welcome and apologies for absence

The chair welcomed the participants. Apologies were received from Just Vlak, Leng Heng (Nutrition Unit), Rosella Brozzi (Feed Unit) and Frédérique Istace (Pesticides 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 Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topics for discussion

4.1. Self-task mandate for Scientific opinion on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA⁴

The initial chapters of the draft Opinion were further discussed by the WG. The screening of possible safety concerns published in literature related to the taxonomic units included in the QPS list, for the period between January to June 2018, was initiated by experts supported by AMU Unit.

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

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

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684>

Professor Malcom Richardson was invited as a hearing expert to provide expertise data and information for the revision of the current qualification on “*Absence of resistance to antimicrobials used for medicinal treatment of yeast infections, in cases where viable cells are added to the food or feed chain*”. The deadline proposed for this mandate and this opinion is December of 2019.

4.2. Self-task mandate for a statement on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA. 9: Suitability of taxonomic units notified to EFSA until September 2018⁵

The draft Panel Statement was finalised by the WG. The QPS notification list was updated with 22 applications, received from April and September 2018 for market authorisation: 15 biological agents already had QPS status and 4 were excluded of the QPS exercise from the previous QPS mandate (2 filamentous fungi) or from further evaluations within the current mandate (one notification of *Enterococcus faecium* and one of *Escherichia coli*). One taxonomic unit was (re)evaluated: *Pseudomonas fluorescens* had been previously evaluated in 2016, and was now re-evaluated within this mandate, and *Mycobacterium setense* and *Komagataeibacter sucrofermentans* were evaluated for the first time. The deadline for this Panel Statement is December 2018.

5. Any Other Business

Not Applicable

6. Next meeting

- 23 October in Parma

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00830>

Scientific Panel on BIOHAZ

Minutes of the 6th meeting of the Working Group on QPS

**Held on 2 May (14:00-18:00) and 3 May 2018 (08:30-16:00) in
Parma**

(Agreed on 28 May 2017)

Participants

- **Working Group Members:**

Lieve Herman (chair)
Pablo S. Fernandez Escamez
Pier Sandro Cocconcelli
Miguel Prieto Maradona
Luisa Peixe
Amparo Querol
Ingvar Sundh
Juan E. Suarez
Marianne Chemaly (joined by web conference)
Just Vlak

- **Hearing Experts¹:**

Not Applicable

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

Not Applicable

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>.

- **EFSA:**

BIOCONTAM Unit: Sandra Correia, Michaela Hempen

AMU Unit: Fulvio Barizzzone, Ana Garcia

Nutrition Unit: Wolfgang Gelbmann

Pesticides Unit: Frederique Istace, Benedicte Vagenende

Feed Unit: Rosella Brozzi

- **Others:**

Not Applicable

1. Welcome and apologies for absence

The chair welcomed the participants. Apologies were received from Leng Heng (Nutrition Unit) and Jaime Aguilera (FIP 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 Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topics for discussion

4.1. Self-task mandate for Scientific opinion on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA⁴

The initial chapters of the draft Opinion were further discussed by the WG. The screening of possible safety concerns published in literature related to the taxonomic units included in the QPS list, for the period between June and December 2017, was finalised by experts. AMU is supporting this

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

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

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684>

activity as well on applying “machine learning technique” to screen references. EFSA Units were invited to provide input to this meeting. Some relevant aspects that may play a more important role within the QPS assessment (whole genome sequencing - WGS, antimicrobial resistance - AMR, antimycotic resistance, definition of body of knowledge, etc.) were further discussed. The deadline proposed for this mandate and this opinion is December of 2019.

4.2. Self-task mandate for a statement on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA. 8: Suitability of taxonomic units notified to EFSA until September 2017⁵

The draft Panel Statement was finalised by the WG. The QPS notification list was updated with 46 applications, received from September 2017 and March 2018 for market authorisation: 28 biological agents already had QPS status and 15 were not included as they are filamentous fungi or bacteriophages. Two notifications of *Streptomyces albus* and one of *Escherichia coli* were not considered for the assessment as they belong to taxonomic units that were excluded from further evaluations within the current QPS mandate. Three taxonomic units were evaluated: *Paracoccus carotinifaciens*, already evaluated in 2008, and *Paenibacillus lentus*, already evaluated in 2014, were now reevaluated within this mandate. The deadline for this Panel Statement is June 2018.

5. Any Other Business

Not Applicable

6. Next meeting

- 17 September by web-conference
- 23 October in Parma

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00829>

Scientific Panel on BIOHAZ

Minutes of the 5th meeting of the Working Group on QPS

**Held on 26 February (09:00-13:00) 2017 by WEB/TELE-
conference**

(Agreed on 26 March 2017)

Participants

- **Working Group Members:**

Lieve Herman (chair)
Pablo S. Fernandez Escamez
Pier Sandro Cocconcelli
Miguel Prieto Maradona
Luisa Peixe
Amparo Querol
Ingvar Sundh
Juan E. Suarez
Marianne Chemaly
Just Vlak

- **Hearing Experts¹:**

Not Applicable

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

Not Applicable

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>.

- **EFSA:**

BIOCONTAM Unit: Sandra Correia, Michaela Hempen

AMU Unit: Fulvio Barizzzone, Ana Garcia

Feed Unit: Rosella Brozzi, Jaime Aguilera

FIP Unit: Margarita Aguilera-Gómez

- **Others:**

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Leng Heng (Nutrition Unit) and Frederique Istace (Pesticides 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 Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topics for discussion

4.1. Self-task mandate for Scientific opinion on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA⁴

The initial chapters of the draft Opinion were further discussed by the WG. The screening of possible safety concerns published in literature related to the taxonomic units included in the QPS list, for the period between June and December 2017, is being finalised by experts. The 2nd phase, article

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

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

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684>

evaluation, will be started as soon all PDFs are uploaded in DistillerSR. AMU is supporting this activity as well on applying “machine learning technique” to screen references. EFSA Units were invited to provide input to this meeting. Some relevant aspects that may play a more important role within the QPS assessment (whole genome sequencing - WGS, antimicrobial resistance - AMR, antimycotic resistance, definition of body of knowledge, etc.) were further discussed. The deadline proposed for this mandate and this opinion is December of 2019.

4.2. Self-task mandate for a statement on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA. 8: Suitability of taxonomic units notified to EFSA until September 2017⁵

The draft Panel Statement was discussed and agreed by the WG. The QPS notification list was updated with 33 applications, received from September 2017 and March 2018 for market authorisation: 19 biological agents already had QPS status and 9 were not included as they are filamentous fungi or bacteriophages. One notification of *Streptomyces albus* and one of *Escherichia coli* were not considered for the assessment as they belong to taxonomic units that were excluded from further evaluations within the current QPS mandate. One notification of *Pseudomonas* sp. is pending the receipt of the complete application in the area of plant protection products. Three taxonomic units were evaluated: *Paracoccus carotinifaciens*, already evaluated in 2008, and *Paenibacillus lentus*, already evaluated in 2014, were now reevaluated within this mandate. The deadline for this Panel Statement is June 2018.

5. Any Other Business

Not Applicable

6. Next meeting

- 2 and 3 May 2018 in Parma
- 17 September by web-conference
- 23 October in Parma

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00829>

Scientific Panel on BIOHAZ

Minutes of the 4th meeting of the Working Group on QPS

**Held on 16 (14:00-18:00) and 17 (09:00- 17:00) October 2017 in
Parma**

(Agreed on 4 December 2017)

Participants

- **Working Group Members:**

Lieve Herman (chair)
Pablo S. Fernandez Escamez
Pier Sandro Cocconcelli
Miguel Prieto Maradona
Luisa Peixe
Amparo Querol
Ingvar Sundh
Juan E. Suarez
Marianne Chemaly
Just Vlak

- **Hearing Experts¹:**

Not Applicable

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

Not Applicable

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>.

- **EFSA:**
BIOCONTAM Unit: Sandra Correia
AMU Unit: Fulvio Barizzzone, Ana Garcia
- **Others:**
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Michaela Hempen (BIOCONTAM), Leng Heng (Nutrition Unit), Rosella Brozzi (Feed Unit) and Margarita Aguilera-Gómez (FIP Unit) and Frederique Istace (Pesticides 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 Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topics for discussion

4.1. Self-task mandate for Scientific opinion on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA⁴

The state of the art of scientific opinion and the approach to follow were further discussed by the WG. A search for possible safety concerns published in literature related to the taxonomic units included in the QPS list was run for the period June 2016 to June 2017. Experts are finalising the extraction from the literature of safety concerns identified as relevant

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

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

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684>

for the QPS exercise. AMU is supporting the WG on this latter activity as well on developing a “machine learning technique” pilot trial for screening references containing possible safety concerns. EFSA Units were invited to provide input to this meeting. There was a thorough discussion of several relevant aspects that may play a more important role within the QPS assessment (WGS, AMR, definition of body of knowledge, place of genetic modifications, etc). The deadline proposed for this mandate and this opinion is December of 2019.

4.2. Self-task mandate for a statement on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA. 7: Suitability of taxonomic units notified to EFSA until September 2017⁵

The draft Panel Statement was discussed and agreed by the WG. The QPS notification list was updated with 46 applications for market authorisation: 14 biological agents already had the QPS status and did not require further evaluation in this Statement, 16 are filamentous fungi or enterococci which were excluded from the QSP exercise, one notification of *Streptomyces* K-61 (notified as former *S. griseoviridis*) and four of *Escherichia coli* were excluded from further QPS evaluations within the current QPS mandate, eight of *Bacillus thuringiensis* and one of an oomycete are pending the reception of the complete application. Two new taxonomic units were considered for the QPS assessment within this Statement: *Kitasatospora paracochleata* which had not been evaluated before and *Komagataella phaffii*, which had been previously notified as *Pichia pastoris*, was now included due to that change in the taxonomic identity. The deadline for this Panel Statement is December of 2016.

5. Any Other Business

Not Applicable

6. Next meeting

WG meeting dates for 2018 to be defined

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00828>

Scientific Panel on Biological Hazards

Minutes of the 3rd meeting of the Working Group on QPS

**Held on 18 September (14:00-18:00) 2017 by WEB/TELE-
conference**

(Agreed on 02 October 2017)

Participants

- **Working Group Members:**

Lieve Herman (chair)
Pablo S. Fernandez Escamez
Pier Sandro Cocconcelli
Miguel Prieto Maradona
Luisa Peixe
Amparo Querol
Ingvar Sundh
Juan E. Suarez
Marianne Chemaly
Just Vlak

- **Hearing Experts¹:**

Not Applicable

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

Not Applicable

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>.

- **EFSA:**

BIOCONTAM Unit: Sandra Correia, Michaela Hempen

AMU Unit: Fulvio Barizzzone

Pesticides Unit: Frederique Istace

Feed Unit: Jaime Aguilera

- **Others:**

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Ana Garcia (AMU Unit), Leng Heng (Nutrition Unit), Rosella Brozzi (Feed Unit) and Margarita Aguilera-Gómez (FIP 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 Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topics for discussion

4.1. Self-task mandate for Scientific opinion on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA⁴

The state of the art of scientific opinion and the approach to follow were further discussed by the WG. A search for possible safety concerns published in literature related to the taxonomic units included in the QPS

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

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

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684>

list was run at the end of June 2017. Experts are going through the selection phase of the hits found. AMU is supporting the WG on this latter activity as well on developing a “machine learning technique” pilot trial for screening references containing possible safety concerns. EFSA Units were invited to the meeting. Feed Unit was invited to present the report from the contract for a database on the potential toxigenic capacities of microorganisms used for production of food enzymes and feed additives which have not a recommendation for a QPS status. The deadline proposed for this mandate and this opinion is December of 2019.

4.2. Self-task mandate for a statement on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA. 7: Suitability of taxonomic units notified to EFSA until September 2017⁵

The draft seventh Panel Statement was discussed by the WG. The QPS notification list was updated with 42 applications for market authorisation which were received between April of 2017 and September 2017. From these, 12 biological agents already had a QPS status, and 17 were not included in the evaluation as they are filamentous fungi or enterococci. *Streptomyces* K-61 (notified as former *S. griseoviridis*), *Bacillus thuringiensis* (eight notifications) and *Escherichia coli* (one notification) were not considered for the assessment. *Streptomyces* spp. and *E. coli* were excluded from further QPS evaluations within the current QPS mandate. The assessment of *Bacillus thuringiensis* is pending the reception of the complete application. The TU related to a previous notification of *Pichia pastoris* is now considered a new species *Komagataella pastoris* therefore it may be included in the current assessment.

5. Any Other Business

Not Applicable

6. Next meeting

- 4th WG meeting – 16, 17 October 2017

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00828>

Scientific Panel on Biological Hazards

Minutes of the 2nd meeting of the Working Group on QPS¹

Held on 23 (9:00-18:00), 24 (14:00-18:00) May 2017, Parma, Italy

(Agreed on 15 June 2017)

Participants

- **Working Group Members:**

Lieve Herman (chair)
Pablo S. Fernandez Escamez
Pier Sandro Cocconcelli
Miguel Prieto Maradona
Luisa Peixe
Amparo Querol
Ingvar Sundh
Juan E. Suarez
Marianne Chemaly

- **Hearing Experts¹:**

Not Applicable

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

Not Applicable

- **EFSA:**

BIOCONTAM Unit: Sandra Correia, Michaela Hempen
FIP Unit (23 May, 13:30 – 15:30): Margarita Aguilera-Gómez
AMU Unit (24 May, 10:45 – 12:30): Fulvio Barizzzone, Ana Garcia

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 Just Vlak, Leng Heng (Nutrition Unit), Frederique Istace, Christopher Lythgo (Pesticides 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 Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topics for discussion

4.1. Self-task mandate for a statement on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA. 6: Suitability of taxonomic units notified to EFSA until March 2017⁴

The sixth Panel Statement was finalised by the WG. It includes the assessment of the 10 taxonomic units notified to EFSA between September of 2016 and March 2017 which were not yet included in the QPS list. From these, only one was recommended for the QPS list (*Lactobacillus animalis*). After re-evaluation, the Panel has agreed that *Escherichia coli* and *Streptomyces* spp. will be excluded from further QPS evaluations within the current mandate. The WG considered the opinion ready to be proposed for adoption at the next BIOHAZ plenary meeting.

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

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

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00827>

4.2. Self-task mandate for Scientific opinion on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA⁵

The state of the art of scientific opinion and the approach to follow were discussed by the WG. It included the changes to be made in the approach for the extensive literature search (ELS). It is foreseen to run a new search for possible safety concerns published in literature at the end of June, concerning the taxonomic units included in the QPS list. AMU is supporting the WG on this latter activity as well on developing a “machine learning technique” pilot trial for screening references related to possible new safety concerns. The relevant EFSA Units were invited to the meeting to reinforce collaboration experts. The deadline proposed for this mandate and this opinion is December of 2019.

5. Any Other Business

Not Applicable

6. Next meeting

- 3rd WG meeting – 18 September 2017
- 4th WG meeting – 16, 17 October 2017

⁵<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684>

Scientific Panel on Biological Hazards

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

Held on 18 March 2017, by WEB/TELE-conference

(Agreed on 03 April 2017)

Participants

- **Working Group Members:**

Lieve Herman
Pablo S. Fernandez Escamez
Pier Sandro Cocconcelli
Miguel Prieto Maradona
Luisa Peixe
Amparo Querol
Ingvar Sundh
Juan E. Suarez

- **Hearing Experts¹:**

Not Applicable

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

Not Applicable

- **EFSA:**

BIOCONTAM Unit: Sandra Correia
AMU Unit: Fulvio Barizzzone, Ana Garcia

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 Marianne Chemaly, Just Vlak, Leng Heng (Nutrition Unit), Frederique Istace, Christopher Lythgo (Pesticides Unit), Rosella Brozzi (Feed Unit), Margarita Aguilera-Gomez (FIP 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 Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topics for discussion

4.1. Scientific Opinion on the update of the list of Qualified Presumption of Safety (QPS) recommended biological agents intentionally added to food or feeds as notified to EFSA⁴

The self-task mandate and its terms of reference were presented by the EFSA scientific secretariat to the experts. The proposal for the work plan was discussed and agreed. Tasks were defined in accordance to the work plan and attributed to the working group experts. Frequent extensive literature searches (ELS) will be continued in order to collect new scientific information for the review of the current list of QPS microorganisms and their qualifications. The deadline for adoption is December of 2019.

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

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

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684>

4.2. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. 6: Suitability of taxonomic units notified to EFSA until March 2017⁵

The updated list of microorganisms notified by the EFSA Units was presented to the experts. The list of microorganisms notified to the four EFSA Units (Feed, FIP, Pesticides and Nutrition) has been updated and the new taxonomic units that require an evaluation for a possible QPS recommendation have been identified. From all notifications received since September 2016 until the beginning of March 2017, 11 microorganisms will go through the QPS assessment process.

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 2017.

5. Any Other Business

Not Applicable

6. Next meeting

- 2nd WG meeting – 23/24 May 2017
- 3rd WG meeting – July/ September 2017 (TBD) – web conference
- 4th WG meeting – October 2017

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00827>