

Scientific Panel on Biological Hazards

Minutes of the 6th meeting of the Working Group on “an updated Quantitative Risk Assessment (QRA) of the BSE risk posed by Processed Animal Protein (PAP)”

Physical Meeting on 26-27 April 2018

(Agreed on 4 May 2018)¹

Participants

- **Working Group Members:**

Amie Adkin (AA), Daniela Marchis (DM), Marta Prado (MP), Giuseppe Ru (GR), Marion M. Simmons (MMS) (Chair)

- **EFSA:**

BIOCONTAM Unit: Angel Ortiz Pelaez (AOP)

1. Welcome and apologies for absence

The Chair welcomed the participants. Matthias Greiner sent apologies.

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

¹ The publication of the minutes shall be made without delay in compliance with the Founding Regulation and no later than 15 working days following the day of their agreement.

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

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 topic(s) for discussion⁴

A review of the actions from the previous meeting was conducted. On day 1, a thorough review of the current content of the background, data and methodologies and assessment sections to address ToR1 was conducted. Most of the comments were either deleted or transformed into new actions. Answer to TOR1 was consolidated in a more mature draft.

On Day 2 the modelling part was discussed and a number of decisions were made: a) to maintain the batch size for continuous processing as in the 2011 model, and 2) report the scenario analysis of the starting point with the full infectivity of one single animal not reduced/inactivated by any of the steps in the feed chain, in order and estimate the risk of new BSE cases in cattle should the controls be removed. For the FEED model a review was conducted during the meeting and it was agreed to run the model at a higher probability of contamination of a feed sample as an alternative scenario for the potential lift of the feed ban (pig in poultry and vice versa) and test the linearity of the outputs. As scenario analysis to assess the variability of the sampling in the EU, it was also agreed to run the model with the number of samples collected in 2015 and 2016.

The section 'Conclusions' was deleted. The section 'Recommendations' was reviewed and amended substantially. There was no time to review the Appendices and Annex. There was no time to address the issues of uncertainty, biological relevance and weight of evidence during her meeting and will have to be elaborated by the WG members and added to their contributions after the meeting.

5. Work plan: tasks and deadlines

Actions were agreed during the discussion of the ToRs. This was the last meeting of the WG. No other points for discussion were raised. The Chair and EFSA Secretariat thanked the members for their contributions during the lifespan of the mandate and the Chair closed the meeting.

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

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00705>

Scientific Panel on Biological Hazards

Minutes of the 5th meeting of the Working Group on “an updated Quantitative Risk Assessment (QRA) of the BSE risk posed by Processed Animal Protein (PAP)”

Web-conference on 26 March 2018

(Agreed on 2 April 2018)¹

Participants

- **Working Group Members:**

Amie Adkin (AA), Daniela Marchis (DM), Marta Prado (MP), Giuseppe Ru (GR), Marion M. Simmons (MMS) (Chair)

- **EFSA:**

BIOCONTAM Unit: Maria Teresa da Silva Felicio (TF), Angel Ortiz Pelaez (AOP), Pietro Stella (PS).

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies received from Matthias Greiner *a posteriori*.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

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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 topic(s) for discussion⁴

A review of the actions from the previous meeting was conducted. The chair provided feedback on the first reading of the opinion to the BIOHAZ panel. The Panel welcomed the approaches adopted by the WG but some members were concerned about the lack of time and suitable data, and the difficulty to expand the current model and to develop a new one in the available time. It was agreed to apply the 2011 EFSA PAP model with the single risk pathway and updated data and finalise the simplified FEED model. It was also agreed to submit the two models to selected Panel members for their review before the next plenary meeting.

The updates of the PAP and FEED models were presented and discussed, trying to reduce uncertainty and differentiating it from variability. Some parameters were questioned, as well as the data sources applied to inform probability distributions. A number of proposals in the form of sensitivity analysis and the application of alternative models were agreed, to evaluate the impact of the uncertain parameters on the outputs. There was no time to discuss the content of the Assessment section in the current version of the opinion to address the ToR1. A draft of the answer to the ToR1 was discussed briefly. Due to lack of time, it was agreed to circulate bullet points to start drafting the answers to the three ToRs even if the results of the models are not yet available.

5. Work plan: tasks and deadlines

Actions were agreed during the discussion of the ToRs. As agreed prior to this meeting, the 6th WG meeting will be a physical meeting in Parma on 26-27 April 2018 lunch to lunch.

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-2017-00705>

Scientific Panel on Biological Hazards

Minutes of the 4th meeting of the Working Group on “an updated Quantitative Risk Assessment (QRA) of the BSE risk posed by Processed Animal Protein (PAP)”

Physical Meeting on 26-27 February 2018

(Agreed on 5 March 2018)¹

Participants

- **Working Group Members:**

Amie Adkin (AA), Matthias Greiner (MG) (Day 2), Daniela Marchis (DM), Marta Prado (MP), Giuseppe Ru (GR), Marion M. Simmons (MMS) (Chair)

- **EFSA:**

BIOCONTAM Unit: Angel Ortiz Pelaez (AOP), Maria Teresa da Silva Felicio (TF) (via web-conference, except 27 February 9-12am)

- **European Commission:**

DG-SANTE: Sara Perucho Martinez (SPM) (G4)

1. Welcome and apologies for absence

The Chair welcomed the participants. MG sent apologies for day 1.

2. Adoption of agenda

The agenda was adopted without changes.

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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.

GR and DM were not present at the start of the meeting but they joined after point 3 and the chair asked them if they had any new interest to declare. MG only attended day 2 and the chair asked at the beginning of the session if he had any new interest to declare. Nothing was declared.

4. Scientific topic(s) for discussion⁴

A review of the actions from the previous meeting was conducted. On day 1, a thorough review of the current content of the background, data and methodologies and assessment sections to address ToR1 was conducted. The WG went through the different sections and minor changes and corrections were agreed. The concluding remarks were agreed by the WG, which will be the basis to answer ToR1. On Day 2 the modelling part was discussed. An extra developed model was presented attempting to simulate the impact of the technical zero on the ability to detect within the feed chain contaminated feed with ruminant content (feed model). This model assumes uniform distribution of contamination in the feed and estimates the feed fraction from which the samples are taken. An alternative route assuming heterogeneous distribution will be pursued to complement the output. The WG agreed to pursue the development of this model and add two possible scenarios. This model will contribute to answer ToR1 and Tor3. The 2011 EFSA model has been already updated with a new add-in estimating the amount of TSE infectivity reclassified as Category 3 material due to changes in the SRM list. It was agreed to pursue three risk pathways in the QRA model: a) the current pathway as in the 2011 model; b) the access to ruminant PAP via non-ruminant feed; and c) the access to contaminated fishmeal via milk replacers for unweaned calves. As a worst-case scenario, it was also agreed to run an alternative scenario with starting point the full infectivity of one single

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

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⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00705>

animal not reduced/inactivated by any of the steps in the feed chain in order and estimate the risk of new BSE cases in cattle should the controls be removed.

5. Work plan: tasks and deadlines

Actions were agreed during the discussion of the ToRs. As agreed prior to this meeting, the 5th WG meeting will be web-conference on Monday 26 March 2018 pm and the 6th WG meeting a physical meeting in Parma on 26-27 April 2018 lunch to lunch.

Scientific Panel on Biological Hazards

Minutes of the 3rd meeting of the Working Group on “an updated Quantitative Risk Assessment (QRA) of the BSE risk posed by Processed Animal Protein (PAP)”

Web-conference on 8 February 2018

(Agreed on 14 February 2018)¹

Participants

- **Working Group Members:**

Amie Adkin (AA), Matthias Greiner (MG), Daniela Marchis (DM), Marta Prado (MP), Giuseppe Ru (GR), Marion M. Simmons (MMS) (Chair)

- **EFSA:**

BIOCONTAM Unit: Teresa da Silva Felício (TF), Angel Ortiz Pelaez (AOP)

1. Welcome and apologies for absence

The Chair welcomed the participants.

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

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4. Scientific topic(s) for discussion⁴

A review of the actions from the previous meeting was conducted. The data and information received so far from the industry and the National Reference Laboratories (NRL) was presented. The summary of the review of the FVO reports on relevant topics (ABP, aquafeed, organic fertilisers/soil improvers, feed ban, hazards in the feed chain) was presented to the WG.

A review of the surveillance system for the compliance with the feed ban was conducted in order to take stock of the shortcomings along the feed chain and the uncertainties associated to the processes. It was agreed to aggregate testing data from the four selected member states (Germany, Italy, Spain and the United Kingdom), when available, to identify at which points of the feed chain contamination with ruminant content occurs. That will allow the ranking of all possible risk pathways. The update of the 2011 EFSA model was discussed and whether it can/should be modified by introducing other risk pathways. The difficulty to amend the model without hard data on alternative pathways and with the time constraints for delivery of the opinion was highlighted. The WG agreed with this position. However this would have implications for the ability to address ToR2 and ToR3 as they stand, especially if the testing cannot be run in the model as alternative scenarios.

5. Work plan: tasks and deadlines

Actions were agreed during the discussion of the ToRs. The 4th WG meeting will be a 1.5 day physical meeting in London from Monday 26 February 2018 (pm) to Tuesday 27 February 2018 (full day) (venue still to be decided). There was no time to schedule further meetings.

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-2017-00705>

Scientific Panel on Biological Hazards

Minutes of the 2nd meeting of the Working Group on “an updated Quantitative Risk Assessment (QRA) of the BSE risk posed by Processed Animal Protein (PAP)”

Physical on 10-11 January 2018

(Agreed on 19 January 2018)¹

Participants

- **Working Group Members:**

Amie Adkin (AA), Matthias Greiner (MG), Daniela Marchis (DM), Marta Prado (MP), Giuseppe Ru (GR), Marion M. Simmons (MMS) (Chair)

- **EFSA:**

BIOCONTAM Unit: Teresa da Silva Felício (TF), Angel Ortiz Pelaez (AOP), Yves van Der Stede (Wednesday 10 January 2018) (BIOCONTAM Unit)

- **European Commission:**

Lucie Carroueé-Pook (LC) (Thursday 11 January 2018 09:00-11:30) (European Commission – DG-SANTE G4)

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

1

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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 topic(s) for discussion⁴

A review of the actions from the previous meeting was conducted. All contributions received before the meeting were presented inserted in the template of the scientific opinion. An open discussion on the scope, and approaches to address the Terms of Reference was held on day 1. The working group was split into two sub-groups at the beginning of day 2 to discuss, respectively, the technical zero and feed testing, and the QRA model. The scope of the answer to ToR1 will be sufficiently broad to accommodate the entire feed chain, including: National Sampling Plans, sampling protocols, sample collection, sample manipulation, preparation and fractioning, diagnostic protocol, and, finally, the sensitivity of the diagnostic tests, including the technical zero. The main assumptions of the 2011 model were reviewed, and consideration given to possible changes in the model for 2018. The 2011 QRA model considered a single risk pathway through contamination of ruminant feed with non-ruminant PAP contaminated with ruminant PAP and did not consider the sensitivity of the diagnostic test applied in feed testing. Other possible routes of contamination were discussed, like cattle having access, through human error, to aquafeed or pet food contaminated with ruminant PAP, via fertilisers, etc. The possible ways to account for the technical zero in the model were also discussed.

5. Work plan: tasks and deadlines

Actions were agreed during the discussion of the ToRs. The 3rd WG meeting will be a web-conference on 8 February 2018 (13:30-17:30). The 4th WG meeting will be a 1.5 day physical meeting in London from

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

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Monday 26 February 2018 (pm) to Tuesday 27 February 2018 (full day)
(venue still to be defined)

Scientific Panel on Biological Hazards

Minutes of the 1st meeting of the Working Group on “an updated Quantitative Risk Assessment (QRA) of the BSE risk posed by Processed Animal Protein (PAP)”

Web-conference on 15 December 2017

(Agreed on 22 December 2017)¹

Participants

- **Working Group Members:**

Amie Adkin (AA), Daniela Marchis (DM), Marta Prado (MP), Giuseppe Ru (GR), Marion M. Simmons (MMS) (Chair)

- **EFSA:**

BIOCONTAM Unit: Teresa da Silva Felicio (TF), Angel Ortíz Peláez (AOP), Pietro Stella (PS) (9:30-11:30h)

- **European Commission:**

Lucie Carroué (LC), Sara Perucho Martínez (SP) (DG-SANTE G4)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Matthias Greiner.

2. Adoption of agenda

The agenda was adopted without changes.

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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 topic(s) for discussion⁴

The background of the mandate and terms of reference were presented by the EFSA secretariat and discussed by the WG, with the clarifications of the representative of DG-SANTE. A brainstorm session was led by the Chair on the overall approaches to address the questions of the ToRs, including the assumptions and structure of the quantitative risk model applied in the 2011 EFSA opinion. Topics like the feed testing for the monitoring of the feed ban in the EU, the application of the "technical zero" in the estimation of the BSE risk, the lack of data to parameterize different components of the model and the new/alternative routes of contamination of ruminant feed were discussed.

5. Work plan: tasks and deadlines

Actions were agreed during the discussion of the ToRs. The 2nd WG meeting had already been fixed prior to the web-conference for Wednesday 10 January 2018 (pm) to Thursday 11 January 2018 (full day) as a physical meeting in Parma. The Chair presented a proposal for the calendar of meetings taking into account that the draft opinion should be presented for first reading to the BIOHAZ Panel in the March meeting. The WG agreed on the proposed dates and venues for the 3rd and 4th WG meetings: a) the 3rd WG meeting: a web-conference on w/c 5 February 2018. A doodle poll will be circulated to fix the date and time; b) the 4th WG meeting: a 1.5 day physical meeting in London from 26 (pm) to 27 February (full day) 2018.

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

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

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