

## Scientific Panel on Biological Hazards

### Minutes of the 4<sup>th</sup> meeting of the Working Group on a "request of the EC for scientific and technical assistance to evaluate applications of Member States to be recognised as having a negligible risk of classical scrapie"

**Held on 6-7 October 2015, Parma (Italy)**

**(Agreed on 14 October 2015)**

#### **Participants**

- **Working Group Members:**

Marion M. Simmons

Giuseppe Ru

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

Lucie Carrouée-Pook (DG SANTE G4)

- **EFSA:**

BIOCONTAM Unit: Valentina Rizzi (Chair), Angel Ortiz Peláez, Pietro Stella

AMU Unit: Fulvio Barizzone, Ana Belén García

- **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 Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, 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 discussion**

### **4.1. Actions from previous meetings: methodological approach<sup>3</sup>**

The Chair and Secretariat presented the actions agreed from the previous meeting, the state of the scientific report and the contributions received prior to the meeting.

### **4.2. Expert data elicitation exercise**

The decision to conduct an expert knowledge elicitation exercise was made after the last meeting in order to address the uncertainty around a key parameter of the model, as discussed in the previous meeting. Methodology and results were presented and discussed.

### **4.3. Presentation results: scenario-tree modelling deterministic & stochastic**

Results of the outputs of the model using different set of parameters agreed during the previous meeting and via email were presented and discussed.

### **4.4. Presentation results: Bayesian analysis of historic data**

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

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

<sup>3</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00240>

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00261>

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00262>

The draft of the paper to explain the Bayesian methodology as proposed by the BIOHAZ Panel was presented as well as the comments received by a Panel member. Steps ahead were discussed and agreed.

#### **4.5. Methods and final results to be reported**

The parameters to be used in the analysis of the evaluation of the surveillance system for the applying MS were discussed and agreed. Results and conclusions were discussed in the light of the outputs of the model.

#### **4.6. Draft scientific report: introduction, data and methodology, assessment, conclusions, concluding remarks, recommendations and appendices.**

The draft of the sections conclusions and recommendations were agreed. The review of the entire document was then conducted in what was considered the final draft, pending for contributions after the meeting.

### **5. Next meeting(s)**

No other meetings were scheduled.

## Scientific Panel on Biological Hazards

### Minutes of the 3<sup>rd</sup> meeting of the Working Group on a "request of the EC for scientific and technical assistance to evaluate applications of Member States to be recognised as having a negligible risk of classical scrapie"

**Held on 10 September 2015, Parma (Italy)**

**(Agreed on 18 September 2015)**

#### **Participants**

- **Working Group Members:**

Marion M. Simmons

- **EFSA:**

BIOCONTAM Unit: Valentina Rizzi (Chair), Angel Ortiz Pelaez, Pietro Stella

AMU Unit: Fulvio Barizzone

- **Others:**

Not Applicable

#### **1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Giuseppe Ru (BIOHAZ Panel) and Gabriele Zancanaro (EFSA).

#### **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 Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, 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 discussion**

#### **4.1. Actions from previous meetings: update on data requests<sup>3</sup>**

The Secretariat reported the additional data requested to the three Member States (MS).

#### **4.2. Feedback from BIOHAZ Panel members**

Following the plenary meeting of the BIOHAZ Panel, the Working Group discussed recommendations of the Panel and discussed the position of the EC with regards the methodological approach.

#### **4.3. Review analytical approach and results**

The Working Group reviewed the preliminary results applying the risk-based approach and discussed the calculation of the input parameters.

#### **4.4. Draft Scientific Reports**

The draft report was reviewed by the Working Group.

#### **4.5. Tasks and deadlines**

Tasks and deadlines were agreed until the next Working Group meeting.

### **5. Next meeting(s)**

4<sup>th</sup> meeting: 6-7 October 2015. Physical meeting. Parma.

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

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

<sup>3</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00240>

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00261>

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00262>

## Scientific Panel on Biological Hazards

### Minutes of the 2<sup>nd</sup> meeting of the Working Group on a "request of the EC for scientific and technical assistance to evaluate applications of Member States to be recognised as having a negligible risk of classical scrapie"

**Held by WEB-conference, 13 July 2015**

**(Agreed on 17 July 2015)**

#### **Participants**

- **Working Group Members:**

Giuseppe Ru, Marion M. Simmons

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

Lucie Carrouée-Pook, Martial Plantady (DG SANTE) (Point 4.1)

- **EFSA:**

BIOCONTAM Unit: Valentina Rizzi (Chair), Angel Ortiz Pelaez, Pietro Stella

AMU Unit: Fulvio Barizzone

- **Others:**

Not Applicable

#### **1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Gabriele Zancanaro (EFSA).

## **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 Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, 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 discussion**

### **4.1. Clarification Terms of reference**

The WG discussed internally and with European Commission (EC) a number of issues regarding the interpretation of the mandate as in Regulation (EU) 630/2013.

### **4.2. Methodology of the evaluation**

The alternative methods to analyse the surveillance data of the three applicants were discussed. Assumptions, input parameters and data sources to be used were agreed.

### **4.3. Data necessary for analysis**

The three dossiers were reviewed and based on the agreement on 4.2, the missing data and information for each applicant were identified. It was agreed to request it to each MS.

## **5. Any Other Business**

Not Applicable

## **6. Next meeting(s)**

3<sup>rd</sup> meeting: 10 September 2015 (TBC). Half-day physical, Parma.

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

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

4<sup>th</sup> meeting: 6-7 October 2015 (TBC). Physical meeting, Parma.



## Scientific Panel on Biological Hazards

### Minutes of the 1<sup>st</sup> meeting of the Working Group on a "request of the EC for scientific and technical assistance to evaluate applications of Member States to be recognised as having a negligible risk of classical scrapie"

**Held on 15 June 2015, Parma (Italy)**

**(Agreed on 22 June 2015 )<sup>1</sup>**

#### **Participants**

- **Working Group Members:**

Giuseppe Ru

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

Lucie Carrouée-Pook (DG SANTE) (morning session)

- **EFSA:**

BIOCONTAM Unit: Valentina Rizzi (Chair), Angel Ortiz Pelaez, Pietro Stella

AMU Unit: Fulvio Barizzone, Gabriele Zancanaro

- **Others:**

Not Applicable

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<sup>1</sup> 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.

## **1. Welcome and apologies for absence**

The Chair welcomed the participants.  
Apologies were received from Marion Simmons.

## **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 Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, 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 discussion**

### **4.1. Mandate and Terms of reference**

The chair introduced the mandate received from the European Commission (EC) and terms of reference (ToRs).

### **4.2. Dossiers<sup>4</sup>**

The EFSA Secretariat presented the three dossiers submitted by the applying Member States (MS). The WG revised the information and data available in the dossiers.

### **4.3. Presentation of the RiBESS tool**

A presentation of the Risk based estimate of system sensitivity (RiBESS) tool in both its web-based and Excel interfaces was given by a WG member, developer of the tool. Its use for the mandate was explored by the WG.

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

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

<sup>4</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00240>  
<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00260>  
<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00261>

#### **4.4. Scope and methodology of the evaluation**

The WG discussed the methodological approaches that could be adopted for the analyses of the data.

#### **5. Any Other Business**

Not Applicable

#### **6. Next meeting(s)**

2<sup>nd</sup> meeting: 13 July 2015. Web-conference

3<sup>rd</sup> meeting: w/c 7 September 2015 (date TBD). Physical meeting, Parma

4<sup>th</sup> meeting: October 2015 (date TBD): web-conference