

Scientific Panel on Biological Hazards

Minutes of the 7th meeting of the Working Group on a “request for a scientific opinion on genetic resistance to TSEs in goats”

Held at Parma, 19 June 2017

(Agreed on 30 June 2017)¹

Participants

- **Working Group Members:**

Pier-Luigi Acutis, Olivier Andreoletti, Wilfred Goldmann, Jan Langeveld, Giuseppe Ru, Emma Snary (Chair), Jack J. Windig

- **EFSA:**

BIOCONTAM Unit: Angel Ortiz Pelaez

- **Others:**

Jianghui Zhu (China National Center for Food Safety Risk Assessment (CFSA))

1. Welcome and apologies for absence

The Chair opened the meeting and welcomed the members of the working group (WG) and the guest scientist from the China National Center for Food Safety Risk Assessment (CFSA): Jianghui Zhu, who is participating as observer. No apologies received.

2. Adoption of agenda

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.

The agenda was adopted with changes. The agenda was adopted with changes. The order of the agenda points was modified, as follows: Point 1,2,3,7,8,4,5, and 6.

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.

In the ADoI and/or SDoI filled for the present meeting Dr M. Simmons declared the following interest: Consultancy support provided at the request of the European Commission to the design and interpretation of the Cypriot studies into genetic resistance in Cypriot goats; and Dr Giuseppe Ru and Dr Pier Luigi Acutis declared the following interest: Based on a specific mandate from the Italian Ministry of Health they were involved in drafting a scientific dossier titled "The K222 allele of the goat PRNP gene as candidate for selective culling in scrapie outbreaks and for future breeding programs for TSE resistance in Italian goat breeds".

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest, and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent a partial Conflict of Interest. This results in exclusion of the experts from appraising their own work (respectively the above mentioned reports) in the frame of the concerned scientific group.

4. Scientific topic(s) for discussion⁴

The answers to the ToRs as in the version circulated prior to the meeting were reviewed and the final draft was agreed. Equally the section on further recommendations was reviewed and the final draft agreed. Minor modifications on the description of the tool to assess genetic resistance were agreed. The position and colour of the alleles of interest was reviewed for the last time. A number of comments still in the draft opinion were reviewed. Some actions were agreed to modify the body of the text before it is submitted to the BIOHAZ panel for adoption.

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-2016-00268>

5. Any Other Business

Not Applicable

6. Next meeting(s)

This was the last WG meeting.

Scientific Panel on Biological Hazards

Minutes of the 6th meeting of the Working Group on a “request for a scientific opinion on genetic resistance to TSEs in goats”

Web-conference on 18 May 2017

(Agreed on 22 May 2017)¹

Participants

- **Working Group Members:**

Pier Luigi Acutis, Olivier Andreoletti, Wilfred Goldmann, Jan Langeveld, Giuseppe Ru, Marion Simmons, Emma Snary (Chair).

- **EFSA:**

BIOCONTAM Unit: Angel Ortiz Pelaez, Pietro Stella

- **Others:**

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies received from Jack Winding.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

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4. Scientific topic(s) for discussion⁴

The chair informed the WG that given the steady progress in the production of the scientific opinion and its advanced state, it will be submitted for thorough reading to the next plenary of the BIOHAZ Panel on 7-8 June 2017 (originally planned to be the first reading). Therefore the opinion will be submitted for adoption in the July plenary. The tool to assess genetic resistance was reviewed thoroughly and minor changes were agreed for its two components: the weight of evidence and the strength of resistance. There were minor changes made to ToR1 and ToR2. The chair proposed to submit contributions after the meeting for the next version of the opinion considering measures both at herd and at population levels. Equally section 5 (other recommendations) has not been discussed previously. The chair asked WG members to submit ideas for the next round.

5. Any Other Business

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-2016-00268>

Not Applicable

6. Next meeting(s)

The date for the 7th and last WG meeting will take place on Monday 19 June 2017, as a physical meeting in Parma at EFSA HQ.

Scientific Panel on Biological Hazards

Minutes of the 5th meeting of the Working Group on a “request for a scientific opinion on genetic resistance to TSEs in goats”

Web-conference on 5 April 2017

(Agreed on 12 April 2017)¹

Participants

- **Working Group Members:**

Olivier Andreoletti, Wilfred Goldmann, Jan Langeveld, Giuseppe Ru, Marion Simmons, Emma Snary (Chair), Jack J. Windig

- **EFSA:**

BIOCONTAM Unit: Angel Ortiz Pelaez, Pietro Stella

- **Others:**

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies received from Pier-Luigi Acutis. The Chair welcome back Marion Simmons as reinstated member of the WG.

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.

In the ADoI and/or SDoI filled for the present meeting Dr M. Simmons declared the following interest: Consultancy support provided at the request of the European Commission to the design and interpretation of the Cypriot studies into genetic resistance in Cypriot goats; and Dr Giuseppe Ru and Dr Pier Luigi Acutis declared the following interest: Based on a specific mandate from the Italian Ministry of Health they were involved in drafting a scientific dossier titled "The K222 allele of the goat PRNP gene as candidate for selective culling in scrapie outbreaks and for future breeding programs for TSE resistance in Italian goat breeds".

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest, and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent a partial Conflict of Interest. This results in exclusion of the experts from appraising their own work (respectively the above mentioned reports) in the frame of the concerned scientific group.

4. Scientific topic(s) for discussion⁴

It was agreed by the chair and it was proposed that MMS and PL-A could do it. PL-A was not present but will be consulted by email. With regards to the tool to assess the genetic resistance, it was agreed a) to highlight the differences between the K222 and D/S 146 alleles in the text, in the strain section, and add a columns in the evidence table emphasizing the evidence of resistance in single/multiple strains; b) to add a new colour (grey: not sufficient data are available) to the strength of resistance component of the tool; c) to reclassify the three colours of the level of resistance: resistance-green, some resistance-amber, no resistance-red), d) and to modify the last column of the weight of evidence with multi-strains to accommodate K222. The D145 and G-stop polymorphisms were also discussed and was agreed to be re-instated in the list in grey colour. The draft answers to ToR 1-2-3-4 were reviewed and amended accordingly.

5. Any Other Business

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-2016-00268>

Not Applicable

6. Next meeting(s)

The Secretariat will explore this possibility of having an extra short web-conference before the opinion is submitted for first reading to the BIOHAZ pane and will inform back to the chair and WG. The date for the 6th WG meeting (end of June-beginning of July) as a physical meeting was not set and will be discussed either during the extra web-conference or by a doodle poll to be circulated by the Secretariat.

Scientific Panel on Biological Hazards

Minutes of the 4th meeting of the Working Group on a “request for a scientific opinion on genetic resistance to TSEs in goats”

Held at Parma, 14 February 2017

(Agreed on 22 February 2017)¹

Participants

- **Working Group Members:**

Pier-Luigi Acutis, Olivier Andreoletti, Wilfred Goldmann, Jan Langeveld, Giuseppe Ru, Emma Snary (Chair), Jack J. Windig

- **EFSA:**

BIOCONTAM Unit: Angel Ortiz Pelaez

- **Others:**

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies received from Marion Simmons. The Chair informed that Marion Simmons is no longer member of the WG.

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.

In the ADoI and/or SDoI filled for the present meeting Dr Giuseppe Ru and Dr Pier Luigi Acutis declared the following interest: Based on a specific mandate from the Italian Ministry of Health they were involved in drafting a scientific dossier titled "The K222 allele of the goat PRNP gene as candidate for selective culling in scrapie outbreaks and for future breeding programs for TSE resistance in Italian goat breeds".

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest, and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent a partial Conflict of Interest. This results in exclusion of the experts from appraising their own work (respectively the above mentioned reports) in the frame of the concerned scientific group.

4. Scientific topic(s) for discussion

4.1. Review actions previous meeting⁴

The table of actions as in the secretarial notes of the previous meeting was reviewed. All actions had been completed except the first draft section of the epidemiology of scrapie in goats, the standardised maps, concluding remarks to sections 3.1, 3.4 and 3.5, the description of the goat industry, the use of the literature review of the doppel gene and the initial drafts of the answers to ToR1 and ToR2.

4.2. Tool for the evaluation of resistance and answers to the ToRs

Following comments by BIOHAZ Panel members, The Chair led a discussion on the two-tier tool drafted in the previous meeting using a combination of weight of evidence (types of studies available) and level of resistance. Three levels of resistance were finally agreed: red) allele with susceptibility similar to the wild type; amber) increased incubation period in natural host and Tg mice compared to wild type; green) rare field cases

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and no p.o. transmission to natural host and i.c. in Tg mice. The approaches to the ToRs were reviewed and further discussed. The final list of alleles was agreed and so was the level of resistance of each of them. A ranking of alleles was provisionally agreed by the WG. The evidence to substantiate the answer to ToR4 was reviewed and a set of brainstormed recommendations to include in the answer to ToR5 was listed.

5. Any Other Business

Not Applicable

6. Next meeting(s)

It was agreed to have the 6th WG meeting as a physical meeting in Parma on Thursday 8 June 2017 pm and Friday 9 June 2017 full day. The 5th WG meeting remains as agreed in the previous meeting: web-conference on Wednesday 5 April 2017, 14:00-18:00h.

Scientific Panel on Biological Hazards

Minutes of the 3rd meeting of the Working Group on a “request for a scientific opinion on genetic resistance to TSEs in goats”

Held at Parma, 31 October 2016

(Agreed on 10 November 2016)¹

Participants

- **Working Group Members:**

Pier-Luigi Acutis, Olivier Andreoletti, Wilfred Goldmann, Jan Langeveld, Giuseppe Ru, Emma Snary (Chair), Jack J. Windig

- **EFSA:**

BIOCONTAM Unit: Angel Ortiz Pelaez

- **Others:**

Not Applicable

1. Welcome and apologies for absence

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

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

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In the ADoI and/or SDoI filled for the present meeting Dr M. Simmons declared the following interest: Consultancy support provided at the request of the European Commission to the design and interpretation of the Cypriot studies into genetic resistance in Cypriot goats; and Dr Giuseppe Ru and Dr Pier Luigi Acutis declared the following interest: Based on a specific mandate from the Italian Ministry of Health they were involved in drafting a scientific dossier titled "The K222 allele of the goat PRNP gene as candidate for selective culling in scrapie outbreaks and for future breeding programs for TSE resistance in Italian goat breeds".

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest, and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent a partial Conflict of Interest. This results in exclusion of the experts from appraising their own work (respectively the above mentioned reports) in the frame of the concerned scientific group.

4. Scientific topic(s) for discussion

4.1. Review actions previous meeting⁴

The table of actions as in the secretarial notes of the previous meeting was reviewed. All actions had been completed except the first draft section of the epidemiology of scrapie in goats.

4.2. Draft Scientific Opinion: review contributions current version, and answers to the ToR1, ToR2 and Tor3

The Chair led the revision of the current status of the scientific opinion section by section. Amendments and additions to the background sections were agreed. A selection criterion of alleles to be included in the answer to ToR1 was agreed by the WG. Necessary information and data to answer ToR2 and ToR3 are available in the background sections but needed to be drafted in stand-alone sections. ToR4 was discussed for the

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

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

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first time and the approach to address the questions included in it was also agreed.

5. Any Other Business

Not Applicable

6. Next meeting(s)

The calendar for future meetings was discussed considering the dates of the BIOHAZ plenary meetings in 2017 and the progress of the work. It was agreed to have the 4th WG meeting as a physical meeting in Parma in February and the 5th WG meeting as a web-conference in end of March-beginning of April. The Secretariat will circulate doodle polls to fix the dates of the two meetings.

Scientific Panel on Biological Hazards

Minutes of the 2nd meeting of the Working Group on a “request for a scientific opinion on genetic resistance to TSEs in goats”

Web-conference on 5 September 2016

(Agreed on 12 September 2016)¹

Participants

- **Working Group Members:**

Pier-Luigi Acutis, Olivier Andreoletti, Wilfred Goldmann, Jan Langeveld, Giuseppe Ru, Marion Simmons, Emma Snary (Chair), Jack J. Windig

- **EFSA:**

BIOCONTAM Unit: Ernesto Liebana Criado, Angel Ortiz Pelaez

- **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

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4. Scientific topic(s) for discussion

4.1. Feedback discussion with the EC on the ToRs⁴

The Secretariat provided feedback on the discussion between EFSA and the EC held on 2 September 2016 about the interpretation of the ToRs. The WG discussed them in depth taking on board the proposal submitted by the EC and agreed the approach to follow.

4.2. Shortlist literature review and approaches ToR 1-2-3: next steps

The output of the literature search agreed and conducted over the summer was presented. Extraction of data from the short list of papers and description on the scientific opinion were discussed.

4.3. Assessment: criteria/tools for assessing genetic resistance

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-2016-00268>

The layout of the Assessment section of the draft opinion was discussed and subsections were outlined. It was agreed to review internally the two reports included in the mandate.

5. Any Other Business

Not Applicable

6. Next meeting(s)

3rd meeting: 31 October 2016. Physical meeting, Parma (Italy)

Scientific Panel on Biological Hazards

Minutes of the 1st meeting of the Working Group on "Genetic resistance to TSEs in goats"

Held at Parma, 28-29 June 2016

(Agreed on 4 July 2016)

Participants

- **Working Group Members:**

Pier-Luigi Acutis,
Olivier Andreoletti,
Wilfred Goldmann,
Jan Langeveld,
Giuseppe Ru,
Marion Simmons,
Emma Snary (Chair)

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

Lucie Carrouée-Pook (DG SANTE G4)

- **EFSA:**

BIOCONTAM Unit: Angel Ortíz Peláez
Ernesto Liébana Criado (28 June 2016)

- **Others:**

Not Applicable

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

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4. Scientific topic(s) for discussion

4.1. Mandate – administrative issues, background and terms of reference³

The details of the mandate, background of the request and terms of reference were presented to the WG.

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

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

³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00268>

4.2. Terms of reference: discussion

The scientific background and scope of the questions included in the terms of reference were discussed with the European Commission (WG) representative. Interpretation of the terms of reference were proposed by the EC and reviewed and expanded by the WG.

4.3. Scope and methodology of the assessment for each ToR

Data requirements, potential data sources and methodology to address each of the terms of reference were discussed and agreed.

4.4. Draft Scientific Opinion: Table of contents

EFSA template for scientific opinions and standard table of contents were presented to the WG.

4.5. Work plan: tasks and deadlines

Tasks were assigned to all WG members according to the agreed approaches to address the questions of the terms of reference.

4.6. Future meetings

It was agreed to hold the second meeting as a web-conference on Monday 5 September 2015. The third meeting was agreed to be a physical one in Parma in October. Date to be confirmed.

4.7. Any Other Business

Not applicable