

## Scientific Panel on Biological Hazards

## Minutes of the 11<sup>th</sup> meeting of the Working Group on Reduction of the need to use antimicrobials

## Held by WEB-conference, 25 October 2016

## (Agreed on 9 November 2016)

### Participants

- Working Group Members:
  - Pier Sandro Cocconcelli Christian Ducrot Simon More Gregers Jungersen John Threlfall
- Hearing Experts<sup>1</sup>: Not applicable
- European Commission and/or Member States representatives: Not applicable
- EFSA:

AHAW Unit: Denise Candiani BIOCONTAM Unit: Ernesto Liebana, Pietro Stella FEED Unit: Rosella Brozzi

• Others:

EMA Working Group Members: Boudewijn Catry, Christian Friis, Helen Jukes, Pascal Sanders

EMA Staff: Zoltan Kunsagi

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <u>http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.</u>



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

The Chair welcomed the participants.

Apologies were received from Robert Davies (Working Group Member).

This Working Group is working jointly with a corresponding EMA Working Group, to address the request for a Joint Scientific Opinion to EFSA and EMA.

## 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 Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

## 4. Scientific topic

### **4.1.** Reduction of the need to use antimicrobials <sup>4</sup>

The Working Group reviewed the last contributions received on the draft opinion, and the feedback provided by the EFSA BIOHAZ, AHAW and FEEDAP Panels, by EMA CVMP, and by the ECDC. The Working Group was informed that the EFSA AHAW and FEEDAP Panels endorsed the sections of the draft opinion of their competence during the last respective Panel Plenary meetings in October. The Working Group discussed in detail the draft conclusions and recommendations, including the draft answer to the Terms of Reference.

The Working Group discussed the timelines for finalising the draft opinion, and agreed remaining tasks and respective deadlines.

<sup>&</sup>lt;sup>2</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

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

<sup>&</sup>lt;sup>4</sup> <u>http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00216</u>



No further meetings are planned at present.



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

In the ADoI or in the SDoI filled for the present meeting Prof. Gregers Jungersen declared the following interest: private funding for research on the efficacy of vaccine against infectious disease in cattle, private funding for the development of a *Staphylococcus aureus* vaccine, and being co-inventor of a patent on a vaccine against *Mycobacterium avium paratuberculosis*. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>5</sup> and the Decision of the Executive Director on Declarations of Interest<sup>6</sup>, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest. This results in the exclusion of the expert from any discussion, voting or other

processing of item "vaccination in cattle, vaccination against *Mycobacterium avium paratuberculosis*, and vaccination against *Staphylococcus aureus*" by the concerned scientific group.

<sup>&</sup>lt;sup>5</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

<sup>&</sup>lt;sup>6</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



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# Scientific Panel on Biological Hazards

## Minutes of the 10<sup>th</sup> meeting of the Working Group on Reduction of the need to use antimicrobials

Held on 20 September 2016, London (United Kingdom)

## (Agreed on 30 September 2016)

## **Participants**

- Working Group Members:
  - Pier Sandro Cocconcelli Robert Davies Simon More Gregers Jungersen John Threlfall
- Hearing Experts<sup>1</sup>:
  Not applicable
- European Commission and/or Member States representatives: Not applicable
- EFSA:

AHAW Unit: Denise Candiani BIOCONTAM Unit: Ernesto Liebana, Pietro Stella FEED Unit: Rosella Brozzi

• Others:

EMA Working Group Members: Boudewijn Catry (TELE-Conference), Christian Friis, Helen Jukes, Cristina Muñoz Madero, Pascal Sanders EMA Staff: Marian Bos, Zoltan Kunsagi, Jordi Torren

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <u>http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.</u>



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

The Chair welcomed the participants.

Apologies were received from Christian Ducrot (Working Group Member).

This Working Group is working jointly with a corresponding EMA Working Group, to address the request for a Joint Scientific Opinion to EFSA and EMA.

## 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 Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

## 4. Scientific topic

### **4.1.** Reduction of the need to use antimicrobials <sup>4</sup>

The Working Group reviewed the last contributions received on the draft opinion, and the feedback provided by the EFSA BIOHAZ, AHAW and FEEDAP Panel and by the European Commission. The Working Group discussed in detail the draft conclusions and recommendations, including the draft answer to the Terms of Reference.

The Working Group discussed the timelines for finalising the draft opinion, and agreed remaining tasks and respective deadlines.

## 5. Next meetings

The next meeting will be held on 25 October 2016, by WEB-Conference.

<sup>&</sup>lt;sup>2</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

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

<sup>&</sup>lt;sup>4</sup> <u>http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00216</u>



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

In the ADoI or in the SDoI filled for the present meeting Prof. Gregers Jungersen declared the following interest: private funding for research on the efficacy of vaccine against infectious disease in cattle, private funding for the development of a *Staphylococcus aureus* vaccine, and being co-inventor of a patent on a vaccine against *Mycobacterium avium paratuberculosis*. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>5</sup> and the Decision of the Executive Director on Declarations of Interest<sup>6</sup>, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest. This results in the exclusion of the expert from any discussion, voting or other

processing of item "vaccination in cattle, vaccination against *Mycobacterium avium paratuberculosis*, and vaccination against *Staphylococcus aureus*" by the concerned scientific group.

<sup>&</sup>lt;sup>5</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

<sup>&</sup>lt;sup>6</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



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# Scientific Panel on Biological Hazards

# Minutes of the 9<sup>th</sup> meeting of the Working Group on Reduction of the need to use antimicrobials

## Held by WEB-conference, 22 June 2016

(Agreed on 5 July 2016)

## **Participants**

• Working Group Members:

Pier Sandro Cocconcelli Robert Davies Christian Ducrot Simon More John Threlfall

- Hearing Experts<sup>1</sup>:
  Not applicable
- European Commission and/or Member States representatives: Dean Bosnjak, Rex Horgan, Marina Marini
- EFSA:

AHAW Unit: Denise Candiani

BIOCONTAM Unit: Beatriz Guerra Román, Ernesto Liebana, Pietro Stella

FEED Unit: Rosella Brozzi

• Others:

EMA Working Group Members: Keith Baptiste, Boudewijn Catry, Christian Friis, Helen Jukes, Pascal Sanders

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <u>http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.</u>



EMA Staff: Zoltan Kunsagi, Jordi Torren

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

The Chair welcomed the participants.

Apologies were received from Gregers Jungersen (Working Group Member).

This Working Group is working jointly with a corresponding EMA Working Group, to address the request for a Joint Scientific Opinion to EFSA and EMA.

## 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 Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

### 4. Scientific topic

## **4.1.** Reduction of the need to use antimicrobials <sup>4</sup>

The Working Group reviewed the last contributions received on the draft opinion, and discussed some of the revised sections of the document (on prophylactic and metaphylactic use of antimicrobials; education, training and communication; alternative measures). The Working Group also discussed draft overall conclusions and recommendations of the draft opinion. Timelines for finalising the draft opinion, remaining tasks and respective deadlines were agreed.

<sup>&</sup>lt;sup>2</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

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

<sup>&</sup>lt;sup>4</sup> <u>http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00216</u>



The next meeting will be held on 20 September 2016, in London.



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

In the ADoI or in the SDoI filled for the present meeting Prof. Gregers Jungersen declared the following interest: private funding for research on the efficacy of vaccine against infectious disease in cattle, private funding for the development of a *Staphylococcus aureus* vaccine, and being co-inventor of a patent on a vaccine against *Mycobacterium avium paratuberculosis*. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>5</sup> and the Decision of the Executive Director on Declarations of Interest<sup>6</sup>, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest. This results in the exclusion of the expert from any discussion, voting or other

processing of item "vaccination in cattle, vaccination against *Mycobacterium avium paratuberculosis*, and vaccination against *Staphylococcus aureus*" by the concerned scientific group.

<sup>&</sup>lt;sup>5</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

<sup>&</sup>lt;sup>6</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



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# Scientific Panel on Biological Hazards

# Minutes of the 8<sup>th</sup> meeting of the Working Group on Reduction of the need to use antimicrobials

## Held by WEB-conference, 1 June 2016

(Agreed on 8 June 2016)

## Participants

• Working Group Members:

Pier Sandro Cocconcelli Robert Davies John Threlfall

- Hearing Experts<sup>1</sup>: Charlotte Dunoyer Maryline Kouba
- European Commission and/or Member States representatives: Not applicable
- EFSA: BIOCONTAM Unit: Ernesto Liebana, Pietro Stella
- Others: EMA Working Group Members: Keith Baptiste, Pascal Sanders EMA Staff: Zoltan Kunsagi

## 1. Welcome and apologies for absence

The Chair welcomed the participants.

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <u>http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.</u>



In agreement with the Working Group, only a subset of experts from the Working group was invited to this meeting, according to the items on the agenda.

This Working Group is working jointly with a corresponding EMA Working Group, to address the request for a Joint Scientific Opinion to EFSA and EMA.

## 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

## **4.1.** Reduction of the need to use antimicrobials <sup>4</sup>

The Working Group welcomed Hearing Experts Charlotte Dunoyer (ANSES) and Maryline Kouba (member of the ANSES WG 'Alternatives to antibiotiques'). EFSA Working Group experts and EFSA staff introduced the ongoing EFSA-EMA mandate, and Charlotte Dunoyer presented the ongoing ANSES mandate on 'Alternatives to antibiotiques'. The WG and Hearing Experts discussed the two mandates and methodologies being followed, with a view of identifying any possible divergence of opinions in the framework of Article 30 of Regulation (EC) No 178/2002.

The Working Group focused this meeting on the discussion of the section of the draft opinion on the alternatives to antimicrobials. The last contributions received were reviewed and discussed, with the aim of harmonising the structure of the text for the different alternatives available. The WG discussed the draft conclusions and recommendations, agreed on how to finalise this section and defined further tasks to be completed.

<sup>&</sup>lt;sup>2</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

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

<sup>&</sup>lt;sup>4</sup> <u>http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00216</u>



The next meeting will be held on 22 June 2016, by WEB-Conference.



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# Scientific Panel on Biological Hazards

# Minutes of the 7<sup>th</sup> meeting of the Working Group on Reduction of the need to use antimicrobials

## Held on 28-29 April 2016, Parma (Italy)

(Agreed on 17 May 2016)

## Participants

• Working Group Members:

Pier Sandro Cocconcelli Robert Davies Christian Ducrot Gregers Jungersen

• Hearing Experts<sup>1</sup>: Atle Lillehaug

John Threlfall

- European Commission and/or Member States representatives: Not applicable
- EFSA:

AHAW Unit: Denise Candiani BIOCONTAM Unit: Beatriz Guerra Román, Ernesto Liebana, Pietro Stella

FEED Unit: Rosella Brozzi

• Others:

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <u>http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.</u>



EMA Working Group Members: Keith Baptiste (29 April), Boudewijn Catry (29 April, by WEB-Conference), Christian Friis (29 April), Helen Jukes, Cristina Muñoz Madero, Pascal Sanders

EMA Staff: Zoltan Kunsagi, Jordi Torren

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

The Chair welcomed the participants.

Apologies were received from Simon More (Working Group Member).

This Working Group is working jointly with a corresponding EMA Working Group, to address the request for a Joint Scientific Opinion to EFSA and EMA.

## 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 Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

## 4. Scientific topic

## **4.1.** Reduction of the need to use antimicrobials <sup>4</sup>

The Working Group reviewed the last contributions received on the draft opinion, and discussed draft conclusions and recommendations on the different sections of the draft opinion. The Working Group welcomed a presentation by and discussion with Dr. Atle Lillehaug (Hearing Expert) in relation to the use of antimicrobials in aquaculture in Norway and the strategy implemented along the years in that country to reduce the use of antimicrobials.

<sup>&</sup>lt;sup>2</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

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

<sup>&</sup>lt;sup>4</sup> <u>http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00216</u>



The Working Group discussed the timelines for finalising the draft opinion, and agreed remaining tasks and respective deadlines.

### **5. Next meetings**

The next meeting will be held on 22 June 2016, by WEB-Conference. Additional meetings on specific topics may be organised if needed in May/June 2016.



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

In the ADoI or in the SDoI filled for the present meeting Prof. Gregers Jungersen declared the following interest: private funding for research on the efficacy of vaccine against infectious disease in cattle and being co-inventor of a patent on a vaccine against *Mycobacterium avium paratuberculosis*. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>5</sup> and the Decision of the Executive Director on Declarations of Interest<sup>6</sup>, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of item "vaccination in cattle and vaccination against *Mycobacterium avium paratuberculosis*" by the concerned scientific group.

<sup>&</sup>lt;sup>5</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

<sup>&</sup>lt;sup>6</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



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## Scientific Panel on Biological Hazards

# Minutes of the 6<sup>th</sup> meeting of the Working Group on Reduction of the need to use antimicrobials

## Held by WEB-conference, 7 March 2016

(Agreed on 17 March 2016)

## Participants

• Working Group Members:

Pier Sandro Cocconcelli Robert Davies

Christian Ducrot

Gregers Jungersen

John Threlfall

- Hearing Experts<sup>1</sup>: Not Applicable
- European Commission and/or Member States representatives: Not applicable
- EFSA:

AHAW Unit: Denise Candiani

BIOCONTAM Unit: Beatriz Guerra Román, Ernesto Liebana, Pietro Stella

• Others:

EMA Working Group Members: Boudewijn Catry, Christian Friis, Helen Jukes, Cristina Muñoz Madero

EMA Staff: Zoltan Kunsagi, Jordi Torren

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <u>http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.</u>



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

The Chair welcomed the participants.

Apologies were received from Simon More (Working Group Member).

This Working Group is working jointly with a corresponding EMA Working Group, to address the request for a Joint Scientific Opinion to EFSA and EMA.

The Chair informed the Working Group of the recent resignation of Working Group Member Elisabeth Marion Broens.

## 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 Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

### **4. Scientific topic**

### **4.1.** Reduction of the need to use antimicrobials <sup>4</sup>

The Working Group reviewed the last contributions received on the draft opinion, and answers received from stakeholders to two questionnaires on the use of antimicrobials in food-producing animals and on agreements between producers and retailers on the use of antimicrobials in animal production.

The Working Group agreed actions and deadlines for drafting the opinion.

<sup>&</sup>lt;sup>2</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

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

<sup>&</sup>lt;sup>4</sup> <u>http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00216</u>



The next meeting will be held on 28 and 29 April 2016 in Parma.



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

In the ADoI or in the SDoI filled for the present meeting Prof. Gregers Jungersen declared the following interest: private funding for research on the efficacy of vaccine against infectious disease in cattle and being co-inventor of a patent on a vaccine against *Mycobacterium avium paratuberculosis*. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>5</sup> and the Decision of the Executive Director on Declarations of Interest<sup>6</sup>, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of item "vaccination in cattle and vaccination against *Mycobacterium avium paratuberculosis*" by the concerned scientific group.

<sup>&</sup>lt;sup>5</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

<sup>&</sup>lt;sup>6</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



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# Scientific Panel on Biological Hazards

# Minutes of the 5<sup>th</sup> meeting of the Working Group on Reduction of the need to use antimicrobials

## Held on 4-5 February 2016, London (United Kingdom)

(Agreed on 18 February 2015)

## Participants

- Working Group Members:
  - Elisabeth Marion Broens (on 5 February) Pier Sandro Cocconcelli Robert Davies Christian Ducrot Gregers Jungersen Simon More (on 5 February) John Threlfall
- Hearing Experts<sup>1</sup>:

Not Applicable

- European Commission and/or Member States representatives:
  Marina Marini
- EFSA:

AHAW Unit: Denise Candiani (via teleconference)

BIOCONTAM Unit: Beatriz Guerra Román (via teleconference on 4 February), Ernesto Liebana, Pietro Stella

FEED Unit: Rosella Brozzi

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <u>http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.</u>



## • Others:

EMA Working Group Members: Boudewijn Catry (via teleconference), Christian Friis, Helen Jukes, Cristina Muñoz Madero, Pascal Sanders EMA Staff: Zoltan Kunsagi, Jordi Torren

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

The Chairs welcomed the participants.

Apologies were received from Els Broens and Simon More for 4 February.

This Working Group is working jointly with a corresponding EMA Working Group, to address the request for a Joint Scientific Opinion to EFSA and EMA.

## 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 Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

## 4. Scientific topic

## **4.1.** Reduction of the need to use antimicrobials <sup>4</sup>

The WG reviewed the different sections of the draft opinion and the new contributions received from the experts since the previous meeting, discussed how to restructure some parts of the draft opinion, and discussed preliminary conclusions and recommendations for some of the sections.

The WG also agreed actions and deadlines for drafting the opinion.

<sup>&</sup>lt;sup>2</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

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

<sup>&</sup>lt;sup>4</sup> <u>http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00216</u>



The next meeting will be held on 7 March 2016 (via WEB-conference).



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

In the ADoI or in the SDoI filled for the present meeting Prof. Gregers Jungersen declared the following interest: private funding for research on the efficacy of vaccine against infectious disease in cattle and being co-inventor of a patent on a vaccine against *Mycobacterium avium paratuberculosis*. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>5</sup> and the Decision of the Executive Director on Declarations of Interest<sup>6</sup>, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of item "vaccination in cattle and vaccination against *Mycobacterium avium paratuberculosis*" by the concerned scientific group.

<sup>&</sup>lt;sup>5</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

<sup>&</sup>lt;sup>6</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



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# Scientific Panel on Biological Hazards

# Minutes of the 4<sup>th</sup> meeting of the Working Group on Reduction of the need to use antimicrobials

## Held on 15 December 2015, London (United Kingdom)

(Agreed on 6 January 2015)

## **Participants**

- Working Group Members: Elisabeth Marion Broens Pier Sandro Cocconcelli Robert Davies Christian Ducrot Gregers Jungersen John Threlfall
- Hearing Experts<sup>1</sup>:

Not Applicable

## • European Commission and/or Member States representatives:

Marina Marini

• EFSA:

AHAW Unit: Denise Candiani

BIOCONTAM Unit: Beatriz Guerra Román, Ernesto Liebana, Pietro Stella

FEED Unit: Rosella Brozzi

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <u>http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.</u>



## • Others:

EMA Working Group Members: Boudewijn Catry, Christian Friis, Helen Jukes, Cristina Muñoz Madero, Pascal Sanders

EMA Staff: Zoltan Kunsagi

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

The Chairs welcomed the participants.

This Working Group is working jointly with a corresponding EMA Working Group, to address the request for a Joint Scientific Opinion to EFSA and EMA.

## 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 Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

## 4. Scientific topic

### **4.1.** Reduction of the need to use antimicrobials <sup>4</sup>

The WG reviewed the different sections of the draft opinion and the new contributions received from the experts since the previous meeting. The WG discussed how to further develop the text of the draft opinion, identified specific data gaps and respective questions to be asked to selected stakeholders.

The WG also agreed actions and deadlines for drafting the opinion and a provisional plan for future meetings.

<sup>&</sup>lt;sup>2</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

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

<sup>&</sup>lt;sup>4</sup> <u>http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00216</u>



The next meeting will be held on 4-5 February 2016 (London).



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

In the ADoI or in the SDoI filled for the present meeting Prof. Gregers Jungersen declared the following interest: private funding for research on the efficacy of vaccine against infectious disease in cattle and being co-inventor of a patent on a vaccine against *Mycobacterium avium paratuberculosis*. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>5</sup> and the Decision of the Executive Director on Declarations of Interest<sup>6</sup>, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of item "vaccination in cattle and vaccination against *Mycobacterium avium paratuberculosis*" by the concerned scientific group.

<sup>&</sup>lt;sup>5</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

<sup>&</sup>lt;sup>6</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



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BIOLOGICAL HAZARDS AND CONTAMINANTS

# Scientific Panel on Biological Hazards

# Minutes of the 3<sup>rd</sup> meeting of the Working Group on Reduction of the need to use antimicrobials

# Held by WEB-conference, 29 October 2015

(Agreed on 10 November 2015)

# Participants

• Working Group Members:

Pier Sandro Cocconcelli Robert Davies Christian Ducrot Gregers Jungersen John Threlfall

- Hearing Experts<sup>1</sup>:
  Not Applicable
- European Commission and/or Member States representatives: Not Applicable
- EFSA:

AHAW Unit: Franck Berthe BIOCONTAM Unit: Beatriz Guerra Román, Pietro Stella FEED Unit: Rosella Brozzi

• Others:

EMA Working Group Members: Keith Baptiste, Boudewijn Catry, Christian Friis, Helen Jukes, Cristina Muñoz Madero, Pascal Sanders EMA Staff: Zoltan Kunsagi

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <u>http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.</u>



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

The Chairs welcomed the participants. Apologies were received from Elisabeth Marion Broens (Working Group Member).

This Working Group is working jointly with a corresponding EMA Working Group, to address the request for a Joint Scientific Opinion to EFSA and EMA.

# 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 Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

# 4. Scientific topic

### **4.1.** Reduction of the need to use antimicrobials <sup>4</sup>

The WG discussed the different sections of the draft opinion, including the distribution of tasks, the allocation of section leaders, the contributions received, the main topics to be covered, the main challenges, some data gaps and some possible questions to stakeholders.

The WG also discussed and agreed deadlines for future drafting of the draft opinion and a provisional plan for future meetings.

### 5. Next meetings

The next meeting will be held on 15 December 2015 (London).

<sup>&</sup>lt;sup>2</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

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

<sup>&</sup>lt;sup>4</sup> <u>http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00216</u>



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

In the ADoI or in the SDoI filled for the present meeting Prof. Gregers Jungersen declared the following interest: private funding for research on the efficacy of vaccine against infectious disease in cattle and being co-inventor of a patent on a vaccine against *Mycobacterium avium paratuberculosis*. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>5</sup> and the Decision of the Executive Director on Declarations of Interest<sup>6</sup>, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of item "vaccination in cattle and vaccination against *Mycobacterium avium paratuberculosis*" by the concerned scientific group.

<sup>&</sup>lt;sup>5</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

<sup>&</sup>lt;sup>6</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



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BIOLOGICAL HAZARDS AND CONTAMINANTS

# Scientific Panel on Biological Hazards

# Minutes of the 2<sup>nd</sup> meeting of the Working Group on Reduction of the need to use antimicrobials

# Held on 15 September, Parma (Italy)

(Agreed on 15 October 2015)

# Participants

- Working Group Members: Elisabeth Marion Broens
   Pier Sandro Cocconcelli
   Robert Davies
   Christian Ducrot
   Gregers Jungersen
   John Threlfall
- Hearing Experts<sup>1</sup>: Not Applicable

# • European Commission and/or Member States representatives:

Dean Bosnjak (DG SANTE) Laszlo Kuster (DG SANTE)

• EFSA:

AHAW Unit: Denise Candiani

BIOCONTAM Unit: Pierre-Alexandre Beloeil, Beatriz Guerra Román, Pietro Stella

FEED Unit: Rosella Brozzi

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <u>http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.</u>



### • Others:

EMA Working Group Members: Keith Baptiste, Boudewijn Catry, Christian Friis, Helen Jukes, Cristina Muñoz Madero, Pascal Sanders EMA Staff: Zoltan Kunsagi, Jordi Torren

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

The Chairs welcomed the participants.

No apologies were received.

Christian Ducrot (Working Group Member) participated by web-conference in the morning session of the meeting.

This Working Group is working jointly with a corresponding EMA Working Group, to address the request for a Joint Scientific Opinion to EFSA and EMA.

# 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 Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

# 4. Scientific topic

### **4.1.** Reduction of the need to use antimicrobials <sup>4</sup>

The Working Group discussed again the mandate and clarified some issues related with the terms of reference of the request with the European Commission. The following issues were discussed by the Working Group: revised table of contents of the draft Joint Scientific

<sup>&</sup>lt;sup>2</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

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

<sup>&</sup>lt;sup>4</sup> <u>http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00216</u>



Opinion, draft Scientific Opinion, possible technical hearing with selected stakeholders, literature searches in the framework of the opinion, distribution of tasks among WG experts, future meetings.

# **5. Next meetings**

The next meetings for 2015 will be held on 29 October (web-conference) and 15 December (London).



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

In the ADoI or in the SDoI filled for the present meeting Prof. Gregers Jungersen declared the following interest: private funding for research on the efficacy of vaccine against infectious disease in cattle and being co-inventor of a patent on a vaccine against *Mycobacterium avium paratuberculosis*. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>5</sup> and the Decision of the Executive Director on Declarations of Interest<sup>6</sup>, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of item "vaccination in cattle and vaccination against *Mycobacterium avium paratuberculosis*" by the concerned scientific group.

<sup>&</sup>lt;sup>5</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

<sup>&</sup>lt;sup>6</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



BIOLOGICAL HAZARDS AND CONTAMINANTS

# Scientific Panel on Biological Hazards

# Minutes of the 1<sup>st</sup> meeting of the Working Group on Reduction of the need to use antimicrobials

# Held by WEB-conference, 16 July 2015

(Agreed on 15 August 2015)

# Participants

- Working Group Members: Elisabeth Marion Broens
   Pier Sandro Cocconcelli
   Robert Davies
   Christian Ducrot
   John Threlfall
- Hearing Experts<sup>1</sup>:

Not Applicable

• European Commission and/or Member States representatives:

Dean Bosnjak (DG SANTE) Barbara Logan (DG SANTE) Marina Marini (DG SANTE) Rosa Peran (DG SANTE)

• EFSA:

AHAW Unit: Denise Candiani BIOCONTAM Unit: Pierre-Alexandre Beloeil, Beatriz Guerra Román, Ernesto Liebana-Criado, Valentina Rizzi, Pietro Stella

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <u>http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.</u>



FEED Unit: Rosella Brozzi

### • Others:

EMA Working Group Members: Boudewijn Catry, Christian Friis, Helen Jukes, Cristina Muñoz Madero, Pascal Sanders

EMA Staff: Zoltan Kunsagi, Jordi Torren

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

The Chairs welcomed the participants.

Apologies were received from Gregers Jungersen (Working Group Member) and Keith Baptiste (EMA Working Group Member).

This Working Group is working jointly with a corresponding EMA Working Group, to address the request for a Joint Scientific Opinion to EFSA and EMA.

# 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 Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

# 4. Scientific topic

### **4.1.** Reduction of the need to use antimicrobials <sup>4</sup>

The Working Group discussed the mandate and clarified the terms of reference of the request with the European Commission. A preliminary table of contents of the draft Joint Scientific Opinion was presented

<sup>&</sup>lt;sup>2</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

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

<sup>&</sup>lt;sup>4</sup> <u>http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00216</u>



and reviewed. The Working Group discussed the opportunity to hold a technical hearing with stakeholders to gather data and information useful for the development of the Joint Scientific Opinion. A repository of relevant scientific documents obtained through a literature search was presented.

# 5. Next meetings

The next meeting will be held in September in Parma. After that, two additional meetings (one by WEB-conference and one physical meeting) will take place in 2015. Dates of the meetings will be defined based on the availability of the Working Group Members.



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

In the ADoI or in the SDoI filled for the present meeting Prof. Gregers Jungersen declared the following interest: private funding for research on the efficacy of vaccine against infectious disease in cattle and being co-inventor of a patent on a vaccine against *Mycobacterium avium paratuberculosis*. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>5</sup> and the Decision of the Executive Director on Declarations of Interest<sup>6</sup>, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of item "vaccination in cattle and vaccination against Mycobacterium avium paratuberculosis" by the concerned scientific group.

 <sup>&</sup>lt;sup>5</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>
 <sup>6</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014</u>