

Scientific Panel on Biological Hazards

Minutes of the 12th meeting of the Working Group on Indicators on AMR and antimicrobial use

Held by WEB-conference, 1 September 2017

(Agreed on 8 September 2017)

Participants

- **Working Group Members:**

Antonia Ricci (Chair)

Gertraud Schüpbach-Regula

Christopher Teale

Bernd-Alois Tenhagen

John Threlfall

- **EFSA:**

BIOCONTAM Unit: Raquel Garcia-Fierro, Francesca Latronico, Ernesto Liebana, Pietro Stella

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Benno ter Kuile (WG member).

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest,² 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 topics for discussion

4.1. Joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals³

The Chair opened the meeting and welcomed the members of the working group (WG). This WG is running in parallel to respective WGs of the European Centre for Disease Prevention and Control (ECDC) and of the European Medicines Agency (EMA).

The Chair informed the WG on the feedback on the interagency Coordination WG meeting held on 30 August jointly with ECDC and EMA WGs.

The WG reviewed the new contributions and recent changes in the draft opinion, focusing on draft conclusions and recommendations and on the section on the future use of indicators. It also reviewed the last test of the proposed AMR indicators in food-producing animals and related methodology. The WG agreed that the draft opinion, after few final tasks, can be now submitted to the BIOAHZ Panel for possible adoption.

5. Next meeting

No more WG meetings are currently scheduled.

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

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

³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00638>

Annex

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

CONFLICT OF INTEREST: In the ADoI filled for the present meeting Dr. Bernd-Alois Tenhagen declared the following interest: *"I am currently involved in a formal risk assessment advice at national level specifically on the establishment of AMR indicators for trend watching (overlapping with the ToRs of the EFSA mandate) under my employment"*. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, 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 in relation to appraising any data on indicators originating from Germany by the concerned scientific group.

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

Minutes of the 11th meeting of the Working Group on Indicators on AMR and antimicrobial use

Held on 30 August 2017, Parma (Italy)

(Agreed on 31 August 2017)

Participants

- **Working Group Members:**

Antonia Ricci (Chair)

- **EFSA:**

BIOCONTAM Unit: Ernesto Liebana, Pietro Stella

- **Others (by web-conference):**

EMA WG Members: Helen Jukes, Katariina Kivilahti-Mäntylä

ECDC staff: Ole Heuer, Elias Iosifidis, Diamantis Plachouras, Klaus Weist

EMA staff: Zoltan Kunsagi, Jordi Torren

European Commission: Angela Bolufer De Gea

WHO observers: Danilo Lo Fo Wong, Pravvarsha Prakash, Elizabeth Tayler

1. Welcome and apologies for absence

The Chair welcomed the participants.

This meeting of the Working Group involved only the Chair of the EFSA Working Group, who met together with the chairs of the corresponding ECDC/EMA Working Groups and ECDC/EFSA/EMA staff, to address the request for a Joint Scientific Opinion to ECDC, EFSA and EMA. It also

involved participation of observers from WHO and WHO/Europe, invited by ECDC.

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topics for discussion

4.1. Joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals³

The Chair opened the meeting and welcomed the participants. Chairs of the EFSA and EMA Working Groups and ECDC staff presented the progress of the Working Groups of the different agencies in the mandate. The draft opinion was reviewed, with a special focus on conclusions, recommendations and newly drafted sections on the joint use of indicators from the different sectors. The timelines for presentation of the draft opinion for possible adoption by the adopting bodies in ECDC, EFSA and EMA was reviewed and agreed. Remaining tasks to finalised the document were agreed.

5. Next meeting

The next meeting will take place on 1 September 2017 (EFSA WG) by web-conference.

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-2016-00638>

Scientific Panel on Biological Hazards

Minutes of the 10th meeting of the Working Group on Indicators on AMR and antimicrobial use

Held by WEB-conference, 8 August 2017

(Agreed on 14 August 2017)

Participants

- **Working Group Members:**

Antonia Ricci (Chair)

Gertraud Schüpbach-Regula

Christopher Teale

Bernd-Alois Tenhagen

Benno ter Kuile

John Threlfall

- **EFSA:**

BIOCONTAM Unit: Raquel Garcia-Fierro, Francesca Latronico, Pietro Stella

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest,² 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 topics for discussion

4.1. Joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals³

The Chair opened the meeting and welcomed the members of the working group (WG). This WG is running in parallel to respective WGs of the European Centre for Disease Prevention and Control (ECDC) and of the European Medicines Agency (EMA).

The Chair informed the WG on the feedback from the BIOHAZ Panel on the draft opinion, received during the 2017 July Panel's Plenary meeting, and related suggestions for the calculation of the indicators. The Chair also provided feedback to the WG on the interagency Coordination WG meeting held on 13 July jointly with ECDC and EMA WGs.

The WG reviewed the new contributions, and agreed on draft conclusions and recommendations of the draft opinion.

The WG identified remaining tasks and agreed on the schedule of future meetings.

5. Next meeting

The next meetings will take place on 30 August 2017 (interagency Coordination WG) and 1 September 2017 (EFSA WG).

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

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

³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00638>

Annex

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

CONFLICT OF INTEREST: In the ADoI filled for the present meeting Dr. Bernd-Alois Tenhagen declared the following interest: *"I am currently involved in a formal risk assessment advice at national level specifically on the establishment of AMR indicators for trend watching (overlapping with the ToRs of the EFSA mandate) under my employment"*. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, 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 in relation to appraising any data on indicators originating from Germany by the concerned scientific group.

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

Minutes of the 9th meeting of the Working Group on Indicators on AMR and antimicrobial use

Held on 13 July 2017, Parma (Italy)

(Agreed on 8 August 2017)

Participants

- **Working Group Members:**

Antonia Ricci (Chair)

- **EFSA:**

BIOCONTAM Unit: Raquel Garcia-Fierro, Francesca Latronico, Ernesto Liebana, Pietro Stella

- **Others (by web-conference):**

EMA WG Members: Helen Jukes, Katariina Kivilahti-Mäntylä

ECDC staff: Ole Heuer, Elias Iosifidis, Dominique Monnet

EMA staff: Jordi Torren

European Commission: Martial Plantady

WHO observers: Elizabeth Tayler, Veronica Walford (WHO)

1. Welcome and apologies for absence

The Chair welcomed the participants.

This meeting of the Working Group involved only the Chair of the EFSA Working Group, who met together with the chairs of the corresponding ECDC/EMA Working Groups and ECDC/EFSA/EMA staff, to address the request for a Joint Scientific Opinion to ECDC, EFSA and EMA. It also involved participation of observers from WHO and WHO/Europe, invited by ECDC.

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topics for discussion

4.1. Joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals³

The Chair opened the meeting and welcomed the participants. Chairs of the EFSA and EMA Working Groups and ECDC staff presented the progress of the Working Groups of the different agencies in the mandate. The draft opinion was reviewed and actions were agreed to harmonise the contributions from the different agencies and finalise the draft opinion.

The progress will be reviewed in the next meeting.

5. Next meeting

The next meetings will take place on 8 August 2017 (EFSA WG) and on 30 August 2017 (joint meeting with EMA/ECDC WGs) by web-conference.

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-2016-00638>

Scientific Panel on Biological Hazards

Minutes of the 8th meeting of the Working Group on Indicators on AMR and antimicrobial use

Held by WEB-conference, 4 July 2017

(Agreed on 13 July 2017)

Participants

- **Working Group Members:**

Antonia Ricci (Chair)

Gertraud Schüpbach-Regula

Christopher Teale

Bernd-Alois Tenhagen

Benno ter Kuile

- **EFSA:**

BIOCONTAM Unit: Raquel Garcia-Fierro, Ernesto Liebana, Pietro Stella

- **Others:**

ECDC observers: Ole Heuer, Diamantis Plachouras

EMA staff: Zoltan Kunsagi, Jordi Torren

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from John Threlfall.

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest,² 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 topics for discussion

4.1. Joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals³

The Chair opened the meeting and welcomed the members of the working group (WG). This WG is running in parallel to respective WGs of the European Centre for Disease Prevention and Control (ECDC) and of the European Medicines Agency (EMA).

The Chair informed the WG on the feedback from the BIOHAZ Panel on the draft opinion, and the WG agreed on how to address those comments.

The WG agreed on the final list of antimicrobial resistance indicators in food-producing animals to be presented to the BIOHAZ Panel. It discussed the technical details to retain in Appendix to the document, and reviewed the whole draft opinion.

ECDC and EMA observers introduced to the WG their preliminary text for the draft opinion, and timelines for their finalisation. EFSA, ECDC and EMA Secretariat agreed to hold the next interagency Coordination WG meeting on 13 July 2017.

The WG identified remaining tasks and agreed on the schedule of future meetings.

5. Next meeting

The next meetings will take place on 8 August 2017 (confirmed) and 1 September 2017 (to be confirmed).

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

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

³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00638>

Annex

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

CONFLICT OF INTEREST: In the ADoI filled for the present meeting Dr. Bernd-Alois Tenhagen declared the following interest: *"I am currently involved in a formal risk assessment advice at national level specifically on the establishment of AMR indicators for trend watching (overlapping with the ToRs of the EFSA mandate) under my employment"*. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, 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 in relation to appraising any data on indicators originating from Germany by the concerned scientific group.

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

Minutes of the 7th meeting of the Working Group on Indicators on AMR and antimicrobial use

Held on 15 May 2017, Parma (Italy)

(Agreed on 22 May 2017)

Participants

- **Working Group Members:**

Antonia Ricci (Chair)

Gertraud Schüpbach-Regula

Christopher Teale

Bernd-Alois Tenhagen

Benno ter Kuile

John Threlfall

- **EFSA:**

BIOCONTAM Unit: Raquel Garcia-Fierro, Francesca Latronico,
Valentina Rizzi, Pietro Stella

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest,² 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 topics for discussion

4.1. Joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals³

The Chair opened the meeting and welcomed the members of the working group (WG). This WG is running in parallel to respective WGs of the European Centre for Disease Prevention and Control (ECDC) and of the European Medicines Agency (EMA).

The Chair and EFSA Secretariat provided feedback to the WG on the outcome of the sixth WG meeting, held on 3 May together with representatives from the ECDC and EMA WG and staff responsible for the joint mandate.

The WG discussed the last contributions to the draft opinion, and defined the indicators for antimicrobial resistance in food-producing animals and food thereof to be selected. The WG reviewed the draft opinion and identified remaining tasks. The meeting schedule was revised to take into account the needs during the final development stages of the opinion.

5. Next meeting

The next meeting will take place on 4 July 2017.

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

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

³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00638>

Annex

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

CONFLICT OF INTEREST: In the ADoI filled for the present meeting Dr. Bernd-Alois Tenhagen declared the following interest: *"I am currently involved in a formal risk assessment advice at national level specifically on the establishment of AMR indicators for trend watching (overlapping with the ToRs of the EFSA mandate) under my employment"*. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, 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 in relation to appraising any data on indicators originating from Germany by the concerned scientific group.

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

Minutes of the 6th meeting of the Working Group on Indicators on AMR and antimicrobial use

Held by WEB-conference, 3 May 2017

(Agreed on 9 May 2017)

Participants

- **Working Group Members:**

Antonia Ricci (Chair)

- **EFSA:**

BIOCONTAM Unit: Raquel Garcia-Fierro, Ernesto Liebana, Pietro Stella

- **Others:**

EMA WG Members: Katariina Kivilahti-Mäntylä

ECDC staff: Ole Heuer, Diamantis Plachouras

EMA staff: Zoltan Kunsagi, Jordi Torren

WHO observers: Danilo Lo Fo Wong (WHO/Europe), Elizabeth Tayler, Saskia Nahrgang (WHO)

1. Welcome and apologies for absence

The Chair welcomed the participants.

This meeting of the Working Group involved only the Chair of the EFSA Working Group, who met together with the chairs of the corresponding ECDC/EMA Working Groups and ECDC/EFSA/EMA staff, to address the request for a Joint Scientific Opinion to ECDC, EFSA and EMA. It also involved participation of observers from WHO and WHO/Europe, invited by ECDC.

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topics for discussion

4.1. Joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals³

The Chair opened the meeting and welcomed the participants. Chairs of the EFSA and EMA Working Groups and ECDC staff presented the progress of the Working Groups of the different agencies in the mandate. The draft opinion was reviewed and actions were agreed to harmonise the contributions from the different agencies. It was agreed to use a modified EFSA template for the opinion, with final publication in the EFSA Journal.

The progress will be reviewed in the next meeting.

5. Next meeting

The next meeting will take place in June/July 2017 (date to be defined) by web-conference.

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-2016-00638>

Scientific Panel on Biological Hazards

Minutes of the 5th meeting of the Working Group on Indicators on AMR and antimicrobial use

Held by WEB-conference, 20 April 2017

(Agreed on 28 April 2017)

Participants

- **Working Group Members:**

Antonia Ricci (Chair)

Gertraud Schüpbach-Regula

Christopher Teale

Bernd-Alois Tenhagen

Benno ter Kuile

John Threlfall

- **EFSA:**

BIOCONTAM Unit: Raquel Garcia-Fierro, Ernesto Liebana, Pietro Stella

- **Others:**

ECDC observer: Ole Heuer

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest,² 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 topics for discussion

4.1. Joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals³

The Chair opened the meeting and welcomed the members of the working group (WG). This WG is running in parallel to respective WGs of the European Centre for Disease Prevention and Control (ECDC) and of the European Medicines Agency (EMA).

The Chair and EFSA Secretariat provided feedback to the WG received from the BIOHAZ Panel, who supported the methodological approach selected. An update on the progress at ECDC was given by the ECDC observer.

The WG discussed the last contributions to the draft opinion, and revised the possible indicators for antimicrobial resistance in food-producing animals and food to be selected.

Tasks were distributed among the WG members.

5. Next meeting

The next meeting will take place on 15 May 2017 (physical meeting).

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

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

³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00638>

Annex

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

CONFLICT OF INTEREST: In the ADoI filled for the present meeting Dr. Bernd-Alois Tenhagen declared the following interest: *"I am currently involved in a formal risk assessment advice at national level specifically on the establishment of AMR indicators for trend watching (overlapping with the ToRs of the EFSA mandate) under my employment"*. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, 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 in relation to appraising any data on indicators originating from Germany by the concerned scientific group.

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

Minutes of the 4th meeting of the Working Group on Indicators on AMR and antimicrobial use

Held on 14 March 2017, Parma (Italy)

(Agreed on 24 March 2017)

Participants

- **Working Group Members:**

Antonia Ricci (Chair)

Gertraud Schüpbach-Regula

Christopher Teale

Bernd-Alois Tenhagen has participated via teleconference (morning session)

Benno ter Kuile

John Threlfall

- **EFSA:**

BIOCONTAM Unit: Pierre-Alexandre Beloeil, Raquel Garcia-Fierro, Beatriz Guerra, Francesca Latronico, Ernesto Liebana, Pietro Stella

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest,² 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 topics for discussion

4.1. Joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals³

The Chair opened the meeting and welcomed the members of the working group (WG). This WG is running in parallel to respective WGs of the European Centre for Disease Prevention and Control (ECDC) and of the European Medicines Agency (EMA).

The Chair and EFSA Secretariat provided feedback to the WG on the outcome of the third WG meeting, held on 9 March together with representatives from the ECDC and EMA WG and staff responsible for the joint mandate.

The WG discussed the last contributions to the draft opinion, and the possible indicators for antimicrobial resistance in food-producing animals and food thereof to be selected, which would be finalised during the next meetings.

Tasks were distributed among the WG members.

5. Next meeting

The next meeting will take place on 20 April 2017 (web-conference).

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

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

³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00638>

Annex

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

CONFLICT OF INTEREST: In the ADoI filled for the present meeting Dr. Bernd-Alois Tenhagen declared the following interest: *"I am currently involved in a formal risk assessment advice at national level specifically on the establishment of AMR indicators for trend watching (overlapping with the ToRs of the EFSA mandate) under my employment"*. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, 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 in relation to appraising any data on indicators originating from Germany by the concerned scientific group.

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

Minutes of the 3rd meeting of the Working Group on Indicators on AMR and antimicrobial use

Held by WEB-conference, 9 March 2017

(Agreed on 17 March 2017)

Participants

- **Working Group Members:**

Antonia Ricci (Chair)

- **EFSA:**

BIOCONTAM Unit: Pierre-Alexandre Beloeil, Francesca Latronico, Ernesto Liebana, Pietro Stella

- **Others:**

EMA WG Members: Katariina Kivilahti-Mäntylä

ECDC staff: Ole Heuer, Diamantis Plachouras

EMA staff: Zoltan Kunsagi, Jordi Torren

European Commission: Angela Bolufer De Gea

WHO observers: Danilo Lo Fo Wong (WHO/Europe), Elizabeth Tayler, Veronica Walford (WHO)

1. Welcome and apologies for absence

The Chair welcomed the participants.

This meeting of the Working Group involved only the Chair of the EFSA Working Group, who met together with the chairs of the corresponding ECDC/EMA Working Groups and ECDC/EFSA/EMA staff, to address the request for a Joint Scientific Opinion to ECDC, EFSA and EMA. It also involved participation of observers from WHO and WHO/Europe, invited by ECDC.

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topics for discussion

4.1. Joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals³

The Chair opened the meeting and welcomed the participants. Chairs of the EFSA and EMA Working Groups and ECDC staff presented the progress of the Working Groups of the different agencies in the mandate. All confirmed a preliminary discussion on the possible indicators on consumption of antimicrobials in humans and in food-producing animals, and of antimicrobial resistance (AMR) in humans, food-producing animals and food thereof, has taken place. Representatives from the three Working Groups and agencies agreed on the structure of the draft opinion, on the respective tasks in the development of the draft opinion and on the template to be used.

The progress will be reviewed in the next meeting.

5. Next meeting

The next meeting will take place in April 2017 (date to be defined) by web-conference.

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-2016-00638>

Scientific Panel on Biological Hazards

Minutes of the 2nd meeting of the Working Group on Indicators on AMR and antimicrobial use

Held on 7 February 2017, Parma (Italy)

(Agreed on 17 February 2017)

Participants

- **Working Group Members:**

Antonia Ricci (Chair)

Gertraud Schüpbach-Regula

Christopher Teale

Bernd-Alois Tenhagen

Benno ter Kuile

John Threlfall

- **EFSA:**

BIOCONTAM Unit: Pierre-Alexandre Beloeil, Francesca Latronico,
Ernesto Liebana, Pietro Stella

- **Others:**

ECDC observers: Ole Heuer, Dominique Monnet (WEB-conference)

EMA observers: Zoltan Kunsagi (WEB-conference)

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest,² 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 topics for discussion

4.1. Joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals³

The Chair opened the meeting and welcomed the members of the working group (WG). This WG is running in parallel to respective WGs of the European Centre for Disease Prevention and Control (ECDC) and of the European Medicines Agency (EMA).

The WG discussed the clarifications to the terms of reference of the mandate received from the European Commission. The WG acknowledged that the number of indicators to be provided cannot exceed the number indicated in the mandate (five primary and ten secondary indicators), and that indicators should not be designed specifically for the different Member States but rather applicable to all of them.

The WG discussed the draft opinion, the different types of indicators that could be designed and the criteria to do so.

ECDC and EMA observers updated the WG on the progress of their work on the mandate. It was agreed to further exchange information between the agencies to ensure a common drafting of the joint opinion.

Tasks were distributed among the WG members.

5. Next meeting

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

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

³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00638>

The next meeting will take place on 14 March 2017, in Parma.

Annex

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

CONFLICT OF INTEREST: In the ADoI filled for the present meeting Dr. Bernd-Alois Tenhagen declared the following interest: *"I am currently involved in a formal risk assessment advice at national level specifically on the establishment of AMR indicators for trend watching (overlapping with the ToRs of the EFSA mandate) under my employment"*. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, 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 in relation to appraising any data on indicators originating from Germany by the concerned scientific group.

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Scientific Panel on Biological Hazards

Minutes of the 1st meeting of the Working Group on Indicators on AMR and antimicrobial use

Held by WEB-conference, 19 December 2016

(Agreed on 6 January 2017)

Participants

- **Working Group Members:**

Antonia Ricci (Chair)

Gertraud Schüpbach-Regula

Christopher Teale

Bernd-Alois Tenhagen

Benno ter Kuile

John Threlfall

- **EFSA:**

BIOCONTAM Unit: Pierre-Alexandre Beloeil, Francesca Latronico,
Ernesto Liebana, Pietro Stella

- **Others:**

ECDC observers: Ole Heuer, Dominique Monnet

EMA observers: Zoltan Kunsagi, Jordi Torren

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from European Commission representatives.

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest,² 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 topics for discussion

4.1. Joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals³

The Chair opened the meeting and welcomed the members of the working group (WG). This WG will run in parallel to respective WGs of the European Centre for Disease Prevention and Control (ECDC) and of the European Medicines Agency (EMA).

EFSA Secretariat presented to the WG a number of topics: EFSA DoI policy, administrative issues and submission of documents for reimbursement of travel expenses related to physical meetings, the mandate and terms of reference (ToRs) as received from the European Commission (EC), the parties involved in the mandate (ECDC, EFSA and EMA), the relationships between the WG and the BIOHAZ Panel, the adoption process by the BIOHAZ Panel, and the timelines for finalisation of the draft opinion. Ongoing EFSA mandates on topics related to the present mandate were also presented.

The WG discussed the mandate and terms of reference, highlighting few issues that should be clarified with the EC, such as the aim of the indicators, the differentiation of indicators by animal species and food thereof, and the need for EU versus Member States-specific indicators.

The WG had a preliminary discussion on the methodology to approach the mandate, which will be finalised during the next meeting.

Tasks were distributed among the WG members.

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

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

³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00638>

5. Next meeting(s)

The next meeting will take place around the end of January or beginning of February 2017. In due time, EFSA Secretariat will go back to the WG with proposals for meeting dates.

Annex

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

CONFLICT OF INTEREST: In the ADoI filled for the present meeting Dr. Bernd-Alois Tenhagen declared the following interest: *"I am currently involved in a formal risk assessment advice at national level specifically on the establishment of AMR indicators for trend watching (overlapping with the ToRs of the EFSA mandate) under my employment"*. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, 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 in relation to appraising any data on indicators originating from Germany by the concerned scientific group.

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>