



# SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 30<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues, SubWG-AMR)

WEB-conference, 26 August 2021

(Agreed on 13 September 2021 by written procedure)

### **Participants**

Working Group Members:

SubWG AMR:

Luisa Peixe

Dan I Anderson

Johan Bengtsson-Palme

Damien Bouchard

**Rob Davies** 

Aude Ferran

Søren Saxmose Nielsen

Hearing Experts<sup>1</sup>:

Not Applicable.

European Commission and/or Member States representatives:See apologies.

EFSA:

BIOCONTAM Unit: Beatriz Guerra, Michaela Hempken

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





ALPHA Unit: Alesandro Broglia (partially)

ED: Pilar García-Vello

Others:

EMA: Sebastien Girault (partially)

# 1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

# 2. Adoption of agenda

The agenda was adopted without changes.

# 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

# 4. Agreement of the minutes of the 29th Working Group meeting held on 19 August 2021, Web-conference.

The minutes of the 29<sup>th</sup> Working Group meeting held on 19 August 2021 were agreed by written procedure on 19 July 2021<sup>4</sup>.

### 5. Scientific topic(s) for discussion

# 5.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed. Discussion on AMR aspects (ToR1)<sup>5</sup>.

The members of the SubWG-AMR met specifically to revise the latest updates done on the draft output scientific opinions: Part 1- Methodology, data gaps and uncertainties, and the AMR assessments included in the Part 2-13 documents, assessment of the 24 substances grouped by antimicrobial classes. Open comments were discussed, abstracts, conclusions and recommendations were agreed.

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>&</sup>lt;sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

<sup>5</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00221





Assessments done by the SubWG-GP to address ToR2 (growth promotion/yield increase) were presented for endorsement at the FEEDAP Plenary on 7 September after the meeting.

Updates on the Part 1 and Part-7-Amphenicols assessments were presented to the CVMP at their meeting on 9 September.

The Joint assessments (containing both the assessments to address ToR1 and ToR2) will be presented for possible adoption to the BIOHAZ Panel on 15-16 September.

# 6. Next meetings

No further meetings planned.





# SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 29<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues, SubWG-GP Feed Residues)

WEB-conference, July 19

(Agreed on 19 July 2021)

### **Participants**

Working Group Members:

SubWG GP Feed Residues: Vasileios Bampidis (Chair of the Sub-WG), Mayline Kouba, Secundino López Puente, Marta López-Alonso, Alena Pechová and Mariana Petkova

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission:

Not Applicable

EFSA:

FEED Unit: Angelica Amaduzzi<sup>2</sup> and and Gloria López Gálvez

BIOHAZ Unit: Beatriz Guerra<sup>2</sup>

Others:

Not Applicable

# Welcome and apologies for absence

The Chair welcomed the participants.

### 1. Adoption of agenda

<sup>2</sup> Partially

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





The agenda was adopted without changes.

# 2. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

# 3. Agreement of the minutes of the 28<sup>th</sup> Working Group meeting held on 9 July 2021 Web (SubWG-AMR).

The minutes of the 28<sup>th</sup> Working Group meeting, SubWG-AMR, held on 9 July 2021, were agreed by written procedure on 12 July 2021.<sup>5</sup>

# 4. Scientific topic(s) for discussion (SubWG-GP Feed Residues)

# 4.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed, Growth Promotion Feed Residues aspects (SubWG-GP Feed Residues)<sup>6</sup>:

The WG focused the discussion on the finalisation of the documents reporting overall items (such as the Data gaps and General conclusions/recommendations), the revision on Penicillin V document as well as on the revision of comments received on documents of specific substances.

The draft documents above listed may be ready for presentation and possible endorsement by the FEEDAP Panel in the first Plenary meeting of September 2021.

#### 5. AOB

N/A

# 6. Next meetings

The next meeting of the SubWG AMR will be on 26<sup>th</sup> August.

No more meetings are foreseen for the SubWG GP.

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>&</sup>lt;sup>5</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

<sup>6</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00221





# SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 28<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues, SubWG-AMR/GP)

WEB-conference, 09 of July 2021

(Agreed on 12 July 2021 by written procedure)

### **Participants**

Working Group Members:

SubWG AMR:

**Rob Davies** 

Aude Ferran

Søren Saxmose Nielsen

SubWG GP:

Vasileios Bampidis

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission and/or Member States representatives:

See apologies.

EFSA:

BIOCONTAM Unit: Beatriz Guerra

Others:

EMA: see apologies

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





# 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Sebastien Girault (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<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

# 4. Agreement of the minutes of the 27th Working Group meeting held on 07 July 2021, Web-conference.

The minutes of the 27th Working Group meeting held on 07 July 2021 were agreed on 7 July 2021.4

### 5. Scientific topic(s) for discussion

# 5.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed. Discussion on AMR aspects (ToR1).<sup>5</sup>

The meeting took place with few experts of each subWG to discuss specific topics in relation with Table 1, which contains the animal related data used to do the FARSC calculations. The table will be updated according to the discussions.

### 6. Next meetings

The next Web-meeting of the WG, SubWG GP will take place on 19 July.

The next Web-meeting of the WG, SubWG AMR will take place on 26 August.

2

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

<sup>5</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00221





# SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 27<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues, SubWG-GP Feed Residues)

WEB-conference, July 7

(Agreed on 7 July 2021)

### **Participants**

Working Group Members:

SubWG GP Feed Residues: Vasileios Bampidis (Chair of the Sub-WG), Mayline Kouba, Secundino López Puente, Marta López-Alonso, Alena Pechová and Mariana Petkova

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission:

Wolfgang Trunk<sup>2</sup>

EFSA:

FEED Unit: Matteo L. Innocenti (partially in the PM session), Gloria López Gálvez, Anita Radodnicovic (AM session)

Others:

Not Applicable

# Welcome and apologies for absence

The Chair welcomed the participants.

### 1. Adoption of agenda

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.

<sup>&</sup>lt;sup>2</sup> Partially on day 10.06





The agenda was adopted without changes.

# 2. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

# 3. Agreement of the minutes of the 26<sup>th</sup> Working Group meeting held on 2 July 2021 Web (SubWG-AMR).

The minutes of the 26<sup>th</sup> Working Group meeting, SubWG-AMR, held on 2 July 2021, were agreed by written procedure on 6 July 2021.<sup>5</sup>

# 4. Scientific topic(s) for discussion (SubWG-GP Feed Residues)

# 4.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed, Growth Promotion Feed Residues aspects (SubWG-GP Feed Residues)<sup>6</sup>:

The WG focused the discussion on the finalisation of the documents on Chlortetracycline and Oxytetracyline. The issues related to the use of specific forms/compounds were revised in the rest of relevant documents. Some documents reporting overall items as the Uncertainty analysis, Data gaps and General conclusions/recommendations were also revised.

The draft documents above listed may be ready for presentation and possible endorsement by the FEEDAP Panel in the first Plenary of September 2021.

#### 5. AOB

N/A

# 6. Next meetings

The next meeting of the SubWG AMR will be on 9 July.

No more meetings are foreseen for the SubWG GP.

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>4</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>&</sup>lt;sup>5</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

<sup>6</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00221





# SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 26<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues, SubWG-AMR)

WEB-conference, 02 July 2021

(Agreed on 06 July 2021 by written procedure)

### **Participants**

Working Group Members:

SubWG AMR:

Luisa Peixe

Dan I Anderson

**Rob Davies** 

Søren Saxmose Nielsen

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission and/or Member States representatives:See apologies.

, ,

EFSA:

BIOCONTAM Unit: Beatriz Guerra, Ernesto Liébana and Pietro Stella

Others:

EMA: Sebastien Girault (partially)

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





# 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Damien Bouchard, Johan Bengtsson-Palme and Aude Ferran (sub-WG AMR), Wolfgang Trunk (EC) and Alessandro Broglia (EFSA).

# 2. Adoption of agenda

The agenda was adopted without changes.

# 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

# 4. Agreement of the minutes of the 25th Working Group meeting held on 28 June 2021, Web-conference.

The minutes of the  $25^{th}$  Working Group meeting held on 28 June 2021 were agreed by written procedure on 30 June  $2021.^4$ 

#### 5. Scientific topic(s) for discussion

# 5.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed. Discussion on AMR aspects (ToR1).<sup>5</sup>

The members of the SubWG-AMR met specifically to revise the conclusions, recommendations and the proposals to address the comments received from CVMP.

#### 6. Next meetings

The next meeting of the WG, SubWG AMR will be a Web-conference that will take place on 7 July.

2

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>&</sup>lt;sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

<sup>5</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00221





# SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 25<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues)

WEB-conference, 28 June 2021

(Agreed on 30 June 2021 by written procedure)

### **Participants**

Working Group Members:

SubWG AMR:

Luisa Peixe

Dan I Anderson

Damien Bouchard

**Rob Davies** 

Aude Ferran

SubWG GP:

Vasileios Bampidis

Mayline Kouba

Secundino López Puente

Marta López-Alonso

Alena Pechová

Mariana Petkova

Hearing Experts<sup>1</sup>:

Not Applicable

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





European Commission and/or Member States representatives:See apologies.

EFSA:

BIOCONTAM Unit: Beatriz Guerra, Ernesto Liébana (partially) and Pietro Stella (partially)

FEED Unit: Matteo L. Innocenti and Gloria López-Gálvez

Others:

EMA: Sebastien Girault

# 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Johan Bengtsson-Palme and Søren Saxmose Nielsen (sub-WG AMR), Wolfgang Trunk (EC) and Alessandro Broglia (EFSA).

# 2. Adoption of agenda

The agenda was adopted without changes.

### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

# 4. Agreement of the minutes of the 24th Working Group meeting held on 21 June 2021, Web-conference.

The minutes of the  $24^{th}$  Working Group meeting held on 21 June 2021 were agreed by written procedure on 23 June  $2021.^4$ 

# 5. Scientific topic(s) for discussion

#### 5.1. General update:

<sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf





This was the third Joint meeting of the WG experts. The focus of the first part of this meeting was to give a general update to all experts on the activities performed so far by SubWG-AMR and SubWG-GP. The experts, as well as EFSA and EMA secretariat, provided feed-back from the BIOHAZ Panel, AHAW Panel, FEEDAP Panel and EMA CVMP. The draft structure of the opinion was presented. Open issues were discussed.

Those sections under the remit of the AHAW Panel were endorsed in the Plenary meeting of 23-24 June.

The thorough reading of the output by the BIOHAZ Panel will take place in the meeting of 7-8 July.

# 5.2. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed. Discussion on AMR aspects (ToR1). 5

Following the joint meeting, the members of the SubWG-AMR met specifically to discuss the updates on the draft opinions: revision of the interpretation of terms of reference, conclusions, recommendations, proposals to address the comments received from CVMP and other open issues.

# 5.3. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed. Discussion on GP aspects (ToR2).

Following the joint meeting, the members of the SubWG-GP met specifically to discuss remaining work to be done, including the general conclusions and recommendations, analysis of uncertainties and open issues from the substances not endorsed by the FEEDAP Panel.

### 6. Next meetings

The next meeting of the WG, SubWG AMR will be a Web-conference that will take place on 2 July. The next meeting of the WG, SubWG AMR will be a Web-conference that will take place on 7 July.

3

<sup>5</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00221





# SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 24<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues, SubWG-AMR)

WEB-conference, 21 June 2021

(Agreed on 23 June 2021)

### **Participants**

Working Group Members:

SubWG AMR:

Luisa Peixe

Dan I Anderson

Johan Bengtsson-Palme

Damien Bouchard

**Rob Davies** 

Aude Ferran

Søren Saxmose Nielsen

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission and/or Member States representatives:

See apologies

EFSA:

BIOCONTAM Unit: Beatriz Guerra

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





ALPHA Unit: Alessandro Broglia

Others:

EMA: Sebastien Girault

# Welcome and apologies for absence

The Chair welcomed the participants.

# 1. Adoption of agenda

The agenda was adopted without changes. Apologies were received from Wolfgang Trunk (EC) and Ernesto Liébana (EFSA).

#### 2. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

# 3. Agreement of the minutes of the 23th Working Group meeting held on 15 June 2021, Web (SubWG-AMR).

The minutes of the 23th Working Group meeting, SubWG-AMR, held on 15 June 2021 were agreed by written procedure on 17 June 2021.<sup>4</sup>

# 4. Scientific topic(s) for discussion (SubWG-AMR)

#### 4.1. General update:

Those parts of the draft opinions under the remit of the AHAW Panel, will be presented for endorsement at their Plenary 23-24 June.

An update on the current developments was done by EFSA Secretariat at the CVMP meeting on 17 June. Current assessments were shared with the CVMP for feed-back.

<sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

4 http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf





# 4.2. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed, AMR aspects (SubWG-AMR)<sup>5</sup>:

During the meeting, the members of the SubWG-AMR discussed the draft assessments developed to answer ToR 1 (AMR) for the following substances: first discussion: 1) polymixins: colistin; revision: 2) aminoglycosides: apramycin, neomycin, spectinomycin, paromomycin; 3) amprolium; 4) amphenicols: florfenicol and thiamphenicol; 5) beta-lactams: amoxicillin, penicillin V; 6) lincosamides: lincomycin; 7) macrolides: tilmicosin, tylosin, tylvalosin; 8) pleuromutilins: tiamulin, valnemulin; 9) sulfonamides; 10) tetracyclines: tetracycline, oxytetracycline, chlortetracycline, doxycycline; 11) trimethroprim.

The conclusions of the main draft opinion were discussed.

# 5. Next meetings

The next Joint WG meeting, as well as meetings of the SubWG-AMR and SubWG-GP will take place on 28 June.

5 https://open.efsa.europa.eu/questions/EFSA-Q-2019-00221





# SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 23<sup>rd</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues, SubWG-AMR)

WEB-conference, 15 June 2021

(Agreed on 17 June 2021)

# **Participants**

Working Group Members:

SubWG AMR:

Luisa Peixe

Dan I Anderson

Johan Bengtsson-Palme (partially)

Damien Bouchard (partially)

**Rob Davies** 

Aude Ferran

Søren Saxmose Nielsen

Hearing Experts<sup>1</sup>:

Not Applicable

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

BIOCONTAM Unit: Beatriz Guerra ALPHA Unit: Alessandro Broglia

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





Others:

EMA: see apologies

# Welcome and apologies for absence

The Chair welcomed the participants.

# 1. Adoption of agenda

The agenda was adopted without changes. Apologies were received from Wolfgang Trunk (EC), Sebastien Girault (EMA), Ernesto Liébana (EFSA).

# 2. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

# 3. Agreement of the minutes of the 22<sup>nd</sup> Working Group meeting held on 10, 11, and 15 June 2021, Web (SubWG-GP).

The minutes of the 22<sup>nd</sup> Working Group meeting, SubWG-GP, held on 10 (PM), 11 (AM) and 15 June 2021 were agreed by written procedure on 15 June 2021.<sup>4</sup>

# 4. Scientific topic(s) for discussion (SubWG-AMR)

#### 4.1. General update:

EFSA secretariat (BIOCONTAM Unit) reminded the next steps for the assessment of the different substances by the BIOHAZ Panel: Plenary 8-9 July, thorough reading; Plenary 15-16 September, possible adoption of the whole opinions.

During the BIOHAZ Panel plenary hold on 3-4 June, it was agreed that the assessments for the substances belonging to the same antimicrobial class will be published as single scientific opinions, and together with the draft scientific opinion containing the methodology, uncertainties and data gaps (main draft opinion), will be published in a virtual issue of the EFSA Journal.

Those parts of the draft opinions under the remit of the AHAW Panel, will be presented for endorsement at their Plenary 23-24 June. All the assessments performed so far where shared for feed-back.

<sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

4 http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf





Current assessments were also shared with the CVMP for feed-back. A short update on the current developments will be done by the Chair of the WG at the CVMP meeting on 15-17 June.

#### 4.2. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed, AMR aspects (SubWG-AMR)5:

During the meeting, the members of the SubWG-AMR discussed the draft assessments developed to answer ToR 1 (AMR) for the following substances: first discussion i) sulfonamides; revision ii) amphenicols: florfenicol and thiamphenicol; iii) amprolium; and iv) aminoglycosides. The updates of the Tables with animal-related data were discussed.

The WG experts were informed on the updates on the main draft scientific opinion and tetracyclines and trimethoprim assessments.

# 5. Next meetings

The next meetings of the SubWG-AMR will be on 21 and 28 June.

The next meeting of the SubWG-GP will take place on 28 June.

The next Joint WG meeting will take place on 28 June.

<sup>5</sup>\_Please be aware that EFSA's Register of Questions is unavailable from 21 January until March. The temporary suspension of the tool is necessary to allow us to implement the launch of our new OpenEFSA portal. We apologise for the inconvenience. Further information is available here





# SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 22<sup>nd</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues, SubWG- GP Feed Residues)

WEB-conference, June 10 PM, 11 AM and 15 2021

(Agreed on 15 June 2021)

### **Participants**

Working Group Members:

SubWG GP Feed Residues: Vasileios Bampidis (Chair of the Sub-WG), Mayline Kouba, Secundino López Puente, Marta López-Alonso, Alena Pechová and Mariana Petkova

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission:

Wolfgang Trunk<sup>2</sup>

■ EFSA:

FEED Unit: Gloria López Gálvez

Others:

Not Applicable

# Welcome and apologies for absence

The Chair welcomed the participants.

# 1. Adoption of agenda

The agenda was adopted without changes.

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.

<sup>&</sup>lt;sup>2</sup> Partially on day 10.06





# 2. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

# 3. Agreement of the minutes of the 21<sup>st</sup> Working Group meeting held on 26-27 May 2021 Web (SubWG-AMR).

The minutes of the 21<sup>st</sup> Working Group meeting, SubWG-AMR, held on 26-27 May 2021, were agreed by written procedure on 8 June 2021.<sup>5</sup>

# 4. Scientific topic(s) for discussion (SubWG-GP Feed Residues)

# 4.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed, Growth Promotion Feed Residues aspects (SubWG-GP Feed Residues)<sup>6</sup>:

The WG focused the discussion on the description of the studies, the 'Discussion, uncertainties and limitations' and the 'General conclusions'. The agreed template and working procedures were applied to the documents of the following substances to compile the draft final report: Chlortetracycline and Oxytetracyline.

The draft documents of these substances may be ready for presentation and possible endorsement by the FEEDAP Panel in the Plenary of September 2021, or by written procedure.

#### 5. AOB

N/A

# 6. Next meetings

The next meeting of the SubWG AMR will be on 21 June.

The next meeting of the SubWG GP will be on 28 June.

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>5</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

<sup>6</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00221





# SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 21<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues, SubWG-AMR)

WEB-conference, 26-27 May 2021

(Agreed on 08 June 2021)

### **Participants**

Working Group Members:

SubWG AMR:

Luisa Peixe

Dan I Anderson

Johan Bengtsson-Palme

Damien Bouchard

**Rob Davies** 

Aude Ferran

Søren Saxmose Nielsen

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission and/or Member States representatives:Wolfgang Trunk (26.05.2021, partially)

EFSA:

BIOCONTAM Unit: Beatriz Guerra, Ernesto Liébana (26.05.2021, partially; 27.05.2021)

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





ALPHA Unit: Alessandro Broglia

FEED Unit: Gloria López Gálvez (partially, 27.05.2021)

Others:

EMA: Sebastien Girault (26-27.05.2021, partially)

# Welcome and apologies for absence

The Chair welcomed the participants.

# 1. Adoption of agenda

The agenda was adopted without changes.

# 2. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

# 3. Agreement of the minutes of the 17th Working Group meeting held on 15 March 2021, Web (SubWG-AMR).

The minutes of the 17th Working Group meeting, SubWG-AMR, held on 15 MArch 2021 were agreed by written procedure on 24 March 2021.<sup>4</sup>

# 4. Scientific topic(s) for discussion (SubWG-AMR)

#### 4.1. General update:

EFSA secretariat (BIOCONTAM Unit) reminded the next steps for the assessment of the different substances by the BIOHAZ Panel: Plenary 7-8 June, first reading; Plenary 8-9 July, thorough reading; Plenary 15-16 September, possible adoption of the whole opinion(s). Those parts of the draft opinion(s) under the remit of the AHAW Panel, will be endorsed at their Plenary 23-24 June.

EFSA secretariat (FEED Unit) updated the WG on the activities of the SubWG-GP: The assessments of nine antimicrobial substances (florfenicol, lincomycin, sulfonamides, tetracycline, thiamphenicol, tiamulin, tilmicosin, tylvalosin and valnemulin), prepared by the SubWG-GP, were presented to the FEEDAP Panel on 6 May and endorsed by it. The assessments of further 13 substances (Amoxicillin,

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf





Amprolin, Apramycin, Colistin, Doxycycline, Flumequine, Neomycin, Paromomycin, Penicillin V, Spectinomycin, Trimethoprim, Tylosin and Oxolinic acid) will be scheduled in the agenda of the FEEDAP Panel meeting of 23-24 June for presentation and possible endorsement. The latter assessments have been shared with the SubWG-AMR for revision.

EMA secretariat informed that comments were made by EMA CVMP on the draft opinion at the CVMP meeting of 10-12 May 2021. Current assessments will be shared with the CVMP for feed-back. A short update on the current developments will be done by the Chair of the WG at the CVMP meeting on 15-17 June.

Different publication options - one single document vs. different opinions for each class of substances- are under evaluation in agreement with EC. The latest option seems the most suitable for EFSA.

# Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed, AMR aspects (SubWG-AMR)5:

During the meeting, the members of the SubWG-AMR discussed the preliminary draft assessments developed to answer ToR 1 (AMR) for the following substances: i) aminoglycosides: apramycin, neomycin, spectinomycin and paromomycin; Ii) beta-lactams: amoxicillin and penicillin V; iii) lincosamides: lincomycin. The WG also revised the changes done for the opinions discussed in the previous meeting: iV) macrolides: tilmicosin, tylosin, tylvalosin; and v) phenicols: florfenicol and thiamphenicol.

To gather additional MIC data for animal pathogens for some of the antimicrobial substances included in the Mandate for which few or no data are available in the EUCAST Database, the EARS-Vet members were contacted.

Comments received from the EMA CVMP on the main body of the draft opinion (interpretation of ToRs and uncertainties) were discussed.

### 5. Next meetings

The next meetings of the SubWG GP will be Web-conferences on 15, 21 and 28 June.

The next meetings of the SubWG AMR will be Web-conferences on 10, 11, 15 June.

The next Joint WG meeting will take place on 28 June.

<sup>5</sup>\_Please be aware that EFSA's Register of Questions is unavailable from 21 January until March. The temporary suspension of the tool is necessary to allow us to implement the launch of our new OpenEFSA portal. We apologise for the inconvenience. Further information is available <u>here</u>





# SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 20<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues, SubWG- GP Feed Residues)

WEB-conference, 12 and 14 May 2021

(Agreed on 14 May 2021)

### **Participants**

Working Group Members:

SubWG GP Feed Residues: Vasileios Bampidis (Chair of the Sub-WG), Mayline Kouba, Secundino López Puente, Marta López-Alonso, Alena Pechová and Mariana Petkova

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission:

Not Applicable

■ EFSA:

FEED Unit: Gloria López Gálvez

Others:

EMA: Zoltan Kunsagi<sup>2</sup>

# Welcome and apologies for absence

The Chair welcomed the participants.

# 1. Adoption of agenda

The agenda was adopted without changes.

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.

<sup>&</sup>lt;sup>2</sup> Present on Wednesday 12<sup>th</sup>





# 2. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

# 3. Agreement of the minutes of the 19th Working Group meeting held on 16 April 2021 Web (SubWG-GP Feed Residues).

The minutes of the 19<sup>th</sup> Working Group meeting, SubWG-GP Feed Residues, held on 16 April 2021, were agreed by written procedure on 22<sup>nd</sup> April 2021.<sup>5</sup>

# 4. Scientific topic(s) for discussion (SubWG-GP Feed Residues)

# 4.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed, Growth Promotion Feed Residues aspects (SubWG-GP Feed Residues)<sup>6</sup>:

The WG focused the discussion on the description of the studies, the 'Discussion, uncertainties and limitations' and the 'General conclusions'. The agreed template and working procedures were applied to the documents of the following substances to compile the draft final report: Amoxicillin, Amprolium, Apramycin, Colistin, Doxycycline, Flumequine, Neomycin, Oxonilic acid, Paromomycin, Penicillin V, Spectinomycin, Trimethoprim and Tylosin.

The draft documents of these substances may be ready for presentation and possible endorsement by the FEEDAP Panel in the Plenary of June 2021.

#### 5. AOB

N/A

# 6. Next meetings

The next meeting of the SubWG AMR will be on 26 May.

The next meeting of the SubWG GP will be on 10/11 and 15 June.

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>4</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>&</sup>lt;sup>5</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

<sup>6</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00221





# SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 19<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues, SubWG- GP Feed Residues)

WEB-conference, 16 April 2021

(Agreed on 22 April 2021, by written procedure)

### **Participants**

Working Group Members:

SubWG GP Feed Residues: Vasileios Bampidis (Chair of the Sub-WG), Mayline Kouba, Secundino López Puente, Marta López-Alonso and Alena Pechová

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission:

Wolfgang Trunk

■ EFSA:

FEED Unit: Matteo L. Innocenti and Gloria López Gálvez

Others:

Not Applicable

# Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Mariana Petkova.

# 1. Adoption of agenda

The agenda was adopted without changes.

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





# 2. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

# 3. Agreement of the minutes of the 18th Working Group meeting held on 31 March 2021 Web (SubWG-GP Feed Residues).

The minutes of the 18<sup>th</sup> Working Group meeting, SubWG-AMR, held on 31 March 2021, were agreed by written procedure on 6<sup>th</sup> April 2021.<sup>4</sup>

# 4. Scientific topic(s) for discussion (SubWG-GP Feed Residues)

# 4.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed, Growth Promotion Feed Residues aspects (SubWG-GP Feed Residues)<sup>5</sup>:

The WG focused the discussion on the layout of the papers and the template for the chapters on 'Discussion, uncertainties and limitations' and the 'General conclusions'. An agreement was reached. The template and working procedure will be applied to the following substances: Florfenicol, Tilmicosin, Tylosin, Tylvalosin, Tiamulin, Lincomycine, Sulfonamides and Tetracycline. The draft documents of these substances may be ready for presentation and possible endorsement

by the FEEDAP Panel in the Plenary of May 2021.

#### **5. AOB**

N/A

# 6. Next meetings

The next meeting of the SubWG GP will be on 12 May.

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

<sup>&</sup>lt;u>https://open.efsa.europa.eu/questions/EFSA-Q-2019-00221</u>





# SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 18<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues, SubWG- GP Feed Residues)

WEB-conference, 31 March 2021

(Agreed on 6 April 2021, by written procedure)

### **Participants**

Working Group Members:

SubWG GP Feed Residues: Vasileios Bampidis (Chair of the Sub-WG), Mayline Kouba, Secundino López Puente, Marta López-Alonso, Alena Pechová and Mariana Petkova

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

BIOCONTAM Unit: Beatriz Guerra (partially)

FEED Unit: Gloria López Gálvez

Others:

EMA: Zoltan Kunsagi

### Welcome and apologies for absence

The Chair welcomed the participants.

### 1. Adoption of agenda

The agenda was adopted without changes.

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





# 2. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

# 3. Agreement of the minutes of the 17th Working Group meeting held on 15 March 2021 Web (SubWG-AMR).

The minutes of the 17<sup>th</sup> Working Group meeting, SubWG-AMR, held on 15 March 2021, were agreed by written procedure on 24<sup>th</sup> March 2021.<sup>4</sup>

# 4. Scientific topic(s) for discussion (SubWG-GP Feed Residues)

#### 4.1. General update:

The EFSA coordinator of the WG gave a presentation, focusing on the work done in the antimicrobial part of the mandate and the foreseen content of the WG meetings to be held. The opinion shall be delivered to the EC on the  $30^{th}$  September.

# 4.2. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed, Growth Promotion Feed Residues aspects (SubWG-GP Feed Residues)<sup>5</sup>:

The WG discussed the following substances: Florfenicol, Tilmicosin, Tylosin, Tylvalosin, Tiamulin, Valnemulin, Lincomycine and Sulfonamides. The preparatory work that was done by experts in the field via a procurement contract was revised. For each substance, the relevancy of the studies and their description were discussed, and a draft conclusion was proposed on the minimum level in feed that would have an effect on performance and/or yield in the relevant target species.

The draft documents on these substances may be ready for presentation and possible endorsement by the FEEDAP Panel in the Plenary of May 2021.

#### 5. AOB

N/A

# 6. Next meetings

The next meeting of the SubWG GP will be a Web-conference on 16 April.

The next meeting of the SubWG AMR will be on 21 April.

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

<sup>5</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00221





# SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 17<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues, SubWG-AMR)

WEB-conference, 15 March 2021

(Agreed on 24 March 2021)

### **Participants**

Working Group Members:

SubWG AMR:

Luisa Peixe

Dan I Anderson

Johan Bengtsson-Palme

Damien Bouchard

**Rob Davies** 

Aude Ferran

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission and/or Member States representatives:

Wolfgang Trunk

EFSA:

BIOCONTAM Unit: Beatriz Guerra, Ernesto Liébana (partially)

ALPHA Unit: see apologies

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





FEED Unit: Matteo Innocenti (partially), Gloria López Gálvez

Others:

EMA: Sebastien Girault (partially)

# Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Søren Saxmose Nielsen and Alessandro Broglia (EFSA).

# 1. Adoption of agenda

The agenda was adopted without changes.

# 2. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

# 3. Agreement of the minutes of the 16th Working Group meeting held on 14 January 2020, Web (SubWG-AMR).

The minutes of the 16th Working Group meeting, SubWG-AMR, held on 14 January 2021 were agreed by written procedure on 03 February 2021.<sup>4</sup>

# 4. Scientific topic(s) for discussion (SubWG-AMR)

#### 4.1. General update:

The Chair of the WG and EMA secretariat informed that the draft public consultation technical report and the updated scientific opinion were presented by the Chair of the WG at the last CVMP meeting on 17 February for discussion. The updated version of the draft opinion including the new assessments, as well as any update on data gaps, uncertainties, and/or recommendations will be shared with the CVMP before the summer.

The work plan for the SubWG-GP was presented by the EFSA Secretariat (FEED Unit).

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf





# 4.2. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed, AMR aspects (SubWG-AMR)<sup>5</sup>:

In order to gather feed-back from the SubWG-AMR experts, EFSA secretariat-(FEED Unit) presented the tetracycline and thiamphenical draft assessments developed by the SubWG-GP to address ToR2 (growth promotion/yield effect). Comments were provided and will be shared with the SubWG-GP and the FEEDAP Panel experts for consideration and potential updates of the two documents.

During the meeting, the members of the SubWG-AMR discussed the preliminary draft assessments developed to answer ToR 1 (AMR) for the following substances: i) macrolides: tilmicosin, tylosin, tylvalosin: ii) phenicols: florfenicol and thiamphenicol; iii) pleuromutilins: tiamulin, valnemulin, and iv) amprolium. EMA has shared with the WG different reports available (MRLs, referrals, central marketing authorisations) for the substances to be used by the experts of the WG, and has highlighted the public or confidential status of these reports.

The SubWG-AMR also discussed about the lack of MIC data for some substances (no data available or only for very few species/number of isolates in the EUCAST database), and how to proceed. After discussing different possibilities, it was agreed that EFSA will contact different sources to try to get access to data from different data collections already identified.

# 5. Next meetings

The next meeting of the SubWG GP will be a Web-conference on 31 March.

The next meeting of the SubWG AMR will be on 21 April.

<sup>5</sup>\_Please be aware that EFSA's Register of Questions is unavailable from 21 January until March. The temporary suspension of the tool is necessary to allow us to implement the launch of our new OpenEFSA portal. We apologise for the inconvenience. Further information is available <a href="here">here</a>





# SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 16<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues, SubWG-AMR)

WEB-conference, 14 January 2021

(Agreed on 03 February 2021)

### **Participants**

Working Group Members:

SubWG AMR:

Luisa Peixe

Dan I Anderson

Johan Bengtsson-Palme (partially)

Damien Bouchard

**Rob Davies** 

Aude Ferran

Søren Saxmose Nielsen

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission and/or Member States representatives:

Wolfgang Trunk

■ EFSA:

BIOCONTAM Unit: Beatriz Guerra, Pietro Stella (partially)

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





ALPHA Unit: Alessandro Broglia FEED Unit: Matteo Innocenti

Others:

**EMA: Sebastien Girault** 

# 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Ernesto Liébana (EFSA).

# 2. Adoption of agenda

The agenda was adopted without changes.

# 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

# 4. Agreement of the minutes of the 15th Working Group meeting held on 17 December 2020, Parma.

The minutes of the 15th Working Group meeting, SubWG-GP, held on 17 December 2020 were agreed by written procedure on 23 December 2020.<sup>4</sup>

# 5. Scientific topic(s) for discussion

# 5.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed, AMR aspects (ToR1)<sup>5</sup>

The members of the SubWG-AMR met to review the content of the EFSA Technical Report on the public consultation of the ToR1 proposed methodology (closed on 18 November). This report contains the comments received and the actions taken by EFSA. Changes done in the draft opinion following those comments (if within the scope of the mandate), were also revised. The report will be shared with the BIOHAZ, FEEDAP and AHAW panels and the EMA CVMP. Once adopted by the BIOHAZ panel, it will be published together with the scientific opinion

EC expressed the preference to have the scientific opinion published in one piece, containing the assessment for both ToR1 and ToR2 for all antimicrobials after the deadline of the Mandate (31

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

<sup>5</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2019-00221





September). This will be confirmed by EC. Accordingly, endorsement of the whole scientific opinion is foreseen for the BIOHAZ Plenary to be held on 6-7 September.

#### Next meetings

The next meeting of the WG, SubWG AMR will be a Web-conference in March. Date not confirmed yet.





### SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 15<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues, SubWG-AMR)

WEB-conference, 17 December 2020

(Agreed on 23 December 2020)

#### **Participants**

Working Group Members:

SubWG AMR:

Luisa Peixe

Dan I Anderson

Johan Bengtsson-Palme

Damien Bouchard

**Rob Davies** 

Aude Ferran

Søren Saxmose Nielsen

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission and/or Member States representatives:

See apologies

EFSA:

BIOCONTAM Unit: Beatriz Guerra

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





ALPHA Unit: See apologies FEED Unit: Matteo Innocenti

Others:

**EMA: Sebastien Girault** 

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Wolfgang Trunk (DG-SANTE), Ernesto Liébana (EFSA) and Alessandro Broglia (EFSA).

#### 2. Adoption of agenda

The agenda was adopted without changes.

#### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## 4. Agreement of the minutes of the 14th Working Group meeting held on 4 December 2020, Parma.

The minutes of the 14th Working Group meeting, SubWG-GP, held on 4 December 2020 were agreed by written procedure on 4 December 2020.<sup>4</sup>

#### 5. Scientific topic(s) for discussion

### 5.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed, AMR aspects (ToR1)<sup>5</sup>

The members of the SubWG-AMR met specifically to continue with the discussions on the comments received after the public consultation (closed on 18 November), to revise changes done in the draft scientific opinion following the comments, and to revise the structure of the technical report on the public consultation. Tasks were allocated. This report will be shared with the BIOHAZ, FEEDAP and AHAW panels and the EMA CVMP. Once adopted by the BIOHAZ panel, it will be published together with the scientific opinion.

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>&</sup>lt;sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

 $<sup>{\</sup>color{blue} \underline{\textbf{5}} \ \underline{\textbf{http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00221} \\$ 





Next meetings
The next meeting of the WG, SubWG AMR will be a Web-conference that will take place on 14 January 2021.





### SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 14<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues, SubWG-GP)

WEB-conference, 4 December 2020

(Agreed on 4 December 2020)

#### **Participants**

Working Group Members:

SubWG GP:

Vasileios Bampidis

Mayline Kouba

Secundino López Puente

Marta López-Alonso

Alena Pechová

Mariana Petkova

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

Not Applicable

EFSA:

FEED Unit: Matteo Innocenti

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





#### 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<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

#### 4. Scientific topic(s) for discussion

### 4.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed, GP aspects (ToR1)<sup>4</sup>

The members of the SubWG-GP met to discuss the outcome of the extended literature review and to define the criteria for the assessment of the results. Tasks were allocated.

#### Next meetings

The next meeting of the WG, SubWG AMR will be a Web-conference that will take place on 17 December.

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>4</sup> http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00221





#### SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 13<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues, SubWG-AMR)

WEB-conference, 27 November 2020

(Agreed on 10 December 2020)

#### **Participants**

Working Group Members:

SubWG AMR:

Luisa Peixe

Dan I Anderson

Johan Bengtsson-Palme

Damien Bouchard

**Rob Davies** 

Aude Ferran

Søren Saxmose Nielsen

Hearing Experts<sup>1</sup>:

Not Applicable

■ European Commission and/or Member States representatives:

Wolfgang Trunk

■ EFSA:

BIOCONTAM Unit: Beatriz Guerra, Ernesto Liébana, Alessandro Broglia

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





ALPHA Unit: Alessandro Broglia

FEED Unit: See apologies

Others:

**EMA: Sebastien Girault** 

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Matteo Innocenti (EFSA Feed Unit).

#### 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<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## 4. Agreement of the minutes of the 12th Working Group meeting held on 25 August 2020, Parma.

The minutes of the 12th Working Group meeting held on 25 August 2020 were agreed by written procedure on 15 September 2020.<sup>4</sup>

#### 5. Scientific topic(s) for discussion

### 5.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed, AMR aspects (ToR1)<sup>5</sup>

The public consultation of the methodology proposed to answer the term of reference 1 of the mandate, which is related to antimicrobial resistance development, the uncertainties associated with it, and the data gaps/other considerations identified, ended on 18 November. Additional sections of the draft opinion were shared during the consultation to provide the background, contextualize the methodology, and show an example of the assessment if the methodology would be used (e.g. tetracyclines). These additional sections were provided only for information and were not submitted for consultation, therefore comments on these sections were not expected and would not be taken

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>&</sup>lt;sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

 $<sup>{\</sup>color{blue} \underline{\textbf{5}} \ \underline{\textbf{http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00221} \\$ 





into consideration. Comments were received from 11 different sources, including private capacity, public institutions/academia, and industry organizations.

The members of the SubWG-AMR met specifically to discuss and address the comments received. Answers to those comments will be developed, the draft opinion will be updated, and both answers and updates will be discussed at the next meeting. Accordingly, tasks were allocated.

A report including the comments received and how they were addressed will be produced and shared with the BIOHAZ, FEEDAP and AHAW panels and the EMA CVMP. Once adopted by the BIOHAZ panel, it will be published together with the scientific opinion.

#### Next meetings

The next meeting of the WG, SubWG GP will be a Web-conference that will take place on 4 December.

The next meeting of the WG, SubWG AMR will be a Web-conference that will take place on 17 December.





#### SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 12th MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues)

WEB-conference, 25 August 2020

(Agreed on 15 September 2020)

#### **Participants**

Working Group Members:

SubWG AMR:

Luisa Peixe

Dan I Anderson

Damien Bouchard

Rob Davies

Aude Ferran

Johan Bengtsson-Palme

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission and/or Member States representatives:

See apologies

EFSA:

BIOCONTAM Unit: Beatriz Guerra, Pietro Stella

ALPHA Unit: see apologies

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





FEED Unit: See apologies

Others:

EMA: Sebastien Girault (EMA)

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Søren Saxmose Nielsen, Wolfgang Trunk (EC), Matteo Innocenti (EFSA Feed Unit), Alessandro Broglia (EFSA ALPHA Unit) and Ernesto Liébana (EFSA BIOCONTAM Unit).

#### 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<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## 4. Agreement of the minutes of the 11th Working Group meeting held on 03 July 2020, Parma.

The minutes of the 11th Working Group meeting (SubWG-AMR) held on 03 July 2020 were agreed by written procedure on 7 July 2020.<sup>4</sup>

#### 5. Scientific topic(s) for discussion

# 5.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed. Discussion on AMR aspects (ToR1).<sup>5</sup>

The members of the SubWG-AMR met specifically to revise the draft opinion, and i) to discuss the comments received after the BIOHAZ Panel (Plenary 8-9 July) and the EMA CVMP (meeting 14-16 July), ii) to revise the contributions provided to address those comments. Tasks were allocated.

The Methodology proposed for the assessment, and the uncertainties associated with it will be submitted for endorsement by the BIOHAZ Panel at their next Plenary (22-23). Subsequently, this

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>&</sup>lt;sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

<sup>5</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2019-00221





part of the opinion will be submitted for public consultation (foreseen for the 7 October). The consultation will last for 6 weeks.

#### 6. Next meetings

The next meeting of the WG, SubWG AMR, will be a Web-conference that will take place after the public consultation, still in 2020.





### SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 11th MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues)

WEB-conference, 03 July 2020

(Agreed on 7 July 2020)

#### **Participants**

Working Group Members:

SubWG AMR:

Luisa Peixe

Dan I Anderson

Damien Bouchard

Rob Davies

Aude Ferran

Søren Saxmose Nielsen

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission and/or Member States representatives:

Wolfgang Trunk

EFSA:

BIOCONTAM Unit: Beatriz Guerra, Michella Hempken

ALPHA Unit: see apologies

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





FEED Unit: See apologies

Others:

EMA: Jordi Torren, Barbara Freischem

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Johan Bengtsson-Palme, Sebastien Girault (EMA), and Matteo Innocenti (EFSA Feed Unit), Alessandro Broglia (EFSA ALPHA Unit), Ernesto Liébana (EFSA BIOCONTAM Unit).

#### 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<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## 4. Agreement of the minutes of the 9th Working Group meeting held on 26 June 2020, Parma.

The minutes of the 10th Working Group meeting held on 26 June 2020 were agreed by written procedure on 1 July 2020.<sup>4</sup>

#### 5. Scientific topic(s) for discussion

# 5.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed. Discussion on AMR aspects (ToR1).<sup>5</sup>

The members of the SubWG-AMR met specifically i) to discuss the uncertainty analysis done for the methodology proposed to address the mandate; 2) to agree on the text with the answers to the comments received from EMA CVMP, in order to present these answers to the BIOHAZ Panel for agreement; 3) to revise and agree on the answers to those comments. Tasks were allocated.

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

<sup>&</sup>lt;sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

<sup>5</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2019-00221





These answers will be discussed by the BIOHAZ Panel at their next Plenary (8-9 July). Agreed answers will be shared with the EMA CVMP for discussion at the CVMP meeting (14-16 July).

#### 6. Next meetings

The next meeting of the WG, SubWG AMR will be a Web-conference that will take place on 25 August.





### SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 10th MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED

(AMR and GP Feed Residues)

WEB-conference, 26 June 2020

(Agreed on 1 July 2020)

#### **Participants**

Working Group Members:

SubWG AMR:

Luisa Peixe

Dan I Anderson

Johan Bengtsson-Palme

Damien Bouchard

**Rob Davies** 

Aude Ferran

Søren Saxmose Nielsen

SubWG GP:

Vasileios Bampidis

Mayline Kouba

Secundino López Puente

Marta López-Alonso

Alena Pechová

Mariana Petkova

Hearing Experts<sup>1</sup>:

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





#### Not Applicable

European Commission and/or Member States representatives:See apologies.

EFSA:

BIOCONTAM Unit: Beatriz Guerra, Ernesto Liébana, Pietro Stella

ALPHA Unit: Alessandro Broglia FEED Unit: Matteo Innocenti

Others:

**EMA: Sebastien Girault** 

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Wolfgang Trunk and Michaela Hempen (EFSA).

#### 2. Adoption of agenda

The agenda was adopted without changes.

#### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## 4. Agreement of the minutes of the 9th Working Group meeting held on 29 May 2020, Parma.

The minutes of the 9th Working Group meeting held on 29 May 2020 were agreed by written procedure on 14 June 2020.<sup>4</sup>

#### 5. Scientific topic(s) for discussion

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf





# 5.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed. Discussion on AMR aspects (ToR1).<sup>5</sup>

This was the second Joint meeting of the WG experts. The focus of the first part of this meeting was to give a general update to all experts on the activities performed so far by SubWG-AMR and SubWG-GP in order to address Tor1 and ToR2, respectively. The experts, as well as EFSA and EMA secretariat, provided feed-back from the BIOHAZ Panel, AHAW Panel, FEEDAP Panel and EMA CVMP. The next steps in the planning of the public consultation of the Methodology proposed to address ToR1 were discussed and agreed.

Following, the members of the SubWG-AMR met specifically to discuss the feed-back and comments received from the EMA CVMP members after their last meeting (16-18 June). The comments will be addressed in the draft opinion. Answers provided to those comments will be discussed by the BIOHAZ Panel, and shared with the EMA CVMP. The experts also revised the draft scientific opinion to address open questions. The uncertainty analysis will be discussed in an extra meeting on 3 July. Tasks were allocated.

The members of the SubWG-GP met specifically to discuss the outcome of the outsourcing for extended literature review. Tasks were allocated.

EMA informed that the updated scientific opinion and the answers provided will be discussed at the next EMA CVMP meeting (14-16 July). Feed-back from the discussions will be given to the WG after that meeting.

As previously agreed, public consultation on the methodology proposed including one assessment example, will be done after endorsement by the BIOHAZ Panel (planned for the BIOHAZ Panel Plenary meeting on 22-23 September).

#### 6. Next meetings

The next meeting of the WG, SubWG AMR will be a Web-conference that will take place on 3 July. The following meeting, will be on 25 August.

<sup>5</sup>\_http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2019-00221





### SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 9th MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED (AMR and GP Feed Residues)

WEB-conference, 29 May 2020

(Agreed on 14 June 2020)

#### **Participants**

Working Group Members:

Luisa Peixe

Dan I Anderson

Johan Bengtsson-Palme

Damien Bouchard

**Rob Davies** 

Aude Ferran

Søren Saxmose Nielsen

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission and/or Member States representatives:

Wolfgang Trunk

EFSA:

BIOCONTAM Unit: Beatriz Guerra, Ernesto Liébana

ALPHA Unit: Alessandro Broglia

FEED Unit: Matteo Innocenti (partially)

Others:

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





EMA: Sebastien Girault, Jordi Torren (partially)

#### 1. Welcome and apologies for absence

The Chair welcomed the participants, SubWG-AMR experts. Pietro Stella and Michaela Hempken (EFSA).

Sebastian Girault took the role of EMA Secretariat for this Opinion in substitution of Julia Fábrega.

#### 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<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

### 4. Agreement of the minutes of the 8th Working Group meeting held on xx April 2020, Parma.

The minutes of the 8th Working Group meeting held on 23 April 2020 were agreed by written procedure on 8 May 2020.<sup>4</sup>

#### 5. Scientific topic(s) for discussion

# 5.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed. Discussion on AMR aspects (ToR1).<sup>5</sup>

The members of the SubWG-AMR met to discuss aspects needed to address ToR1. The meeting focused on the revision of the draft scientific opinion taking into account the comments received from the experts of the BIOHAZ Panel after their last Plenary (03-04 June). Tasks were allocated.

EMA informed that Opinion will be presented at the next EMA CVMP meeting (16-18 June) and thorough discussed on their meeting 14-16 July. Feed-back from the discussions will be given to the WG.

<sup>&</sup>lt;sup>2</sup> <a href="http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf">http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf</a>

http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>&</sup>lt;sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

<sup>5</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2019-00221





Public consultation on the methodology proposed including one assessment example, will be done after endorsement by the BIOHAZ Panel (planned for the BIOHAZ Panel Plenary meeting on 22-23 September).

#### 6. Next meetings

The next meeting of the WG, SubWG AMR will be a Web-conference that will take place on 26 June. This meeting, originally scheduled as a physical meeting, was converted into a teleconference to avoid travelling to EFSA in line with the measures established to reduce the risk of coronavirus.





#### SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 8<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED (AMR and GP Feed Residues)

WEB-conference, 23 April 2020

(Agreed on 8 May 2020)

#### **Participants**

Working Group Members:

Luisa Peixe

Dan I Anderson

Johan Bengtsson-Palme

Damian Bouchard

**Rob Davies** 

Aude Ferran

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission and/or Member States representatives:

See apologies

EFSA:

BIOCONTAM Unit: Beatriz Guerra, Ernesto Liébana, Michaela Hempken

ALPHA Unit: Alessandro Broglia FEED Unit: Matteo Innocenti

Others:

EMA: see apologies

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





#### 1. Welcome and apologies for absence

The Chair welcomed the participants, SubWG-AMR experts. The Chair welcomed the participants, SubWG-AMR experts. Apologies were received from Julia Fábrega (EMA), Wolfgang Trunk (EC), and Pietro Stella (EFSA).

Valeria Bortolaia resigned as a member of the WG on 17 April and did not participate at the current meeting.

#### 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<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## 4. Agreement of the minutes of the 7th Working Group meeting held on 26 February 2020, Parma.

The minutes of the 7th Working Group meeting held on 31 March 2020 were agreed by written procedure on 14 April 2020.<sup>4</sup>

#### 5. Scientific topic(s) for discussion

# 5.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed. Discussion on AMR aspects (ToR1).<sup>5</sup>

The members of the SubWG-AMR met to discuss aspects needed to address ToR1. The meeting (second part of the meeting hold on 31 March) was used to revise the pilot assessments done for trimethoprim and tetracyclines as well as to discuss open questions on the current draft scientific opinion. Tasks were allocated.

#### 6. Next meetings

<sup>2</sup> <a href="http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf">http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf</a>

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>&</sup>lt;sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

<sup>5</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2019-00221





The next meeting of the WG, SubWG AMR will be a Web-conference that will take place on 29 May. This meeting, originally scheduled as a physical meeting, was converted into a teleconference to avoid travelling to EFSA in line with the measures established to reduce the risk of coronavirus.





#### SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 7<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED (AMR and GP Feed Residues)

WEB-conference, 31 March 2020

(Agreed on 14 April 2020)

#### **Participants**

Working Group Members:

Luisa Peixe

Dan I Anderson

Johan Bengtsson-Palme

Valeria Bortolaia

Damian Bouchard

**Rob Davies** 

Aude Ferran

Søren Saxmose Nielsen

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission and/or Member States representatives:

EC: Wolfgang Trunk

■ EFSA:

BIOCONTAM Unit: Beatriz Guerra, Ernesto Liébana, Pietro Stella (partially).

ALPHA Unit: Alessandro Broglia FEED Unit: Matteo Innocenti

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





Others:

EMA: Julia Fábrega

#### 1. Welcome and apologies for absence

The Chair welcomed the participants, SubWG-AMR experts.

#### 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<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## 4. Agreement of the minutes of the 6th Working Group meeting held on 26 February 2020, Parma.

The minutes of the 6th Working Group meeting held on 26 February 2020 were agreed by written procedure on 6 March 2020.4

#### 5. Scientific topic(s) for discussion

## 5.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed. Discussion on AMR aspects (ToR1).<sup>5</sup>

The members of the SubWG-AMR met to discuss aspects needed to address ToR1. The meeting was used to revise the current draft scientific opinion, specially the description of the methodology selected to address 1) the lowest values developing resistance for those antimicrobials for which there are data available: the predicted minimal selective concentration (PMSC); 2) the approach to infer maximal concentrations of antimicrobials in feed not selecting for antimicrobial resistance in the gut of the animals: adaptation of the microbiological Acceptable Daily Intake (mADI) equation for different animal species in relation to the Feed Daily Intake. Because of lack of time, the pilot assessments done for trimethoprim and tetracyclines will be discuss in the next meeting. Part of the

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

<sup>&</sup>lt;sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

<sup>5</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2019-00221





opinion (AMR development model) will be submitted to public consultation after endorsement by the BIOHAZ panel. Tasks were allocated.

#### 6. Next meetings

The next meeting of the WG, SubWG AMR will be a short Web conference that will take place end of April 2020 (date to de decided). This meeting will be a second part of the present one, originally scheduled as a physical meeting, and converted into a teleconference to avoid travelling to EFSA in line with the measures established to reduce the risk of coronavirus. Additional physical meetings for 2020 are planned for 2-3 July (whole WG including SubWG-AMR and SubWG-GP) and 26-27 November (SubWG-AMR) in Parma.





#### SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 6<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED (AMR and GP Feed Residues)

#### WEB-conference, 26 February 2020

(Agreed on 6 March 2020)

#### **Participants**

Working Group Members:

Luisa Peixe

Dan I Anderson

Johan Bengtsson-Palme

Valeria Bortolaia

Damian Bouchard

Rob Davies

Aude Ferran

Søren Saxmose Nielsen

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission and/or Member States representatives:

EC: Wolfgang Trunk

EFSA:

BIOCONTAM Unit: Beatriz Guerra, Ernesto Liébana (participated on agenda points 1-4).

ALPHA Unit: Alessandro Broglia FEED Unit: Matteo Innocenti

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





Others:

EMA: Julia Fábrega

#### 1. Welcome and apologies for absence

The Chair welcomed the participants, SubWG-AMR experts.

#### 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<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## 4. Agreement of the minutes of the 5th Working Group meeting held on 12-13 November 2019, Parma.

The minutes of the 5th Working Group meeting held on 12-13 December 2019 were agreed by written procedure on 20 December 2020.<sup>4</sup>

#### 5. Scientific topic(s) for discussion

# 5.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed. Discussion on AMR aspects (ToR1). 5

The members of the SubWG-AMR met to discuss aspects needed to address ToR1. The meeting focused on: 1) possible approach to determine the lowest values developing resistance e.g. for those antimicrobials for which there are data available, the inferred minimal selective concentration, MSC<sub>inf</sub>, calculated as the ratio between published MSC values and the MIC value of the most susceptible bacteria from the EUCAST MIC distributions database. 2) Possible approaches to infer maximal concentrations of antimicrobials in feed not selecting for antimicrobial resistance in the gut of the animals, e.g. adaptation of the microbiological Acceptable Daily Intake (mADI) equation for different animal species in relation to the Feed Daily Intake. The approaches, data collected and

<sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>&</sup>lt;sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

 $<sup>{\</sup>color{blue} \underline{\textbf{5}} \ \underline{\textbf{http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00221} \\$ 





results for the tetracyclines and trimethoprim pilot assessments, were presented and discussed. Tasks were allocated.

#### 6. Next meetings

The next meeting of the WG, SubWG AMR will take place on 31 March 2020. This meeting, originally scheduled as a physical meeting, was converted into a teleconference to avoid traveling to EFSA in line with the measures established to reduce the risk of coronavirus. Additional physical meetings for 2020 are planned for 2-3 July (whole WG including SubWG-AMR and SubWG-GP) and 26-27 November (SubWG-AMR) in Parma.





#### SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 5<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED (AMR and GP Feed Residues)

#### Held on 12-13 December 2019, Parma

(Agreed on 20 December 2019)

#### **Participants**

Working Group Members:

Luisa Peixe

Dan I Anderson

Johan Bengtsson-Palme

Valeria Bortolaia

Rob Davies

Aude Ferran (participated via teleconference)

Søren Saxmose Nielsen

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission and/or Member States representatives:

EC: Wolfgang Trunk

EFSA:

BIOCONTAM Unit: Beatriz Guerra, Pietro Stella (participated on agenda point 7-9 on 12.12.2019; participated via teleconference on 13.12.2019).

ALPHA Unit: Alessandro Broglia (12.12.2019 in Parma; via teleconference on 13.12.2019)

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





FEED Unit: Matteo Innocenti (13.12.2019)

Others:

See apologies.

#### 1. Welcome and apologies for absence

The Chair welcomed the participants, SubWG-AMR experts. Apologies were received from Damian Bouchard, Ernesto Liébana and Julia Fábrega (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<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## 4. Agreement of the minutes of the 4th Working Group meeting held on 8 November 2019, Parma.

The minutes of the 4th Working Group meeting held on 8 November 2019 were agreed by written procedure on 19 November 2019.4

#### 5. Scientific topic(s) for discussion

# 5.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed. Discussion on AMR aspects (ToR1). 5

The members of the SubWG-AMR met to discuss aspects needed to address ToR1. The meeting focused on: 1) further investigation of differences related to the data sets considered: e.g. lowest MICs for any of the 24 substances reported in European reports for animal pathogens; lowest MIC for any of the 24 substances available at EUCAST for selected bacteria (normal flora, animal pathogens). 2) Possible approaches to infer concentrations of antimicrobials in feed from antimicrobial concentrations in the gut of the animals. Data collected and the approaches suitable to

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>&</sup>lt;sup>4</sup> https://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

<sup>5</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2019-00221





be applied, using as an example trimethoprim and tetracyclines, were presented and discussed. Tasks were allocated.

#### 6. Next meetings

The next meeting of the WG, SubWG AMR, will take place via Web in February 2020. Dates for physical meetings over 2020 will be set soon.





### SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 4<sup>th</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED (AMR and GP Feed Residues)

WEB-conference, 8 November 2019

(Agreed on 19 November 2019)

#### **Participants**

Working Group Members:

Luisa Peixe

Dan I Anderson

Johan Bengtsson-Palme

Valeria Bortolaia

Damian Bouchard

Rob Davies

Aude Ferran

Søren Saxmose Nielsen

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission and/or Member States representatives:

EC: Wolfgang Trunk

■ EFSA:

BIOCONTAM Unit: Beatriz Guerra, Michaella Hempen, Alice Vismarra, Karoline Noerstrud

ALPHA Unit: Francesca Baldinelli, Yves van der Stede

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





Others:

See apologies.

#### 1. Welcome and apologies for absence

The Chair welcomed the participants, SubWG-AMR experts. Apologies were received from Matteo Innocenti, Pietro Stella, Ernesto Liébana, Alessandro Broglia (EFSA); and Julia Fábrega (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<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## 4. Agreement of the minutes of the 3rd Working Group meeting held on 26-27 September 2019, Parma.

The minutes of the 3rd Working Group meeting held on 26-27 September 2019 were agreed by written procedure on 14 October 2019. $^{\prime\prime}$ 4

#### 5. Scientific topic(s) for discussion

# 5.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed. Discussion on AMR aspects (ToR1).<sup>5</sup>

The members of the SubWG-AMR met to discuss aspects needed to address ToR1. The meeting focused on: 1) revision of data available and detection on differences related to the data sets considered: e.g. lowest MICs for any of the 24 substances reported in European national reports for animal pathogens; lowest MIC for any of the 24 substances available at EUCAST for selected bacteria. 2) Possible approaches to infer concentrations of antimicrobials in feed from antimicrobial concentrations in the gut of the animals. The presentations were followed by discussion on the data

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>4</sup> https://www.efsa.europa.eu/sites/default/files/wgs/biological-hazards/wg-amrgpfeedresidues.pdf

<sup>5 &</sup>lt;a href="http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2019-00221">http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2019-00221</a>





and methodologies presented. Apart from the on-going pilot on the Tetracyclines assessment, a parallel pilot to assess Trimethoprim will be performed. Tasks were allocated.

#### 6. Next meetings

The next meeting of the WG, SubWG AMR, will take place in Parma on 12-13 December. Dates for meetings over 2020 and 2021 will be selected soon.





#### SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 3<sup>rd</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED (AMR and GP Feed Residues)

#### held on 26-27 September 2019, Parma

(Agreed on 14 October 2019)

#### **Participants**

Working Group Members:

Luisa Peixe

Dan I Anderson

Johan Bengtsson-Palme

Valeria Bortolaia has participated via teleconference, in agenda points 4-7, and 14-16

Damian Bouchard

**Rob Davies** 

Aude Ferran has participated via teleconference

Søren Saxmose Nielsen

Hearing Experts<sup>1</sup>:

Not Applicable

■ European Commission and/or Member States representatives:

EC: Wolfgang Trunk

■ EFSA:

BIOCONTAM Unit: Beatriz Guerra, Pietro Stella, Ernesto Liébana

ALPHA Unit: Alessandro Broglia

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





FEED Unit: Matteo Innocenti

Others:

European Medicines Agency (EMA): Julia Fábrega.

#### 1. Welcome and apologies for absence

The Chair welcomed the participants, SubWG-AMR experts.

#### 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<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

#### 4. Scientific topic(s) for discussion

## 4.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed. Discussion on AMR aspects (ToR1).<sup>4</sup>

The members of the SubWG-AMR met to discuss aspects needed to address ToR1. The meeting focused on the data availability and methodology to be used. The steps needed to perform the uncertainty assessment according to the EFSA Scientific Committee's Guidance on Uncertainty Analysis in Scientific Assessments<sup>5</sup> were clarified at the beginning of the meeting. The experts presented information on: i) data sources (e.g. for minimal inhibitory concentrations) including those data available at the EMA; ii) data on main bacterial pathogens and commensals in different animal species/animal production systems; iii) main pharmacokinetics aspects to be considered; iv) the three different models identified as suitable to identify lowest levels of antimicrobials developing antimicrobial resistance: minimal selective concentration (MSC), predictive non effect concentrations (PNECs) and acceptable daily intake (ADI), including information on the main uncertainties of each model. The presentations were followed by discussion on the methodologies and the possible approach to be followed (e.g. combination of different models and its adaptation to the matrix feed and different animal species). The pilot exercise done by the experts to assess the tetracyclines

<sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

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<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>4</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2019-00221

<sup>&</sup>lt;sup>5</sup> https://www.efsa.europa.eu/en/efsajournal/pub/5123





(chlortetracycline, oxytetracycline and tetracycline) was also discussed. The AMR experts participating in the meeting were updated on the on-going activities (outsourcing extensive literature) launched to collect information needed to answer ToR2, levels with growth promotion effect. Tasks were allocated.

#### 5. Next meetings

The next meeting of the WG, SubWG AMR, will take place on 8 November (web-conference), followed by a physical meeting in Parma on 12-13 December. Dates for meetings over 2020 and 2021 will be selected soon.





### SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 2<sup>nd</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED (AMR and GP Feed Residues)

#### held on 14 August 2019, WEB-conference

(Agreed on 26 August 2019)

#### **Participants**

Working Group Members:

Luisa Peixe

Dan I Anderson

Johan Bengtsson-Palme

Valeria Bortolaia

Damian Bouchard

**Rob Davies** 

Aude Ferran

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission and/or Member States representatives:

EC: Marta Ponghellini

EFSA:

BIOCONTAM Unit: Beatriz Guerra, Michaela Hempen, Pietro Stella, Ernesto Liébana

ALPHA Unit: Alessandro Broglia

Others:

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





European Medicines Agency (EMA): Rosa Perán, Barbara Freischem, Julia Fábrega.

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. The SubWG-AMR experts invited to the meeting were informed that the AHAW Panel member Paolo Calistri resigned as member of the WG and has been substituted by Søren Saxmose Nielsen, Chair of the AHAW Panel.

#### 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<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

#### 4. Scientific topic(s) for discussion

# 4.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed. Discussion on AMR aspects (ToR1). 4

The members of the SubWG-AMR experts on antimicrobial resistance met to discuss main aspects needed to address ToR1. The meeting focused on data availability, including clarifications from the European Medicines Agency, as well as identification of further data needs and possible data sources (e.g. hearing experts). The experts also discussed on possible models to be used, presenting pros and cons of each of them. The different models will be more extensively explained and discussed in the next physical meeting of the WG, SubWG-AMR, which will take place at the end of September. The experts were asked to collect uncertainties identified for each model, in line with the need to perform uncertainty assessment according to the EFSA Scientific Committee's Guidance on Uncertainty Analysis in Scientific Assessments<sup>5</sup>. Tasks were allocated.

#### 5. Next meetings

<sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

<sup>4</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2019-00221

<sup>&</sup>lt;sup>5</sup> https://www.efsa.europa.eu/en/efsajournal/pub/5123





The next meeting of the WG, SubWG AMR, will take place in Parma on 26-27 September. Next meetings are planned on 8 November (web-conference) and 12-13 December (physical, Parma).





### SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 1<sup>st</sup> MEETING OF THE WORKING GROUP ON MAXIMUM LEVELS OF CROSS-CONTAMINATION FOR 24 ANTIMICROBIAL ACTIVE SUBSTANCES IN NON-TARGET FEED (AMR and GP Feed Residues)

#### held on 12 June 2019, WEB-conference

(Agreed on 17 June 2019)

#### **Participants**

Working Group Members:

Luisa Peixe

Rob Davies

Paolo Calistri

Damian Bouchard

Dan I Anderson

Johan Bengtsson-Palme (SE)

Aude Ferran

Vasileios Bampidis

Mariline Kouba

Secundino López Puente

Marta López-Alonso

Alena Pechová

Mariana Petkova

Hearing Experts<sup>1</sup>:

Not Applicable

European Commission and/or Member States representatives:

EC: Wolfgang Trust

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





EFSA:

BIOCONTAM Unit: Beatriz Guerra, Michaela Hempen, Pietro Stella, Ernesto Liébana

ALPHA Unit: Alessandro Broglia FEED Unit: Matteo Innocenti

TS Unit: Marco Conterbia (for agenda item 4)

Others:

European Medicines Agency (EMA): Rosa Perán, Jordi Torren, Barbara Freischem, Zoltan Kunzagi.

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Valeria Bartolaia.

#### 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<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

#### 4. Induction to Digital Collaboration Platform and administrative issues

EFSA introduced the digital collaborative platform which will allow the WG members to work simultaneously on the same document, i.e. draft opinion and keep conversation together in a single application.

EFSA also introduced the process for delivering scientific opinions and provided information on administrative issues for the experts.

#### 5. Scientific topic(s) for discussion

<sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf





### 5.1. Scientific opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed <sup>4</sup>

As requested by EC and laid down in Regulation EU 2019/4, the assessment will be done by EFSA (with the involvement of the BIOHAZ, FEEDAP and AHAW Panels) in collaboration with EMA (a member of the Antimicrobials Working Party of the Committee for Medicinal Products for Veterinary Use included in the *ad hoc* WG). EFSA leading panel is BIOHAZ and the draft scientific opinion shall be adopted by 30 September 2021.

The background and Terms of Reference (ToR) of the Mandate received from the European Commission (EC) were presented. EC provided additional background information. The WG discussed the two ToRs, clarified these with the EC representative, and agreed on a common understanding of these. Possible approaches to be taken to answer these were discussed. It was agreed that in a first step, ToR1 and ToR2 will be separately be addressed. For this the WG will be subdivided into two subgroups focusing on antimicrobial resistance (ToR1, SubWG-AMR) and on growth promotion and yield increase (ToR2, SubWG-GP), respectively. The results of both assessments will be presented jointly for each substance.

The WG identified data needs and available data sources, and discussed on possible methodology to be used. The need to perform uncertainty assessment according to the EFSA Scientific Committee's Guidance on Uncertainty Analysis in Scientific Assessments<sup>5</sup> was indicated. The preliminary table of contents of the draft opinion was agreed, WG experts were appointed to further develop each of the sections in the draft opinion and tasks were allocated to EFSA staff and WG experts.

A timeline for meetings (meetings planned /year) was proposed.

#### 6. Next meetings

The dates for the planned meetings for 2019 will be agreed in the next weeks.

<sup>4</sup>\_http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00221

<sup>&</sup>lt;sup>5</sup> https://www.efsa.europa.eu/en/efsajournal/pub/5123