Food and Agriculture Organization of the United Nations

Concept Note

Title: Advancing regional contributions to support standard–setting organizations in the development of clinical breakpoints for priority bug–drug combinations in Asia and the Pacific

Responsible Officer: Mary Joy Gordoncillo, AMR Regional Project Coordinator

Background and justification: Antimicrobial susceptibility testing (AST) of disease–causing bacterial pathogens in livestock is an important practice that supports the responsible use of antimicrobials in animals. The lack of clinical breakpoints for many of the priority bug–drug combinations in the region limits the clinical utility of AST in many agriculture sector settings. As a shared concern in the region, this has been put forward as one of the Regional Technical Items (Technical Item number 8) by the AMR Technical Advisory Group for Southeast Asia in 2018, and later by South Asia in 2019.

To progressively address these various gaps in clinical breakpoints for pathogens causing disease in livestock, the Food and Agriculture Organization of the United Nations Regional Office for Asia and the Pacific (FAO RAP), through the USAID AMR projects (OSRO/RAS/502/USA and OSRO/RAS/003/USA), has been working to build cohesive initiatives to contribute to addressing these needs. In response, FAO RAP has so far: (1) organized a regional technical working group to deliberate and develop recommendations on this technical item; (2) reached out to the Veterinary Antimicrobial Susceptibility Testing Sub–Committee (VAST) of the Clinical Laboratory Standards Institute (CLSI) for technical advice; (3) carried out regional and national surveys to identify priority bacterial pathogens in the region (in collaboration with FAVA); (4) facilitated the development of the Regional Guideline on Monitoring and Surveillance of AMR in bacterial pathogens from diseased livestock & poultry; (5) developed a regional roadmap to address priority items for addressing the lack of clinical breakpoints. Regionally–customized broth microdilution plates for the initially identified priorities to complement the efforts towards the development of clinical breakpoints have also been initiated. All these are being made possible with the technical contributions from member countries and various experts and partners within and beyond the region. Please refer to the attached briefer on Technical Item #8 for further details on this.

Continuing the momentum gained toward contributing to the development of clinical breakpoints for pathogens and antimicrobials, regional input and cooperation are needed to support subsequent steps. Each clinical breakpoint (each bug–drug combination) considered for development must be supported by extensive scientific data. Following CLSI guidelines, this data includes microbiological, pharmacological and clinical data that can be gathered from some published literature or prospectively designed studies.

Regional cooperation is needed to evaluate previously published scientific literature. A scoping review of the literature was conducted to survey which antimicrobial-pathogen priorities may be supported by published studies. However, this review did not focus on any single pathogen–antimicrobial combination, as is needed to develop clinical breakpoints, and it only included literature published in English.

To catalyze and organize these next steps forward on this Technical Item for the region, FAO RAP is organizing a back-to-back webinar (**29 November 2022**) and regional consultation (**30 November 2022**) on *"Advancing regional contributions to support standard–setting organizations in the development of clinical breakpoints for priority bug–drug combinations in Asia and the Pacific."* For further questions and inquiries, please email: mary.gordoncillo@fao.org with copy to Jutanat.Srisamran@fao.org and FAORAP–Antimicrobial–Resistance@fao.org

Objectives/Outcomes

1. Provide information on the normative process for clinical breakpoint development, and identify critical areas for potential regional contributions;
2. Obtain feedback on drug–bug survey responses with input regarding the context of antimicrobial use in a specific country to ensure antimicrobial testing priorities are consistent with regulatory statutes and current practice guidelines;

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3. Establish technical working groups (by pathogen or pathogen–antimicrobial combination) to evaluate scientific literature relevant to the development of clinical breakpoints
4. Establish a repository for holding scientific literature gathered to support the development of clinical breakpoints; and
5. Enhance regional cooperation towards evidence–based AMR mitigation while ensuring sustained livestock production

Expected Outputs:

1. Feedback and recommendations from individual countries and the region on:
    a. Core antimicrobials (and the dilution ranges) to be included for testing that will inform antimicrobial resistance surveillance efforts in the region;
    b. Additional antimicrobial agents (and the dilution ranges) that will be included in antimicrobial susceptibility testing that may be used to support the development of clinical breakpoints;
2. Identified potential contributors to pathogen / pathogen–antimicrobial agent working groups to collect and evaluate published literature for supporting clinical breakpoint development; and
3. Improved regional cooperation for major livestock pathogens in the region

Key inputs/ Main Activities:

1. Webinar event (Day 1)
2. Technical discussions and setting up coordination/network (Day 2).
3. Focused reviews for published microbiological, pharmacological and clinical studies relevant to priority pathogens and antimicrobials in the region;
4. Development of a virtual "library" that is capable of housing reviewed, applicable published literature; and
5. Evaluation of draft broth microdilution AST panel format with input regarding the regulatory and clinical considerations for specific antimicrobial use practices

Implementation Methods:

1. Regional stakeholders will be invited to participate in an initial call to review breakpoint development procedures (CLSI) and what published literature is acceptable for developing clinical breakpoints
2. Interested participants will self–assign to pathogen or pathogen–antimicrobial–specific working groups to search published literature for inclusion in the virtual library;
3. Regional stakeholders will review antimicrobials (and specific dilution ranges) for inclusion in the final regional customized microbroth dilution panel(s).

Timing/duration and Location:

Duration: 2 days, 29–30 November 2022

Location: Various locations

Target participants:

Day 1 (Open webinar) – Public and private laboratories, academic and research institutions, AMR stakeholders in the region; general public

Day 2 (Technical Working Group Discussion)

- Countries working on AMR surveillance in animal pathogens from diseased animals
- FAO Reference Centres for AMR working on animal pathogens from diseased animals
- Relevant leading Laboratories in the region (e.g., China, Japan, Republic of Korea, Australia, and others)
- Research institutions working on priority animal pathogens in the region
- National Microbiological Culture Collection Centres
- Federation of Asian Veterinary Associations

Advancing regional contributions to support standard–setting organizations in the development of clinical breakpoints for priority bug–drug combinations in Asia and the Pacific

(Open Webinar)

29 November 2022

(BKK time; GMT +07:00)

Time	Agenda	Resource person
14:00–14:05 (5 min)	Opening remarks	Dr Kachen Wongsathapornchai Regional Manager FAO ECTAD RAP
14:05–14:15 (10 min)	Background and overview of Technical Item number 8 (Lack of clinical breakpoints for bacterial pathogens from diseased animals)	Dr Mary Joy Gordoncillo AMR Regional Project Coordinator FAO ECTAD RAP
14:15–14:30 (15 min)	Findings of the regional survey on bacterial pathogens in major livestock in Asia (bug–drug survey)	Jutanat Srisamran AMR Project Specialist FAO ECTAD RAP
14:30–15:30 (60 min)	Overview of CLSI breakpoint development process	Dr Brian Lubbers Chair, CLSI SubCommittee VAST
15:30 – 16:00 (30 min)	Overview of VETCAST breakpoint development process	Dr Peter Damborg Chair, EUCAST Subcommittee VetCAST
16:00–16:25 (25 min)	Open discussion	All participants
16:25–16:30 (5 min)	Wrap–up	FAO ECTAD RAP

Advancing regional contributions to support standard–setting organizations in the development of clinical breakpoints for priority bug–drug combinations in Asia and the Pacific

(Regional Consultation)

30 November 2022

(BKK time; GMT +07:00)

Time	Agenda	Resource person
14:00–14:05 (5 min)	Welcome and overview of housekeeping points	Dr Mary Joy Gordoncillo AMR Regional Project Coordinator FAO ECTAD RAP
14:05–14:15 (10 min)	Participant introduction	All participants
14:15–14:30 (15 min)	Recap from Webinar including discussions	Dr Brian Lubbers Sub–Committee on Veterinary AST CLSI
14:30–15:30 (60 min)	Brainstorming session • Establishment of pathogen or pathogen–antimicrobial–specific working groups • Action points for each working group	All participants; Facilitated by FAO ECTAD RAP
	• Knowledge management – Establishment of a repository for holding scientific literature	
	• Communication management • Planning for the next meeting	
15:30–15–35	Closing	FAO ECTAD RAP