

From: [Ray McAllister](#)
To: [Anandaraman, Neena - OSEC](#)
Cc: [Lowery, Kenneth - FSIS](#); [Janet Collins](#); [Jim Cranney](#); (b) (6) @us.nufarm.com; [Greg Mattern](#); [Barron, Jim](#); (b) (6) @nufarm.com; [Jim Cranney](#); [Dan Botis](#) (b) (6) @ffva.com; [Michael Aerts](#); [Phil Korson - Cherry Marketing Institute](#) (b) (6); [Mark Seetin](#); [Barbara Madden](#) (b) (6) @nwhort.org; [Bob McClain](#) (b) (6) @calpear.com; [Jim Adaskaveg](#) (b) (6) @ucr.edu; [George Sundin](#); [Fajardo, Julius](#); [Ed Ruckert](#) (b) (6) @mwe.com
Bcc: [Lowery, Kenneth - FSIS](#)
Subject: RE: TFAMR Draft Guidelines on Integrated Surveillance
Date: Monday, March 26, 2018 2:13:55 PM
Attachments: [SurveillanceTFARMUSGComments03.15.18 rsm a.doc](#)

Neena & Ken:

The added paragraph below from page 8 of the comments should distinguish appropriately between *human* pathogens that are AMR, and *crop* pathogens that are AMR. Growers have a strong interest in delaying, avoiding, and preventing AMR among the pathogens attacking their *crops*, which is distinct from the public health interest regarding AMR *human* pathogens. I doubt that detection and monitoring of AMR *crop* pathogens, while potentially aiding in crop protection, are going to serve a public health purpose. I'm skeptical that AMR *human* pathogens are going to originate from crops; if they occur on crops, it is because of ... [contamination from humans during harvesting and handling, other possible reasons beyond my understanding]. I'm not sure that my single added word below ("human") achieves the necessary distinction. You folks can undoubtedly find better ways to express it. [In this context, Crops = strictly plant agriculture, not livestock or animals.]

See another comment I put on page 8 in the attached file.

I'm copying here my grower and registrant colleagues.

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From: Anandaraman, Neena - OSEC <Neena.Anandaraman@osec.usda.gov>
Sent: Monday, March 26, 2018 11:39 AM
To: Ray McAllister (b) (6) @croplifeamerica.org>
Cc: Lowery, Kenneth - FSIS <Kenneth.Lowery@fsis.usda.gov>; Janet Collins (b) (6) @croplifeamerica.org>; Jim Cranney (b) (6) @ccqc.org>
Subject: FW: TFAMR Draft Guidelines on Integrated Surveillance

I also wanted to be sure you saw the new proposed text insertion from the US on page 8 regarding crops and are ok with it. We aren't crop experts and want to make sure our assumptions here and on the first page are accurate.

SECTION 10: DESIGN OF MONITORING AND SURVEILLANCE PROGRAMMES

References to crops should await scientific advice. New text if proposed below ONLY if incoming scientific

advice requested at TFAMR5 supports inclusion of crops. This language should be left bracketed.

[There is limited information regarding the impact to foodborne illness from AMR human pathogens or genes originating from crops. For surveillance of foodborne bacteria derived from crops, standardized antimicrobial susceptibility test methods and interpretive categories for such bacteria would require significant investment to generate methods and data comparable to that of CLSI or EUCAST. Ideally, competent authorities determine with crop experts and stakeholders, the research gaps, food safety priorities, and needs for monitoring for AMR bacteria and/or genes in crops as applicable to national circumstances. As methodology and data collection are refined, food safety priorities are identified, and resources allow, multi-year, region-specific monitoring of AMR bacteria and/or genes can help assess the extent and distribution of AMR bacteria and/or genes in the region to support risk assessments for foodborne AMR bacteria].

From: Ray McAllister [[mailto:\(b\) \(6\)@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)]
Sent: Monday, March 26, 2018 11:26 AM
To: Lowery, Kenneth - FSIS <Kenneth.Lowery@fsis.usda.gov>; Anandaraman, Neena - OSEC <Neena.Anandaraman@osec.usda.gov>
Cc: Janet Collins [\(b\) \(6\)@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org); Jim Cranney [\(b\) \(6\)@ccqc.org](mailto:(b) (6)@ccqc.org)
Subject: RE: TFAMR Draft Guidelines on Integrated Surveillance

Ken & Neena:

I want to make certain I am correct in assuming that this document and associated comments do not address fungicide use.

I have reached out to the crop protection companies who have products in this category (streptomycin, oxytetracycline, kasugamycin) for their feedback. Meanwhile, I have offered a few tracked changes to your draft comments (first page only). I found the draft guidelines document very hard to follow and determine what was added or deleted. Tracked changes would be much easier to follow. I'm glad you folks have taken the time to wade through it all.

I must leave it to my grower colleagues to comment on the feasibility of monitoring crop samples for AMR resistance of relevance to human health.

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From: Lowery, Kenneth - FSIS <Kenneth.Lowery@fsis.usda.gov>
Sent: Monday, March 26, 2018 9:19 AM
Cc: Anandaraman, Neena - OSEC <Neena.Anandaraman@osec.usda.gov>; Chair - Donald Prater

<donald.prater@fda.hhs.gov>; USA - Ron Miller <Ron.Miller@fda.hhs.gov>;
'Ruby.Singh@fda.hhs.gov' <Ruby.Singh@fda.hhs.gov>; Kishore, Rita - FSIS
<Rita.Kishore@fsis.usda.gov>; Green, Alice - FSIS <Alice.Green@fsis.usda.gov>
Subject: RE: TFAMR Draft Guidelines on Integrated Surveillance

Dear U.S. Stakeholders for the Task Force on Antimicrobial Resistance,

We wanted to remind you that comments on the Draft US Comments on the Draft Guidelines on Integrated Surveillance are due by **March 30, 2018**

Please do not limit your comments to reviewing the US comments, but also, look over the draft from the Chair/Co-chairs to add any additional proposed edits and rationale to the US Comments for consideration. Please track your proposed edits and rationale directly into the US Comments for consideration using track changes in the Codex comments format:

“When changes are proposed to specific paragraphs, Members and Observers are requested to provide their proposal for amendments accompanied by the related rationale. New texts should be presented in underlined/bold font and deletion in strikethrough font.”

Please submit any comments you may have to Donald.Prater@fda.hhs.gov and Neena.Anandaraman@osec.usda.gov with a copy to me Kenneth.Lowery@fsis.usda.gov by March 30, 2018.

Ken

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From: Lowery, Kenneth - FSIS
Sent: Thursday, March 15, 2018 3:15 PM
Cc: USA - Neena Anadaraman <Neena.Anandaraman@osec.usda.gov>; Chair - Donald Prater <donald.prater@fda.hhs.gov>; USA - Ron Miller <Ron.Miller@fda.hhs.gov>; 'Ruby.Singh@fda.hhs.gov' <Ruby.Singh@fda.hhs.gov>; Kishore, Rita - FSIS <Rita.Kishore@fsis.usda.gov>; Alice Green <Alice.Green@fsis.usda.gov>
Subject: TFAMR Draft Guidelines on Integrated Surveillance

Dear U.S. Stakeholders for the Task Force on Antimicrobial Resistance,

Attached for your consideration are Draft US Comments (attachment 1) on the Draft Guidelines on Integrated Surveillance (attachment 2) on AMR drafted by the Electronic Working Group on Surveillance, chaired by the Netherlands and co-chaired by Chile, China, and New Zealand.

Please do not limit your comments to reviewing the US comments, but also, look over the draft from the Chair/Co-chairs (attachment 2) to add any additional proposed edits and rationale to the US Comments for consideration. Please track your proposed edits and rationale directly into the US Comments for consideration using track changes in the Codex comments format (attachment 3):

“When changes are proposed to specific paragraphs, Members and Observers are requested to provide their proposal for amendments accompanied by the related rationale. New texts should be presented in underlined/bold font and deletion in strikethrough font.”

Please submit any comments you may have to Donald.Prater@fda.hhs.gov and Neena.Anandaraman@osec.usda.gov with a copy to me Kenneth.Lowery@fsis.usda.gov by March 30, 2018.

Ken

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