UNITED STATES DEPARTMENT OF AGRICULTURE

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GRAIN INSPECTION ADVISORY COMMITTEE

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THURSDAY,
DECEMBER 16, 2021

The meeting came to order at 11:00 a.m. EST via Videoconference, Matthew Kerrigan, Chair, Presiding.

COMMITTEE ATTENDEES:

DAVID AYERS, Champaign Danville Grain Inspection, Inc.

CHAD CHAMBERS, Caledonia Farmers Elevator

JANICE COOPER, Wheat Marketing Center

CURTIS ENGEL, The Scoular Company

NICHOLAS FRIANT, Cargill, Inc.

MATTHEW KERRIGAN, EGT, LLC

RYAN KUHL, Northern Plains Grain Inspection Service

ROBERT SINNER, SB&B Foods, Inc.

JIMMY WILLIAMS, Missouri Department of Agriculture

USDA STAFF:

LEE CAPPER, Chief Innovation Officer

ANTHONY GOODEMAN, Field Management Division

ED JHEE, Technology and Science Division

KENDRA KLINE, Agricultural Marketing

ARTHUR NEAL, FGIS Deputy Administrator

TIMOTHY NORDEN, Scientific Integrity Officer

DENISE RUGGLES, Executive Program Analyst

C-O-N-T-E-N-T-S

PAGE

P-R-O-C-E-E-D-I-N-G-S

11:00 a.m.

MR. KERRIGAN: Good morning, everybody. I just was going through to see who was on currently because our speaker here in a couple minutes, I don't see Nick on just yet. While I am search for Nick and we're waiting for Nick, we'll go ahead and take a roll call. I think we have a pretty good list here. It looks like David Ayers, it looks like you're on.

MR. AYERS: Yes, sir.

MR. KERRIGAN: So we've got Janice.

MS. COOPER: Yep.

MR. KERRIGAN: Jimmy?

(No audible response.)

MR. KERRIGAN: Mr. Sinner?

(No audible response.)

MR. KERRIGAN: We've got Chad.

MR. CHAMBERS: I'm here.

MR. KERRIGAN: Curt Engel?

MR. ENGEL: Here.

MR. KERRIGAN: Ryan Kuhl?

(No audible response.)

MR. KERRIGAN: And we are waiting on, it looks like, Nick and -- oh, I just saw him join.

MR. FRIANT: I'm here. Sorry about that.

MR. KERRIGAN: And how about Tom Tunnell?

(No audible response.)

MR. KERRIGAN: Tom had some conflicts yesterday, and I did not hear back from him about today. So okay. Well, we will keep an eye out on that. Going off the agenda, we do have one discussion to update the group on regarding some subcommittee work regarding the FGIS FDA MOU which I'm going to ask if Nick would walk us through where that subcommittee work is at.

Once we're through that, we will take roll call one more time to see where we are at. If we have a quorum, we can discuss the recommendations. If we don't, we'll open it to public comments. And that may be the wrap.

Nick, do you want to go ahead and take it over as the Chair of the FGIS FDA MOU Subcommittee?

MR. FRIANT: Indeed I will. Thanks, Matt. And thanks everybody for the time today to hear what the subcommittee worked on. And we'll be able to show -- we'll actually be able to show you that.

So what I wasn't able to do before today's meeting -- sorry, I have too many screens to look at here. What I wasn't able to do before this morning's meeting was pull up the actual recommendation that was made by the committee during the last advisory committee meeting. But in essence, it said let's move the former subcommittee to look at -- to develop some pre-approved reconditioning plans when a facility has had an FDA actionable lot of grain.

So that was the basis for the recommendation. We formed the subcommittee. That subcommittee consisted of myself as the Chair as Matt mentioned. We also had Dave Ayers, Ryan Kuhl, Curt Engel. And I think that was it,

wasn't it? I don't even have those -- sorry, I got caught in another call before this one.

I think that was all of the subcommittee. And the intention of the subcommittee was to take a look at the current FGIS FDA MOU, what items were considered actionable under that MOU, and then determine what types of pre-approved reconditioning plans we could have for that. Real quick and I didn't see, is Barry from FGIS on this morning?

MR. GOMOLL: Yes, I am, Nick.

MR. FRIANT: Barry, sorry to put you on the spot. Did you want to maybe just given a quick update on the overall work that you've been doing with FDA on the MOU? Because I think that is pertinent to our discussion.

MR. GOMOLL: Yeah, I haven't had any discussions recently, not since I think our last meeting with the subcommittee. But I've been in continuing talks with several members of FDA CFSAN and others in their policy about possibility of working with sort of pre-approved

plans. They seem to be at times more or less receptive depending on how they're receiving the messages, I guess.

Sorry. I just hit the space key. The mute was on. They see to be more or less receptive. And we'll have to -- once we get some more concrete things, we'll have to figure out which channels to go. I know they had said in the past that with some other agencies, I think talking about with maybe peanuts or some other industry that a lot of the changes were pushed from the industry and not from the U.S. -- hold on one second.

My wife left the dogs behind me. So now they're acting up. Can you not? Sorry. So we've been having discussions. And I think I'm definitely try to have a meeting with them sometime in the early part of the year just to touch base to see where they're at, especially after we hear some more, what comes out of this meeting.

MR. FRIANT: Excellent. Thanks,

Barry. And appreciate -- for sure from my seat, appreciate your continued work with FDA on that front. And I think it could have some good discussions with them on how we can get these pre-approved reconditioning plans in place.

So with that, the process that we took as a subcommittee like I kind of alluded to was we looked at the MOU, looked at the actionable items that were in there and went through it and said, okay, which of these actionable items do we think are ones that we could reasonably have a reconditioning place for that again could be pre-approved? And I think hopefully this will work. I'm going to try and share this. If not, Kendra, I might need you to share it. But I'm going to try and see.

MS. KLINE: Okay.

MR. FRIANT: Okay. Hopefully folks are seeing the draft version. And I believe, Kendra, this was sent out also as part of the meeting announcement too, correct?

MS. KLINE: It was posted to the

public website a couple weeks ago.

MR. FRIANT: A couple weeks ago, yeah. So what you can see here at the top is the types of items, for lack of a better term, that are actionable for which the subcommittee thought we could have some sort of pre-approved reconditioning plan for. And it was things like the animal filth which we know has been a big discussion topic, particularly deer droppings, insect damage grain, aflatoxin which already has a pre-approved condition plan, deleterious foreign matter in grain, and then DLQ I have here on account of large animal excreta.

And the next part of our process was to essentially take the current pre-approved plan for aflatoxin and modify that to fit all of these actionable items. So what you'll see here or what you may have seen if you went through the draft that was posted on the public website basically is following that, the reconditioning plan that is in the mycotoxin handbook, the Section 6 or 6.4 more specifically. And we

basically took that verbiage that was in that reconditioning section and modified it to fit additional types of actionable items that we could see in grain elevators.

So I don't know that we need to read through the whole thing with this group. But maybe what I would call out is a couple points that the subcommittee talked about that we found were important. And I'll start with kind of right here on the middle of my screen.

If the sublot or lot is found to be actionable due to IDK, the affected grain company could elect to divert that lot directly into animal feed without reconditioning. And this is something that we talked about and said, well, maybe the facility doesn't want to deal with reconditioning, try to remove that IDK. And so could go directly into animal feed and more importantly have a little bit more flexibility to go directly into animal feed without necessarily having to go through the full -- if folks aren't familiar with it, the very prescriptive process

of diversion to animal feet.

So that was something I would consider new to kind of the overall reconditioning procedures is the ability to direct the actionable lot directly into animal feed. After that, we did spend some time talking about the concept around, well, how many times can you run the grain? So in most conditions, what we're saying is you can run the grain over a cleaner screener separator, some sort of process to remove that actionable item.

And so we had some discussion around the ability to make multiple passes across the mechanical cleaners. Folks that are familiar with the aflatoxin reconditioning procedure will likely remember that the facility can run the corn, for example, over the cleaners as many times as they want but only have one chance to get that officially regraded and retested for aflatoxin. And so we talked about that piece as well which is number 2 here on the screen of -- the first part is the applicant can pass the

actionable lot over a cleaner -- some sort of mechanical cleaner multiple times.

And a change that we're proposing is not only multiple passes which is consistent with previous procedure. But that grain can also be eligible for the original inspection and a full set of review inspections and follows the FGIS policy around review inspections. So we recognize that this was a potential -- not potential, it is a change from previous policy position and something that likely will be open for discussion with the agency FGIS and potentially FDA as well.

I think that's probably the most substantive change I want to bring to the group. Otherwise, the FGIS procedures, FGIS responsibilities essentially stay the same to what is currently in the aflatoxin section except obviously expanded to cover multiple actionable items, domestic locations, essentially, the same procedure with the official agencies, sample size and preparation, again, essentially the same as

what's currently listed, basically, a cut and paste right out of the current reconditioning requirements in the mycotoxin handbook. And the disposition piece again is essentially the same, just expanding it to not only cover aflatoxin.

It would be any of those actionable items. And so that's what the subcommittee has developed, what we are, I guess in this case, now reporting back to the broader committee. I think if folks had time to review it prior to today's meeting, I think we are certainly open to questions, comments. And then I guess we could probably have some discussion around next steps. But we -- I don't think we can take any official action necessarily on next steps.

MR. KERRIGAN: Thanks, Nick. Regarding next action, obviously the subcommittee put this out there. I'm assuming that our entire group would be to recommend it. Or is this something that FGIS on their own would then be discussing with FDA without a recommendation just from a procedural question?

MR. NEAL: So in light that you all have been working with Barry on this, we can -- and with us and considering we do not have a quorum, I think -- and it's tough right now. It's tough because we've taken this work up as part of the committee. You can't make a formal recommendation on it.

I think what we can do is still have conversations with FDA about the discussions and share industry thoughts. I think from a formal standpoint once we do get quorum, it will be great to have this officially come from industry to FDA because their feedback to us is that they need to hear from industry, not USDA. And so the whole purpose of bringing this issue to the Grain Inspection Advisory Committee is so we can have feedback directly from industry to FDA so that they do know that this is not just us carrying the war.

(Simultaneous speaking.)

MR. FRIANT: I'll just come to that does not prevent us from still engaging and

facilitating conversations about the concepts discussed so that we can still make progress.

MR. GOODEMAN: May I add something real quick, Nick?

MR. FRIANT: Yeah, please, Tony.

MR. GOODEMAN: I think it would definitely help like Arthur was saying. Like, FDA was pretty -- they're big advocates for hearing from the industry. And so it'd be helpful for us knowing this was a really good unified position from the committee.

And if there's not a whole lot of dissension here which I don't think there is. But I think it'd be helpful to have committee's support. I'm also curious if NEAGA would pick up any subcommittee's work and endorse it through their own organizations. I'm not sure if this is the right forum to ask that question. But that is something that might be another means to help push it with FDA.

(Simultaneous speaking.)

MR. FRIANT: I mean, on that front, I

would -- I mean, I'm not sure that many people know this. I chair the NGFA Grades and Weights, and the NEAGA Grades and Inspections Committee. So my intention would be to take this to those committees for review and input.

And then the committees and respective staff would make some decisions on if and how to pursue this with FDA. I think we had talked about it as the committee, right, FDA wants to hear from industry. But I'm not sure that I shared that well or clearly with NGFA and NEAGA.

So that's a key point that FDA would want to hear directly from industry. So I think the short answer to that, Tony, is yes, I think it would be something that NGFA and NEAGA would be interested in for sure, providing input and feedback and then some further discussion on how to approach it potentially with FDA. I think the only thing I wanted to raise, Arthur, before I --

(Simultaneous speaking.)

MR. McCLUER: Nick, I was just going to say totally support what you're saying. As

chairman of the Grain Grades and Weights Committee, I think this is definitely -- this is the initial draft and this would be definitely at our next meeting. We would definitely put this on the agenda for review and kind of go through it. Matt -- Chairman Kerrigan is also a member of the Grain Grades and Weights Committee too. So I think that'd be a good opportunity for feedback from the members and something to take back to the full advisory committee as well because there may be some additional input for the advisory committee to consider too.

MR. FRIANT: Thanks, Jess. So Matt and/or Arthur, I guess, from a procedural perspective, is it fair to say we would essentially -- as a subcommittee, we would still be operating under the current recommendation of forming the subcommittee, developing the draft. And so as a subcommittee, we could still work on it, whether that be subcommittee working with Barry and FDA or subcommittee working with trade associations, right? I see you shaking your

head, Arthur. So we can still operate under that current recommendation and we'll still be okay from a procedural perspective.

MR. NEAL: Yeah, nothing is preventing us as a subcommittee from having a dialogue, sharing a perspective that's been developed to date. What we cannot do is take action on the document as a committee. That's the main thing we can't conduct business on.

MR. FRIANT: Sure. Continuing to accept feedback from the committee is not considered business, though, right?

MR. NEAL: Right. The subcommittee is still working.

MR. FRIANT: Sure.

MR. NEAL: That's no problem. And so what you're doing as a subcommittee, if you're complete -- if you've completed your work, you would then hand that work over to the full committee. And the full committee would take action to either endorse or modify or reject the body of work that the subcommittee has done.

You've not turned the body's work fully over to the committee is what I'm hearing. The subcommittee is going to continue generate input from the industry as well as facilitate dialogue to kind of gauge how open FDA is to entertaining some of these concepts. You're also going to work with other trade groups to garner more input and assess how people feel about those things. So the subcommittee is still working under a previous action that was taken at the last meeting. So we're good.

MR. FRIANT: Thank you for that clarification, Arthur. I appreciate that.

MR. NEAL: Yes, sir.

MR. FRIANT: So with that, I mean, I would ask for the committee members that are on the phone this morning any questions that I or anyone else on the subcommittee could answer about what we've identified, the proposals that we're working on. Any questions or comments from the broader committee?

(Simultaneous speaking.)

MR. KERRIGAN: I would just add for everybody listening here just backing up to the concept of why the subcommittee was formed and why these reconditioning procedures are, I guess, wanted or needed. Is it because of the sheer time that the FDA can take and the, I would say, inconsistent application of reconditioning plans from their own office to office across the country? Like I said, there was a successful model with aflatoxin already out there that had been approved.

With that as far as what procedures could take, that could be under observation by FGIS to complete. And the idea was to replicate that across additional actual items from FGIS to FDA. Sorry, Bob, I think I spoke over you there.

MR. SINNER: No, that's fine. And this may be pretty straightforward, Nick. On that third paragraph there under 6.4 under the wheat, does anything need to be qualified in that statement in regards to mycotoxins?

A lot of times, IDK leads to molds and

mycotoxins. Does that -- because really it's stating that that grain can be moved directly into animal feed without reconditioning and not even needing to notify FDA. Is there anything there that needs to be qualified regarding mycotoxins?

MR. FRIANT: You know what, Bob? That's a really good question. We did not talk about the mycotoxin piece. We were purely focused on just the insect damage kernels. So I think that's -- my answer would be that's something the subcommittee should maybe discuss a little bit further because we did not consider the mycotoxin piece.

MR. SINNER: Okay.

MR. FRIANT: But I appreciate that feedback for sure.

MR. SINNER: Well, I mean, a lot of times, insect damage grain leads to molds and we all know that. And so I just wondered if that should be qualified with this in that statement.

MR. FRIANT: If I could spell. Go it.

Yeah, we'll make sure we consider that. I appreciate that. Thanks, Bob.

MR. SINNER: Good.

MR. NEAL: Nick, I've got a question and this may be just because of my unfamiliarity. That particular highlighted paragraph, would FDA know why we are suggesting that in the case of wheat that we are suggesting that it can be elected that the wheat be diverted into animal feed without reconditioning? Would they understand why we would be recommending that?

MR. FRIANT: That's a good question. Knowing FDA, it's probably not safe to assume that they would understand that which I think is probably where you're getting to a little bit with your question, right? Like, so what I think I hear you saying is maybe we need a little bit more why apply to this section.

MR. NEAL: Yeah, let me -- so my perspective would be don't assume they know anything. And I'm not saying that they don't. But we know that there's turnover happening all

across the lane. And it will be best that if there's something that could appear to be digested and potentially be passed on and consumed by humans or animals. They need to understand why it --

MR. FRIANT: Sorry, I think you froze up on my end, Arthur.

MR. NEAL: Was I frozen?

MR. FRIANT: Yes, you froze up on us.

MR. NEAL: Oh, man. Kendra said, I may be frozen. All right. I don't know. But I was just saying because we're diverting an actionable lot potentially to animals, we need to make sure we address the reason why it would not be an impact on human --

MR. FRIANT: Yeah.

MR. NEAL: -- or animal health and safety. And FDA is going to be looking at things for that type of impact. When people get sick from it, when animals get sick from it, will it be passed on to somebody else?

MR. FRIANT: Yeah, yeah, good call,

Arthur. I appreciate that for sure. Perhaps that's something that's actually needed more broadly. We might need to think about overall for all of these items why. We might need to defend why cleaning is an appropriate -- cleaning and screening is an appropriate reconditioning.

So I appreciate it. I think that's good feedback, and I think you're right. We -- even just from my own seat it was probably making that assumption that FDA understood the grain business in general.

MR. GOODEMAN: Nick, is the assumption that when things are reconditioned that the cleanings or screenings -- and I'm sorry if it's in here -- are they disposed or are they diverted to animal feed?

MR. FRIANT: Yep, so we basically took it right from the aflatoxin document to say that they're not going to reenter the human food channels screenings. Maybe this needs to be expanded further to say any type could be diverted into animal feed. Doesn't necessarily

say that they have to go to just landfill or disposal.

MR. GOODEMAN: Right, right.

MR. FRIANT: And we also say contact the FDA office on other --

MR. GOODEMAN: Right.

MR. FRIANT: -- specific disposition actions for the screenings.

MR. GOODEMAN: If my understanding is accurate, the industry before was concerned if they were able to clean something, screen something, and then only have to worry about dealing with FDA on the clean portion, whatever it is, the ten percent of the -- or five percent, whatever it turns out to be versus and then being free to handle the clean cargo. That would address a big part of the issue, right?

MR. FRIANT: Yeah, yeah.

(Simultaneous speaking.)

MR. GOODEMAN: -- follow up directly with FDA and what to do with the screenings. We were free to move the clean grain, the

reconditioned grain. And that would alleviate a lot of the problem, right?

MR. FRIANT: Yeah, yeah. For sure being able to move the clean grain is the focus. But you're right. And frankly, we focus so much on what I would call the top portion of the document, the procedures --

MR. GOODEMAN: Yeah.

MR. FRIANT: -- and some of the disposition, certainly open for suggestions, comments from anyone on that. And I think that's a good call out, Tony.

MR. NEAL: Nick, would you mind sliding up to the previous page?

MR. FRIANT: Without having both documents side by side, I can't say for sure. But most of this section was cut and paste right from the current aflatoxin reconditioning procedures.

MR. NEAL: I think Tony -- go back up a little bit, Nick. Yeah.

MR. FRIANT: This would've been an

addition or clarification here, right, for example.

MR. NEAL: Yeah, yeah. And that's what I was about to say is that we have to really reiterate what it is we're trying to do to help them carry out their responsibilities. And we're looking at this as an SOP which is fine. I think for us when we sit down to talk with them, we'll need to present it as such that we're not trying to necessarily get you out of the way.

We're really trying to help facilitate your work as well as streamline the food supply chain yet maintain a keen eye and concern for human and animal -- we're not in safety. So we can't necessarily be deputized by them. But we're trying to honor their work considering loose constraints and things of that nature and see whether or not this can fit into their plan for carrying out oversight in this space.

And so I see this more of an SOP. We'll probably have to have another kind of cover that really explains what it is we're trying to

do. But we have already conveyed to them our desire to work with them, the reason why we need to work with them. But when we do finalize this, we want to make sure it's packaged so that they can digest it the way we intend them to.

MR. FRIANT: I think that's a good comment, Arthur. So I've captured that here, right, clear responsibilities. I'll have FGIS help me facilitate FDA's work. Streamline grains, I think those are all good, good language.

And then also what I heard you say is whether it's a cover letter or preamble or something along those lines that gives more that clarification guidance because you're right. The discussions that we as a subcommittee either with Barry or through Barry or directly might have with FDA, those people might change three, six, nine months, years, whatever down the road. So yeah, I'm definitely following what you're saying on that.

MR. NEAL: Yeah, and another thing I

see that's really critical and important and beneficial with this is that it can also be used as a way of facilitating a consistency in the midst of change, changing staff. It helps to reduce that learning curve because we'll be taking some of that responsibility on for them but communicating with them. I think -- and I don't if it is in here. I think that whatever we do on their behalf, there needs to be a responsibility that we document it and convey that to them so that they are aware of the decisions that have been made.

MR. FRIANT: Yep, so I think to your point, Arthur, I think that is covered here.

MR. NEAL: Yeah, you got it. You got it.

MR. FRIANT: Now there might be some question and debate on which that be clear enough for FDA going forward, right? Is there something more that they would want. But yea, you're absolutely right in terms of we don't want anybody from FDA coming back to FGIS or the

industry saying, well, we didn't know you did that.

MR. NEAL: You got it. Thanks.

(Simultaneous speaking.)

MS. COOPER: I just had a question. So you mentioned a lot of the language came from the existing policy. For discussion purposes, I think it would be helpful to do a document where it's clear what the additions or changes are.

MR. FRIANT: Yes.

MS. COOPER: Either attract changes --

MR. FRIANT: I'm not going to try and do that.

MS. COOPER: No, not right now.

MR. FRIANT: Not in this venue. But I think I can do that with the work that we did, Janice, where you can see the tracked changes. If not, we can probably work with someone to get that to you so you can see it more clearly.

MS. COOPER: And then I think it would just present that maybe you're not proposing that may differences, that there's a lot of the policy

already there. You're just tweaking it. And I think that that might be an easier sell with FDA. I don't know. Just from an editorial standpoint, I didn't know what was existing versus what was being changed, so --

MR. KERRIGAN: Was this as much of a change as it is a new document? I realize that we've copied and pasted the aflatoxin with it. So I guess that would be my question knowing that we've added so much. We've based it off the aflatoxin, but do we want to show it as a change? Or do we want to show it as a new document because of everything else that's been added to it?

MS. COOPER: And I'm just unfamiliar with the procedure. So I didn't know.

MR. FRIANT: Yeah, great -- I think great point, Janice, from you and I think great question, Matt, from you. Maybe that's some additional discussion that the subcommittee could have on the best way. Because I think your intention, Janice, is spot on, right?

Demonstrate to FDA what we're proposing for other actionable items is consistent with what's already been in place for aflatoxin which we clearly know is a food and feed safety issue, right? So I think your mind is in the right place. How we do that, yeah, Matt. It might be a good question.

Is it good enough to do like track changes? Or do we need some sort of additional comparison document? That's a valid question. So I think as a subcommittee, maybe we need to regroup on that piece. What I'm hearing, I've heard it from Arthur now and I hear it too now from you, Janice, is the story that we need to tell FDA, right?

We can't just go in front of FDA and say, here it is. This what we want to do. But why, how, the importance, like, there's as much to that story and that preamble or cover letter or introduction, whatever we want to call it, that's going to matter down the road when the next person at FGIS or the next person at FDA

sees this that wasn't part of this subcommittee or committee work.

MS. COOPER: And maybe what I'm suggesting is already going to be covered in what Arthur suggested in the preamble and the explanation. And maybe that will be sufficient. So it was out of -- really out of ignorance that I kind of asked the question about how the document -- how much of the document is current language and what is being proposed. So you can handle that in lots of different ways per Matt's comment. So just I think clarification is the goal of all this discussion.

MR. FRIANT: A hundred percent agree with you. Like I say, I'm not going to embarrass myself in front of everybody with my IT skills to pull up the track changes. But I think we can start from there. I think that's a good point.

MR. KERRIGAN: A question in talking about kind of the preamble and discussing or trying to lay out the basis for animal and human food safety was, are we aware of a document that

covers that currently for when the aflatoxin procedures were put in to kind of see how that was laid out. Or was that kind of pre- and basically all done, I guess, verbally or through staff?

MR. FRIANT: And that'd be a question, I think, for Tony maybe. As long as I've been in my role, I think that's what's been in place.

MR. GOODEMAN: What was it again, please, Nick?

MR. FRIANT: So do we know any of the basis for how the aflatoxin reconditioning procedure was established and agreed to?

MR. GOODEMAN: I think much like this. I think it was an issue and didn't want to have to wait probably -- I'm guessing here, probably during some high aflatoxin years and not having to wait for a bunch of bins to be tied up when the reconditioning procedure was going to be likely the same. I think there's also some research about the broken corn -- the broken kernels containing a higher concentration of

aflatoxin and prompting the cleaning to be allowed, then the retesting. It's --

MR. KERRIGAN: That --

(Simultaneous speaking.)

MR. GOODEMAN: -- for a long time, though.

MR. KERRIGAN: That research is just kind of maybe the question that kind of proves that. As we think about the preamble or trying to explain why the cleaning is available, and I understand it's a little bit different with aflatoxin and mycotoxins and then the whole grain, the broken pieces versus taking out the physical pieces in the case of, like, animal filth, right? It's a very obvious one-to-one.

We were just kind of curious. Either it's something to go off of or if we are going to include aflatoxin with this as a rewrite versus two separate documents, we don't want to lose where we are with aflatoxin by combining them which may be a strategy with the subcommittee. Maybe they do need to be two separate documents

so that way we don't muddy the waters of aflatoxin of somebody new reviewing it and thinking that that's a new procedure as well.

MR. GOMOLL: Let me chime in for a second. That has been one of my challenges. I've been trying for the last probably at least two years now to track down information about when the aflatoxin procedure came into practice.

And I can't find any documentation from talks when it happened. I've been looking. I've been chatting with people that have been around. I just know it's been in place since at least the '90s.

MR. FRIANT: So you got to track down, like, Dave or --

MR. GOMOLL: Right. And I know there was some information from Bob Lijewski's archives about some changes that were made where I know there was a recent -- well, at least in terms of history, a more semi-recent change to allow multiple passes over the cleaner where I think originally I think it was one pass. And then the

changes made to say, okay, as many passes as you want, but we're still only going to test it once.

MR. GOODEMAN: Yeah. And I think it's very fair to say it's over 20 years, right, Barry, that this has been in place, the aflatoxin recondition?

MR. GOMOLL: Yeah, in some of the research, I did find some writing from Dr. Charlie Hurburgh from, like, 1993 it was dated where he referenced this aflatoxin reconditioning procedure, so at least since then.

MR. FRIANT: I know Charlie actually mentioned to me he was going to try and be on today. I don't know if he's here. But I think it's fair we could open it to his comments if he is here. And I don't see him.

No, and so I appreciate this. I think this is all great feedback and great questions. And what I am hearing is we get into the first of the new calendar year. We've got some continuing work for the subcommittee to address on this one which was the whole purpose for bringing it up

for discussion today. So I guess any other comments, questions, feedback from folks on the committee?

MR. CAPPER: Nick, this is Lee Capper with FGIS. Just a comment for clarity. Up above where we're talking about responsibility, Bob called out the FOM and then later also called out the delegated state as applicable. As you're preparing this, just make sure that where the delegate states are appropriate, that's also included.

MR. FRIANT: Okay. So in the -- definitely in the responsibility section, right?

MR. CAPPER: Yeah, right there. The first part of that highlight says FOMs. But I think perhaps it's meaning to say both, field office managers and delegate state officials, at the top of the second page. Or if it's not, it's not.

MR. FRIANT: I agree, and I think that's a good call out because in delegated states, it would be their officials more likely

correctly. Okay. Yeah, I think we can address that too as a subcommittee. Okay, Mr. Chair. I think unless there's any other questions or comments, the subcommittee has direction on continuing forward with this. And we'll keep working under our current program.

MR. KERRIGAN: Okay. Well, appreciate everybody's comments and time on this for the members of the subcommittee, members of the overall GIAC as well as the staff in assisting with this. It's been a big help and, like I say, a lot of work. And we'll see where we get to with it.

MR. FRIANT: I'll echo those comments real quick. A big thanks to the subcommittee members for taking extra time. I really do appreciate that and a special call out for Barry and his work and communications with FDA. Also really appreciate that.

MR. KERRIGAN: Absolutely. Okay. As we've discussed, we do not have a quorum. We will not have a quorum today. But we do have

another opening here for potential for public comments before we move in towards the final section of our meeting, if there are any. There weren't any yesterday. We'll kind of give a few brief moments here to see if anybody has anything that they'd like to discuss.

MR. McCLUER: Hey, Matt. I do have one follow-up questions from yesterday for Arthur regarding the fee reviews that I guess I just want to make sure for clarification I was on the same page. I always think of the national and local tonnage fees, right? The five-year roll in average.

And you're talking reviews. I'm assuming it's some of the other fees, the Schedule B fees. I mean, some of the things such as the -- just like we're talking, the testing, aflatoxin testing, and some of those other services. Is that correct?

MR. NEAL: I'm not quite sure I fully understand the question.

MR. McCLUER: The question I'm just --

I'm following up on a statement that you made and I'll go back here. It was you said that -- where did I write this down? You said that we're going to be reviewing the fees. So you made a statement saying reviewing the fees. And so --

MR. NEAL: Yeah, so --

MR. McCLUER: -- I just want to make sure when you're saying reviewing the fees I'm understanding what particular fees you're going to be reviewing.

MR. NEAL: Yeah, so we'll need to do a periodic review of the fees that we have set for the services that we provide. The national tonnage fee, that formula is set.

MR. McCLUER: Yeah.

MR. NEAL: The reality is that we are -- we've been operating at a discount for about six years now. And so we will not be able to continue to provide service at the current fees that we have set. I'm not saying anything is going to happen.

Something may not happen. But for the

last six years, we've been spending more than we're generating in revenue. And so at some point, we have to review the fees that we have set to do an overall look at what fees we're charging for services.

MR. McCLUER: Correct. So we're not talking those fees that are part of the five-year rolling average. We're talking the other service fees that are -- correct. I mean, is there -- can you give me an example just to make sure what we're talking of? What would be an example of another fee?

MS. RUGGLES: Hourly fees, mycotoxin fees, appeal fees.

MR. GOODEMAN: Any kind of unit fees, right?

MR. McCLUER: Okay, okay.

MR. GOODEMAN: And hourly. And the breakdown between non-contract and contract, they've been both -- I don't want say the same but proportionally the same to one another for many years. And so we're due for a look to see

if the non-contract rate should be higher or lower and if the contract rate should be higher or lower respective to our costs for maintaining those -- really for maintaining non-contract availability.

MR. McCLUER: Okay. That's what I thought and I just wanted to confirm, right, that those are the specific type of fees that were being referred to. And so reviewing that, will that be something that'll be provided to the next official advisory committee meeting as part of the review, I mean, if there's going to be any -- if you decide to -- I guess if there's a decision to be made, whether they're going to increase and when will that be announced when we have January rulemaking?

MR. NEAL: Yeah, that's a totally different process. There's a lot of education and review that has to happen internally inside of USDA. And we'll be engaging with industry as we embark upon that process.

So this is not something that's going

to happen swiftly. It's not something that's going to happen secretly. So just stay tuned. We're just sharing with you all kind of where we are. That was really the whole point of stating it is that we're at a point where we really have to review the fees that we have set so we don't continue operating at a loss like we are.

MR. McCLUER: Okay.

(Simultaneous speaking.)

MR. GOODEMAN: And Arthur, if we do make any changes, that'd be done through rulemaking, right?

MR. NEAL: It'd be done through the Federal Register.

MR. McCLUER: Beforehand, were you doing the research and getting feedback from stakeholders, correct, before you --

MR. NEAL: Say that again, Jess.

MR. McCLUER: I said before you go into the formal rulemaking process, you'd be soliciting feedback from stakeholders to as you're going through this review, correct?

MR. NEAL: So the process we will be working out internally and we'll be communicating how we'll proceed because this is the first time we'll be doing this, I think, in a very long time. It's kind of overall periodically. So how we solicit the comments, when we solicit the feedback, that piece, we don't have worked out just yet. But when we do, we'll engage in a dialogue so that folks can have a clear expectation of how the process will flow. But it will not be done in the dark.

MR. McCLUER: Okay. No, that's helpful. I appreciate that clarification.

MR. KERRIGAN: I think we have a question from Mr. Mark Tess.

MR. TESS: Yeah, this is Mark Tess from Charm Sciences. And I apologize for not being on the call yesterday. But I had a comment about a procedure and submission guidelines for evaluation of technology for the official grain inspection. And my question is, does the ITE process going to apply to existing quality

factors such as mycotoxin testing where there's already a procedure in place for validating test kits?

MR. JHEE: No, no. You're already --

MR. TESS: Okay. And that -- sorry, go ahead.

MR. JHEE: Since the mycotoxin test kit program is already an established program, it doesn't fall within the purview of it.

MR. TESS: Okay. And that won't affect, like, future readers that companies, manufacturers may submit. Or my other question would be, is it going to affect, like, new mycotoxins if FGIS determines that there's a need to have a criterion specification for T-2/HT-2 or the possibility of ergot alkaloids in the future?

MR. JHEE: I think we'll probably have to address that latter question once that type of technology is revealed in terms of being a possible use in the industry.

MR. TESS: Okay.

MR. JHEE: Tim, any other thoughts

from your perspective, Tim Norden?

MR. NORDEN: Yes, I would say if it's a new technology for detecting mycotoxins, whether it'd be some kind of beam that you're aiming through the grain stream or you're taking some grain dust or some brand-new technology, that would fall, I think, under the ITE directly. But if it falls within our existing mycotoxin test kit evaluation program where the -- that technology, then we already have that in place. So it wouldn't fall under the ITE.

MR. TESS: Okay. We have several different people here reading the purpose and scope. And some of us really thought the way that you're commenting on this whereas others kind of thought it may affect current procedures as well. So I don't know if perhaps there needs to be better clarification or more clarification. Or Charm may just not have been privy to some of this information prior to reading this document.

MR. NORDEN: Yes, Section 4 covers that. But we'll read that statement and make

sure that -- we make sure that it's clear. It says that approvals of rapid mycotoxin and biotechnology testing methods are performed through the FGIS rapid test kit evaluation program.

And then it says, for more information, there's a link there. But I understand your point. We could clarify that and make it even more transparent there, I think.

MR. TESS: That is how I interpret it. And I appreciate your comment. But I know later in the document there was a comment that unless specifications already exist. So other people read that as could still be implicated in terms of following this procedure. So thank you for your clarification, though.

MR. NEAL: And by reminded too that this document, once it is released, will be open for comment.

MR. TESS: Thank you.

MR. NORDEN: Great question. Appreciate it.

MR. KERRIGAN: Any other comments or questions from the field?

(No audible response.)

MR. KERRIGAN: I'm not hearing anything. I would like to, Arthur, put you on the spot a little bit to talk a little bit, to explain to the group where we're at as far as the committee selection members, just kind of advise on timing. We're right in the process. We know that it is a long -- can be a long process and what that means for our quorum, if you could, please.

MR. NEAL: Great question. We checked again this morning. And the nominations are with the Secretary. I can't put a definitive time frame on the decision. But if I had to guess, before our next meeting we should have our new members appointed.

We're at the end of the appointment process in terms of him making the selections. And so I don't think we'll be faced with the current challenge that we are. We're also going

to begin working on the new committee charter to make sure we're ahead of that timeline.

And we'll start going out for an announcement for new committee members next year as well. So we'll have a full slate of work ahead of us. But in terms of the five members that we need, I believe that we will have them appointed before we meet again. That's my belief.

MR. FRIANT: Hey, Arthur, to that point, will the -- the selection process, I guess, would also include some alternates. I know in the past, we would have alternates that could fill in if folks were unavailable or retired or left the committee or whatever. Will we go back to trying to have alternates in the future do you think?

MR. NEAL: Great question. Based on legal review that we've received, the alternates are not authorized by statute. And so we've been informed that we can no longer do alternates.

MR. FRIANT: Okay. Thanks for sharing

that. I appreciate that.

MR. KERRIGAN: Thanks, Arthur. I just got a question back. It is regarding the discussion yesterday with AMS Transportation and the -- how this group might be able or FGIS might be able to assist with some of these shuttle train rail transportation scheduling.

Obviously the STB is tackling a lot of it. But comments are always welcome. And I guess there's kind of an open question to this group or to FGIS as far as what we can or can't do or should or should not do maybe, whether it'd be from FGIS, whether it'd be from the GIAC, if that's something we take up, if that could be in a recommendation or if there's any thoughts on that, I guess.

MR. NEAL: I'll speak just from a general perspective. National Grain and Feed Association works very closely with transportation and marketing on filing comments on behalf of ag shifters as it pertains to these type of ag transportation issues. However,

everybody here may not be a part of NGFA.

At the same time, as you saw yesterday, the transportation and marketing team, not familiar with everybody either that's represented in this meeting. And the on the ground examples helps them gain a better perspective and insight to the issues so that they can help convey concern to the surface transportation or along with National Grain and Feed and others. A lot of the other are producer associations that participate in those proceedings that the Surface Transportation Board facilitates around these ag transportation issues.

I would encourage folks that if you got data, if you're collecting data concerning the impact of transportation on the agricultural operations, begin collecting it and sharing it with those who are commenting on behalf of agriculture. And particularly, you may want to start engaging that process too as a GIAC or as individual committee members and represent your

organizations or with NGFA because they've been carrying this torch for a while.

And I think it's a difficult situation to break through in terms of getting more transparency. But we never know when we will break through with the right type of engagement and data. So that's just a general comment that I have because the more people that understand the impact that it's having, you never know what type of outcome it may yield in the deliberations.

MR. McCLUER: And Arthur, thank you very much for that, for your work on this issue. We do have a Rail Shipper/Receiver Committee. And in fact, we're in the process right now of drafting comments to submit to STB on the first mile/last mile issue.

And many of the topics that were discussed yesterday regarding the metrics, right, I know that Jimmy brought up regarding the metrics. A lot of those issues are being addressed in those comments that'll be submitted.

So you are correct. We're very much involved in this.

We have several transportation-related committees within the association. So if there is any -- and I think many of the issues that are raised, as you said, are very important to our members. And so I think any additional as Arthur mentioned, any of the non-NGFA members that are on here that participate in the advisory committee or stakeholders that are participating, anything that you want to submit to the STB, we'd be happy to address maybe some of the questions that you may have on some of these issues.

MR. NEAL: I know you didn't ask that directly. That's really a decision you'll all have to deliberate on. But the reality is that data is key in this process. And the more economic impact that can be demonstrated, I think the better off and the stronger the arguments are for greater transparency in the process that we know has been impacting action.

MR. KERRIGAN: I appreciate those

comments, Arthur and Jess both. And I, Arthur, you keyed in on something that this group does more there. It's made up of more than just grain shippers that may be an NGFA member.

I think my recommendation on this given that it seems to get getting a lot more traction, we know that things don't happen quickly, is maybe we put this as a tentative agenda item for the next meeting if we're going to have one in the spring to discuss if there is a role, what that role would look like from the GIAC given our broad membership on the committee itself to either pull in support, information, and questions that may already be out there. Or if there's anything that we can help groups or even the GIAC itself gather data and information to submit as well. Speaking of agenda items for the next meeting, we know that the FGIS FDA MOU subcommittee will continue work and will likely be on the next meeting as well.

Are there any other topics that anybody can think of that we want to make sure at

this point in time that make it to the meeting or we'll want to consider for the meeting? The group itself will likely have a call for agenda items prior to the Federal Register notice as well. But I did want to give others the opportunity while we all are here together to bring something up. Janice?

MS. COOPER: We traditionally get a report on progress on implementing prior recommendations from the committee. And I know we worked on several of those action items. But it would just be nice to do a recap of former recommendations and what the status is. I think that's usually an agenda item. So we'd just like to see that back next time.

MR. KERRIGAN: Okay. Anything else? Did your hand come back up again, Janice? I looked down for a second there.

(No audible response.)

MR. KERRIGAN: Okay. With that, again, I want thank Janice is the vice chair of this committee, Nick who's the secretary of this

committee, as well as the rest of the members for the robust discussion, the ongoing work outside of just this day and a half meeting here. Obviously, it takes time. It takes effort on a volunteer basis.

So I do want to thank the group. I want to thank FGIS staff as well as all of the other members who are probably not on today who you did line up to speak and give some updates to the group as well as the other -- we're up to 65 total participants here, group and the peanut gallery, so to speak, who chimed in to learn as well as discuss and bring items to our attention. So any closing comments from Arthur or anybody else?

MR. NEAL: I just want to commend the committee on its focus and dedication and commitment and your attention. During virtual meetings, it's not always the easiest. But I mean, I really appreciate everybody's attention and engagement on the topics.

I appreciate the comments that were

offered on the items that were on the agenda. I do believe our next meeting will be more fruitful from the standpoint of participation, recommendations. The goal is to be hybrid where we're in person and virtual next meeting.

Let's all send positive thoughts across the countries that Omicron does not take legs and grow so that we can engage in a more familiar way. I just want to say that it's an honor and a pleasure to be a part of this industry. NEAGA had a meeting down in New Orleans and celebrated resilience of the grain industry.

And I can honestly say that this is a resilient body. And we are glad to serve you. We look forward to continuing to work collaboratively with you.

And we've still got challenges ahead of us. But I believe we're going to work through each and every one of them successfully as we dialogue and keep lines of communication open and keep open minds. So I appreciate how you all

have supported FGIS, and we will continue to do our very best to support you. Thank you.

And I want to thank Kendra as well for helping to organize the meeting. It's a lot that goes on behind the scenes. And she is a perfectionist at times.

And so it can get a little stressful. So we thank Kendra for all of her effort and we thank all of the division directors and staff for their contributions to updates on activities at FGIS. Thank you all.

MR. KERRIGAN: Anybody else?

(No audible response.)

MR. KERRIGAN: With that, I'll entertain a motion to adjourn this meeting.

MR. AYERS: So moved.

MR. KERRIGAN: We've got several of them. All right. You get a big part of the day back for everybody. Thank you very much, and we'll see you on the next go around.

(Whereupon, the above-entitled matter went off the record at 12:12 p.m.)

C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Grain Inspection Advisory Committee

Before: USDA

Date: 12-16-21

Place: teleconference

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R. Gross

Court Reporter