UNITED STATES DEPARTMENT OF AGRICULTURE

+ + + + +

NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

+ + + + +

PLENARY SESSION

+ + + + +

January 17, 2013
9:00 a.m.

Patriots Plaza III
355 E Street, S.W.
Washington, D.C.

CHAIR: MR. ALFRED V. ALMANZA
Administrator
Food Safety and Inspection Service

MODERATOR: MR. KEITH PAYNE
Deputy Director
Outreach and Partnership Division
Office of Outreach, Employee Education
And Training
Food Safety and Inspection Service

Free State Reporting, Inc.
1378 Cape St. Claire Road
Annapolis, MD 21409
(410) 974-0947

COMMITTEE MEMBERS:

MS. PATRICIA K. BUCK
DR. FUR-CHI CHEN
MS. NANCY J. DONLEY
MS. VENERANDA GAPUD
MS. SHERIKA HARVEY
MS. SARAH A. KLEIN
DR. CAROL LORENZEN
DR. JOHN A. MARCY
DR. ROBERT G. REINHARD
DR. MICHAEL L. RYBOLT
DR. CRAIG E. SHULTZ
DR. JOHN D. TILDEN
MR. CHRISTOPHER WALDROP
MR. STEVEN E. WARSHAWER
MR. LEONARD W. WINCHESTER

USDA:

DR. ELISABETH HAGEN

FSIS:

MR. PHILIP DERFLER
DR. DANAH VETTER
MR. CHRISTOPHER ALVARES
MS. NATASHA WILLIAMS

ALSO PARTICIPATING:

MR. SCOTT GOLTRY
DR. ARTHUR LIANG
DR. JORDI SERRATOSA

I-N-D-E-X

I-N-D-E-X

I-N-D-E-X

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

(9:00 a.m.)

MR. PAYNE: We are unfortunately having a little bit of IT difficulty trying to project. We did have this side working, and this side was not working earlier this morning. So the IT technicians are trying to rectify the situation.

But, we should go ahead and get started with the reports from each of the Subcommittees.

According to our agenda, we'll start with the report out from the Subcommittee, the first Subcommittee on Veal Verification. The Chair of that Committee is Dr. Craig Shultz.

What we'll have to do, since we don't have the electronic -- we do have it on our laptop here, but we just have no means of projecting it up on the screen, I think, I believe everybody has hard copies of the reports. If you don't, raise your hand, and we'll get the copy to you.

Okay. We need a copy for Dr. Vetter and for a couple of folks here in the back.

With that said, Dr. Shultz, I will turn the

table over to you.

DR. SHULTZ: Good morning. I will go through these questions and provide you with what we came up.

Question 1: What improvements can be made to existing sanitary dressing verification procedures under 6400.1 to address unique aspects of veal slaughter and processing?

- Are there instructions that do not apply to veal slaughter establishments?
- Are there instructions that need to be added to address unique aspects of veal slaughter and processing?
- Should the frequency of sanitary dressing verification be different for veal as compared to beef?

Our Subcommittee decided that the current regulatory requirements applicable to beef slaughter operations should be equally applicable to veal slaughter operations.

To specifically rewrite an entire set of directions designated or to specify veal, we believe

would be unnecessary. What we see here rather than a situation where there's a vast difference between the two slaughter classes, what we see actually is a situation where we may have a document that doesn't sufficiently reflect the inclusion of veal, and that as this document is reviewed, by the in-plant personnel, that they may not even be aware or fully aware that this does apply to veal.

Leonard pointed out in our discussions in the Subcommittee, that you read a significant portion of the document before you finally see the word veal.

So as having been an in-plant staff person for FSIS for many years, I can tell you when we refer to these documents under in-plant conditions, we often read them very quickly, we look for specific portions of them, and it would be very easy to come to a conclusion in the way that these documents are handled in the field to simply assume that this document does not apply to that class, to that slaughter class.

So we feel that 6400.1 should be revised to

include more veal industry specific language so that there is a clear understanding by FSIS in-plant personnel of its applicability to veal slaughter operations.

So that's how we see the correction that would be effective.

The Subcommittee does not believe that the frequency of sanitary dressing verification should be different for veal as compared to beef. There again, our Subcommittee's conclusion was that we have already a verification procedure that may not be fully appreciated by the individuals, the in-plant personnel who are working in veal plants, and that if that were applied, we don't see any advantage in simply increasing the frequency when we may not have already achieved the frequency that regulatory requirements would dictate.

So any comments or questions on that response?

Okay. Question 2: What improvements can be made to the draft notice on verifying veal slaughter sanitary dressing to address any additional unique

aspects of veal slaughter and processing not currently in the document?

The Committee recognizes the need to modify the draft notice on verifying veal slaughter sanitary dressing procedures to more effectively communicate FSIS regulatory information to small and very small plants and to include more visual aids such as photographs.

Additionally, the Agency should work within its small plant outreach division to develop appropriate educational and training materials.

The Subcommittee recommends that FSIS should seek veal industry expertise on the best practices on sanitary dressing procedures.

The Subcommittees also supports increasing the sanitary dressing verification frequencies to establish a baseline. After some predetermined timeline such as 90 days, the Agency should reevaluate the data and determine the need for further modification to sanitary dressing verification frequencies.

The Subcommittee recommendation is that

verification frequency may be increased based on establishment specific performance.

Again, we recognize certainly the very significant need for small plant outreach in this situation. I think we've determined that all these plants are in the small and very small categories. I do also see that based on the data that FSIS provided us yesterday, that in comparing small and very small plant activities between veal and small and very small plant activities in other slaughter classes, there was no significant difference in activities.

However, with that said, I think we have, as addressed yesterday, a higher risk slaughter class based on a number of variables including the way that these animals arrive at slaughter, the way that they are transported to slaughter, how they're handled prior to slaughter, and many, many other pre-harvest factors that affect the risk once they arrive at the slaughter establishment.

So these were the recommendations that we made based on that knowledge.

Any comments, questions? Yes.

MS. BUCK: Pat Buck from the Center for Foodborne Illness. One of the things that I was not aware of during our Subcommittee meeting yesterday was the practice of having hide-on carcasses for veal, and I just feel that that's such a risky practice that I think we've answered it with what we said here, but I wanted to note that some of the practices are additionally risky and probably FSIS should spend a lot of time carefully reviewing the specific guidance for veal.

DR. SHULTZ: That's a point well taken, and I did take some time to review the guidelines that they provided on sanitary dressing procedures, and it does appear that to comply with those guidelines, to meet those guidelines, that anyone producing hide-on veal will be challenged to meet those standards and produce that product.

So I do think it will apply necessary regulatory encouragement to deal with that particular higher risk class.

MS. BUCK: Do we need to add anything about

that in our comments?

DR. SHULTZ: Well, I don't think we could dictate that that practice would be banned by the industry. I'll refer to Mr. Derfler. It's an established industry practice. It's part of the culture of veal slaughter I would say.

MR. DERFLER: Yeah, we're interested in what you think is the best thing. I mean we'll have to deal with the practicality issue, you know, if -- whether it's a good practice or something like that. But if you think there's a recommendation you want to make, then we encourage you to say whatever you --

DR. SHULTZ: Well, I think, as I said, the guidelines really do address it in terms of, if you're going to produce that product and meet those guidelines, it will place a significant challenge on you, a much greater challenge that you've had in the past. So I do believe that it has been addressed to that extent.

MR. PAYNE: Ms. Gapud, you have a comment or question?

MS. GAPUD: I agree with Dr. Shultz regarding specifying the veal, whatever we have for beef already, that they have at least really specified that we can also use it for veal, but like what I said yesterday, again especially the data that was presented yesterday, where the microbial counts for veal was really high compared to the beef.

Again, I want to emphasize that again there are other factors could have contributed really to that. Based on my experience in my past career, again especially for plants where there are mixed slaughtering, the larger and the smaller animals, there's always the thing about retrofitting the equipment in order to really be able to wash and really clean the carcass, the veal carcass, maybe the feed withdrawal again.

And, also based on my experience, the design of the equipment to clean that carcass, if it's smaller, you know, it's smaller piece of carcass compared to some bigger one, that has something to do with it.

And, I think, like what I said, I just want to share with you my experience in the poultry plant where we have birds that are not always the same size, sometimes bigger, sometimes smaller, and I think that will work specifically for those that have mixed slaughtering process.

DR. SHULTZ: Well, as Dr. Shaw described to us yesterday, FSIS has already identified some characteristic practices in veal slaughter such as hanging off a single hook and some other practices that certainly limit the application of the pathogen reduction interventions.

So again I think it goes back to dealing with the unique problems that exist in very small plants and how we regulate those very small plants compared to large plants. And then with that, certain unique practices in veal slaughter, some of which have already been identified, that will have to change or they will have to modify to meet the pathogen reduction intervention requirement.

MS. GAPUD: Yeah, I also encourage you to look at the farm because that has a big effect on

what is incoming microbial load when it comes to the plant to be processed. So if they can look at what's going on at the farm, that will help a lot.

DR. SHULTZ: And we'll be getting to that in a later comment, a later response.

MS. GAPUD: Thank you.

DR. SHULTZ: Thank you.

MR. PAYNE: We have a response from Dr. Shaw and then Ms. Harvey.

DR. SHAW: I just wanted to also, in Question 2, ask the Committee to potentially provide some greater clarification on the sanitary dressing frequencies because on face value, there seems to be a conflict between the recommendation in Question 1 and the recommendation in Question 2 around it, and potentially some additional clarification of what's really being --

DR. SHULTZ: I think that the Subcommittee's intention was to do a baseline study as described in Question 2 with at the point the acceptance that current frequencies that are established within the requirements for beef are

sufficient, but should that baseline study demonstrate that those frequencies would need to be changed, that that would be based on the outcome of that baseline.

MR. PAYNE: Next we have Ms. Harvey, and I also want to remind everyone to speak loudly enough so the folks in the back here and that side can hear everyone. Ms. Harvey.

MS. HARVEY: Good morning, Dr. Shaw, and the rest of the Committee.

I'm sorry if I missed something, and you have to excuse me. My mind is not here as it was on yesterday, but from my understanding, you had people here from the veal industry, correct?

DR. SHULTZ: Uh-huh.

MS. HARVEY: Okay. Did they not offer this expertise on sanitary dressing as you would have liked? And I also agree with Dr. Shaw. There needs to be more specification on the sanitary dressing because as you know, when you get in these establishments, if it's too broad, they have more room to just do whatever.

DR. SHULTZ: I agree but we do have a very specific guideline document that's been developed that I think has taken a very close look at potential deficiencies in sanitary dressing procedures and I think that we've had a situation in the past where there's been somewhat of a misunderstanding about the frequencies that were applied because we've basically not sent the signal through our directives and notices to our in-plant personnel that this applies to veal as well as beef.

So our conclusion was that the tools are there. It's simply a matter of the message more than changing frequencies just for the sake of saying, if we do this more often, it'll go away.

MR. PAYNE: Next we have Mr. Warshawer and then following Mr. Warshawer, Ms. Donley.

MR. WARSHAWER: Just a small addition was to your question, the Question 1 is about changing generically the regulation and in essence creating veal as another class of slaughter, and that dramatic and complex of a step seems premature.

There may be reasons over time where given

lots more information and more experience with the existing regulation and guidance being followed better, that we want to revisit this, but for the present, we want to be sure that what we know is properly functioning. And, what we know is, veal is cattle, and we don't have an indication that that was clearly communicated to in-plant personnel to the extent that we could be confident that we really got a problem.

Secondly, the idea of deviating, of setting different frequencies for sanitary dressing, based on specific plant performance, gives in-plant personnel then the opportunity, if a particular situation warrants it, to make that move. So we haven't prevented a higher standard from being brought forward in the sanitary dressing area. We've simply made it come out of the work with those specific plants rather than coming out of the regulation itself.

MR. PAYNE: And Ms. Donley or Dr. Shultz, did you have a response?

DR. SHULTZ: No, I'm fine.

MR. PAYNE: Okay. Ms. Donley?

MS. DONLEY: Yeah, I'm honestly kind of conflicted on this and a little confused because I do see where Dr. Shaw had said that there does seem to be kind of a conflict here. We're saying one thing in Question 1 is that,no, beef is the same as veal, and so the frequency shouldn't be different, but then on Question 2, we're saying, well, let's run a pilot to see if we should need to look further at veal as an increased sanitary verification.

But, you know, what's going on here is that there's a should world we're talking about and the real world. Should there be different stuff for beef versus veal? And the answer's probably no.

But in reality, what's really going on out there, and do we need to do something different, in that subset of the beef industry, a subset, that there needs to be some different actions going on.

So I just want to kind of put that out there for discussion because we've got reality, and we've got the shoulds.

MR. PAYNE: Next, Ms. Buck.

MS. BUCK: First of all, in response to your question about were there people who had some expertise in the veal and veal practices, and the answer is yes, and they were immediately invited to join our discussion during our Subcommittee.

And, actually, if you'll look at the last part of the response for Question 3, we very strongly recommended the Agency should submit the modified compliance guidance for stakeholder comment and suggestion. And I think we could have even gone further and suggested in the future maybe, NACMPI would include these people as a regular course when there's a specific topic like this veal situation.

So we feel very much that the information that we got from the veal people that were present and participating with us, was very useful and as I said when I initially asked my first question, I just was not aware of the hide-on practice and that, I thought, was very troubling, and I did not know, if it was troubling enough, if it should be added as a separate thing.

And in response, Nancy, to your concerns,

which were very valid, I think part of what we're doing with the Subcommittee meeting right now is to try and figure out if there is indeed special considerations for a subclass such as veal, and I think this is a real opportunity for FSIS to move forward when they have identified an area that could be problematic such as they have done with the veal. That's just my opinion. Thank you.

MR. PAYNE: Thank you. Mr. Waldrop.

MR. WALDROP: I also want to make a couple of points just to give you, Nancy, a little bit more insight of our discussions.

We were saying for both the regulations and the guidance, not only should FSIS make it clear to the inspection personnel that this applies to veal also, but that they should go through and sort of re-edit the document to pull out the very specific to veal instances where the inspection personnel or industry would need to pay special attention.

So it's not just make sure you know this is also veal, but we were wanting certain things to be highlighted or certain things to be pulled out in

sidebars or whatever that would allow the inspection personnel to recognize that they needed to pay special attention to this when they're in veal plants. So we were also trying to give that sort of emphasis as well.

And then on Question 2, that last paragraph, it was our understanding that this was something that FSIS was already going to engage in, where they were going to spend 90 days of intense verification activities looking at, you know, instructing inspection personnel to spend a whole lot of time on sanitary dressing procedures for 90 days, to see if they can't try to address some of the problems that were identified in that PowerPoint.

And then the idea was if the 90 days works and the plants are back in control, then that would have had an effect. If not, and plants are still not able to control that process, then plant by plant, FSIS could increase that verification activity more than the kind of baseline of once every two weeks. So if the plant was performing

well, then that 90 days would have worked. If the plant is not performing well, the inspector can continue to kind of keep up that high intensity verification activity.

MR. PAYNE: Thank you, Mr. Waldrop. Next, Mr. Winchester.

MR. WINCHESTER: Mr. Waldrop actually sort of said the same thing, but I was going to direct you to the book. The part that came out that was new is that we have the directive on all cattle, but then USDA has a notice in draft that's in its very final that actually is very specific to increased verification of veal, and that's where this 90 day, twice a week, that sanitary dressings would be test performed versus the once every other week in the standard.

So I'm just trying to say that what we were alluding to was in this 90 day period is that there is a draft out there that's basically almost ready to implement for in-plant personnel, and then there is already specific things for veal. I think that helps clarify and clear up a lot of what were

unanswered or maybe not quite clear issues in the general all cattle thing. I guess if you wanted to, look at that draft under the increased verification specifically for veal, and then that answers most of these questions where this comes from, this verification for the 90 day increase.

So I think that covers most of what we're concerned about in following up that, yeah, if they still see a problem that they could continue with that.

MR. PAYNE: Thank you, Mr. Winchester.

Mr. Derfler?

MR. DERFLER: I'd be interested in what Dr. Shaw has to say on this.

DR. SHAW: Just so I understand what I'm hearing, and I want you all to tell me if what I'm hearing is what you mean, what I'm hearing is we can issue the notice and then go through the period of time, 90 days or more, of increased frequency in veal slaughter establishments. While that is happening, assess how it's being implemented, how our inspection personnel are understanding, any

trials and tribulations that go along with that, you know, and then while we're doing this, we can be revising and assessing what needs to change in the long-term inspection procedure, 6410.1 Directive and be sort of incorporating those veal specific things, what we're learning from what's happening with the notice being implemented, and then sort of issue a new 6410 with the new information that's necessary for long-term goal. Is that what I'm --

DR. SHULTZ: Is the Subcommittee in agreement? That's how I would interpret it.

MR. DERFLER: Just so everybody know, I mean just to -- this is Derfler. Just so, and I'm not sure we ever explained this to the Committee. A directive we issue, when we issue it has no expiration date. It's intended to be our procedures or a direction to our field source for the foreseeable future.

Notices are issued with a one-year expiration date. Sometimes we reissue them. So, I mean, it's exactly for this kind of purpose where if we don't know exactly what we want to do but we

think we have a pretty good idea, we put out a notice for a year, get some experience in it, and then either after the end of the year, maybe reissuing it once and after two years have a better sense, that we would then convert it into a directive which would be the longer.

So what you're suggesting sort of fits right in with how we try to manage our policy.

DR. SHULTZ: Okay. Thank you, Mr. Derfler.

Question 3: What improvements can be made to the 2002 beef slaughter compliance guidance document to address unique aspects of veal slaughter?

- Is there guidance that does not apply to this?
- Is there guidance that needs to be added to address unique aspects of veal slaughter?
- Are there other changes to the guidance that are needed in addition to the changes currently under consideration?

And we refer back to Question 1 and our answers in Question 1, which we believe also apply

to this question.

Additionally, we mentioned the Agency should make its necessary changes to the compliance guidance noting the changes and incorporate veal specific guidance language.

The Subcommittee recommends that the Agency then submit the modified guidelines for stakeholder comment and suggestion.

Comments?

Okay. Question 4: Are there differences in the classes of veal (bob veal, formula fed veal, non-formula fed veal and heavy calf) that impact slaughter and should be pointed out in FSIS policy documents?

The Subcommittee recommends that the Agency confer with ARS or other research providers to conduct research into pre-harvest risk factors associated with STEC in veal slaughter. The Subcommittee also recommends that the Agency promote research into development of industry best management practices.

As a long-term goal, the Agency should

address the animal drug residue challenge in bob veal calves.

So that again, we discussed yesterday about the concerns that we have regarding various authorities and where those authorities exist and what can be done in terms of pre-harvest but I think our Subcommittee is very acutely aware that there is certainly a pre-harvest component here, that we cannot avoid and that I guess we would ask FSIS to be as creative as possible in finding means of addressing these critical pre-harvest issues as applied to veal.

MR. PAYNE: Mr. Warshawer has a comment.

MR. WARSHAWER: As part of the Subcommittee, of course, I support our language and I want to just take a minute to amplify the problem and the opportunity just a little bit.

We know that FSIS responsibilities start at the receiving pen. We got that. But the public health problem and the food safety challenge starts before that.

In the spirit of the conversation we had at

the end of the day yesterday, I would like as a member of the Committee, and hopefully with the support of the whole Committee, to raise as a challenge that I would like us to hear more about how you respond to this, that the pathogen loading, as it may relate to production practice, become a concern for FSIS and that it begin to be addressed in some systematic way starting with the challenges in veal.

My hunch is that, and there are other segments of livestock production where different production practices impact pathogen loading upon arrival at the plant, and that there will be other challenges coming forward such as the antibiotic residue challenge that will be informed by production practices.

So using this as my toe in the door, I would like to see us include language that elevates our concern about this problem and our respect for the boundaries that FSIS must honor and that nonetheless, there's a need for something more than to simply say whatever gets to your door has to

leave safe or you can't process it.

I don't know a better way to say this. I'm sure I'm saying it in a complicated and cumbersome way, but it's not just what we've said here gets it. We need to say more and we need to hear about what happens with what we've said.

MR. PAYNE: Thank you, Mr. Warshawer. Next we have a comment from Ms. Buck.

MS. BUCK: Patricia Buck from CFI. I would concur with what Steve just said, and I would emphasize to FSIS that the Subcommittee did look at this as a real opportunity for FSIS to sort of extent its influence or its knowledge base beyond what you have in the past. It's very clear that this product, veal, is very heavily tied to the pre-harvest conditions and practices, and for that reason, if for no other reason, as an Agency that is charged with ensuring the safety of the end product, you should have the right, when you have a product that's so deeply connected to pre-harvest practices, to have some authority to go in and examine and look and make recommendations or perhaps even have

regulations about those pre-harvest activities.

MR. PAYNE: Thank you, Ms. Buck.

Mr. Derfler, do you have a response?

MR. DERFLER: Well, actually I guess I'd like to hear a little bit more and then I'll take --

MR. PAYNE: Okay. Our next commenter is Ms. Klein.

MS. KLEIN: Sara Klein from CSPI. I know the Agency has had several meetings and discussions with stakeholders about pre-harvest on trying to strike that balance between what the Agency has authority to do and doesn't.

But, I like the idea of a more directed charge from this Committee to the Agency, kind of captured in language that says that the Committee, just as Steve was saying, that really elevates this issue to something the Committee believes that it is important for USDA to work with the other agencies that are responsible for pre-harvest including other agencies within USDA that have responsibility there, to develop pre-harvest strategies and that veal might be an opportunity to serve as kind of a pilot

program for some pre-harvest interventions that haven't gotten broad acceptance yet such as, for example, vaccines.

And so I would urge the committee to try and come up with some language that we can actually put in the document aside from just saying it into the record, some language that we could put into the document that would reflect a focus on pre-harvest.

MR. PAYNE: Thank you, Ms. Klein. Next, Ms. Donley.

MS. DONLEY: Yeah, I think that this language can be strengthened a little bit as well, but I'm also just a little confused and concerned that we're saying, hey, yeah, let's look at pre-harvest which I think is really, really necessary but we're not give FSIS any direction of what do they need? The question here is asking does FSIS need to point out in its documents the differences in these classes. And so did you have any discussion about that?

I mean the pre-harvest thing I think is just fine, but I don't think we're helping FSIS

here. They've asked the question, do we need to be doing something different?

I don't know if that came up in your conversations.

MR. PAYNE: Thank you, Ms. Donley. Dr. Tilden.

DR. TILDEN: Yeah, I think this goes back to the whole idea of a farm-to-fork strategy which I believe everybody has endorsed. The devil's in the details as we all know, and in an era of reduced public sector resources, how do we most efficiently and effectively pursue that strategy.

And coming from a State Agency whose resources have been reduced, reduced, reduced over a decade, it's nice to throw out you should do and you should do more, but I think we've got to figure out what isn't going to get done so that if this is high enough priority, how do we identify the less effective activities, and if this is a higher priority, how do we put this on the agenda.

I like the idea, if it's outside the scope of regulatory authorities, doing collaborative pilot

projects but you still have to figure out where the resources are going to come from and how do you decide the relative priority for this.

And I personally believe that the pre-harvest area is critically important and we can't ignore it, but I think you're not going to get something for nothing just by saying do it above and beyond what you're already doing.

MR. PAYNE: Thank you, Dr. Tilden. Next Dr. Reinhard.

DR. REINHARD: I really appreciate the Committee's discussion on the topic, and I just want to make sure that we are keeping the horse in front of the cart because I'm still not sure that we know, and if somebody has the expertise and we do know, that the pre-harvest practices are actually the place to really make an impact.

I know, and certainly intellectually I understand that they potentially have a very big effect, and it may be the issue that's going on here, but doesn't the Subcommittee in Question 4 say do that research and show what that is?

And then once we had that research, then how a regulatory agency would incorporate that into what they do and how they verify the production say for the products would then be able to come forward.

I don't want to in any way infer that what was suggested isn't something that certainly the Agency had challenges with and we had challenges with and improvements can be made, but I think for this particular question, the first step is to look at what does the science tell us and then go.

MR. PAYNE: Thank you, Dr. Reinhard. Next we have Mr. Warshawer.

MR. WARSHAWER: I'm just wondering if Mr. Derfler would comment yet.

MR. DERFLER: Okay. Let me just talk a little bit about what we've done in pre-harvest because I mean obviously our interest is to try and make sure there's as few pathogens in the product that we ultimately put our mark of inspection on as possible and if pre-harvest contributes to that, then it's important.

We don't have authority in pre-harvest, but

we've done two or three things I think.

First of all, we have had at least two public meetings that I can thing of, one in 2006 on poultry and the other within the last year or so on beef, on pre-harvest practices that would improve the safety of the product.

We did the beef meeting with APHIS and I think AMS or ARS, I'm sorry, with ARS to try and help that.

So we have had public meetings. I think we've gotten mixed results from those. The one on beef sort of tended to focus on whether or not the right vaccines were being approved and I'm not sure how much they dealt with on actual production practices, but we're obviously only interested in that.

The other thing that we've done, and we did it with respect to residues, is we did a guidance document to slaughter plants focusing on things that they can do to ensure that the animals that they are buying did not have illegal residues in them, and the illegal residues obviously are introduced pre-

harvest.

So we tried to provide advice to them on things that they could do with their suppliers to try and minimize the risk of illegal residues, and that's actually been fairly effective. Some of the auction barns have changed their practices as a result of the guidance that we've put out and so that turned out to be pretty effective.

So I'll just say we're interested in ideas, and we intend to continue to pursue this but our authority does, as you said, start when animals are being held for slaughter.

MR. PAYNE: Thank you, Mr. Derfler. Next we have Dr. Rybolt.

DR. MARCY: John Marcy, University of Arkansas.

MR. PAYNE: Sorry.

DR. MARCY: Yep, that's okay. I can appreciate what Mr. Derfler was saying but, you know, if we look at the scope of what seems to be the issue here, it seems like it's fairly amenable to being handled within the regulatory authority of

FSIS by just getting the plants to, you know, do what they're supposed to today.

There may be some issues that, you know, need further elucidation but I think there may be opportunities for research at the pre-harvest but, you know, this doesn't seem to be a huge public health impact.

Dr. Liang called CDC and it doesn't show up on their radar as something that is an issue.

MR. PAYNE: Thank you, Dr. Marcy. Next, Ms. Donley.

MS. DONLEY: Okay. I think we'd be remiss as a Committee if we were to just end our response with what is here and just say with the pre-harvest, which I think is terrific, what the Subcommittee came up with here.

But basically Question 4 is a yes or no question. Are there differences that need to be pointed out in FSIS policy documents? If the answer is yes, then yeah, let's do it. If the answer is there are no differences, then, no, it doesn't have to be, but I think, and not having been in that

Subcommittee and not knowing a whole heck of a lot about this, that if the question's being asked, I have a sneaking suspicion that there are some differences that need to be pointed out, and that FSIS frankly has identified somehow that there are differences and they do need to be, and I think we should empower FSIS to do that, to point out these differences in their documents, if the answer is yes.

MR. PAYNE: Thank you, Ms. Donley. Next, Ms. Buck.

MS. BUCK: Patricia Buck with CFI. I think the intention of the Subcommittee was to again give an opportunity for moving FSIS into a new direction. Yes, there are differences, and we did not state that in the response, and perhaps we should amend it to include that simple statement.

But it's because there are differences and there is an opportunity right now to test the waters to see if FSIS can move forward into addressing a problem that is, from the sense that we got, in talking to the various experts that were

participating yesterday, that there are pre-harvest conditions that are very much associated with veal production. And because of that, it's time to see if FSIS, when they have a very specific topic that has a high association, can move with approval from this Committee into those areas.

So while I appreciate some of the comments that Bob made, I really feel that the time is ripe to take this step now. I agree with Sarah. Perhaps we could strengthen this, but we were trying to hit sort of a balance, accord, of things that we felt the Agency can do.

Because they are limited, they do not do their own research, and so asking them to go out to ARS or other USDA agencies or asking them to do collaborative work or pilots with other research providers, we felt that might be one way for us to expand the capabilities of FSIS. I still think it's worth a shot.

MR. PAYNE: Thank you, Ms. Buck. Next, Dr. Shultz.

DR. SHULTZ: This is a bit of a follow up

to what Mr. Derfler said. After many years engaged in working in the National Residue Program and trying to see improvements at the plant level in reducing that problem and controlling that problem in the plants, we had many attempts at pre-harvest efforts that were very, very difficult because of authority, and that's why I made the comments that I made yesterday regarding that, and over the years of trying to work with dealing with the residue situation, I learned that the best that we could do was to provide the regulatory consistency in the plant with regard to surveillance, with regard to feedback to producers, with regard to the application of the HACCP system in the plant, so that the plant was taking its responsibility and identifying this as a hazard reasonably likely to occur, and completing the circle of HACCP compliance.

That was much more successful than many very, very well intended efforts to address pre-harvest when we didn't have the authority to.

Another consideration that somewhat changed

my thinking, and I will freely admit that I came into this after having read these documents, with the conclusion that there are significant pre-harvest factors, and with those, in consideration of those pre-harvest factors, what should the approach be?

But then after Dr. Shaw's report where he compared the two segments of the veal industry, the bob veal where there's basically no producer grow out feedback pre-harvest interventions on the part of the industry, and we look at formula fed veal where there's extensive pre-harvest grow out, technician people out in the field working with the growers, providing best management practice recommendations to those growers, but when we look at the results of the two classes, they're the same with regard to your microbial results. So that somewhat changed my thinking.

So I'll end there, but that's why I basically am not strongly convinced that because of the authority issues, that we can do what we'd like to do.

MR. PAYNE: Thank you, Dr. Shultz. Next, Ms. Klein.

MS. KLEIN: Okay. I wanted to make one point, and then offer some proposed language.

So I just wanted to respond a little bit to what John said about the outbreak data and whether, in fact, this is a human health hazard.

I don't think that it's fair to characterize the lack of veal outbreaks present in the CDC database as evidence that there is not a human health risk. I think the likelihood, as we discussed a little bit yesterday, is that those outbreaks are being captured in the larger category of beef outbreaks. I think that there's no easy way for investigators to categorize things as veal unless the consumer says, I happen to know that I ate a veal chop and that that becomes noted in the data. So I just want to clarify that. I think there are probably more outbreaks out there than we are aware of.

So I have a suggestion for language to strengthen this area. I guess I would insert this

at the beginning of the response to Question 4. The Committee believes that pre-harvest is a critical control point for pathogen contamination. USDA should continue to focus efforts on strengthening interventions on the farm including the Agency should seek additional authority from Congress to regulate in that area.

Authority is not absolute and forever, as we've learned with PHMSA and FDA, and so I think that the discussion doesn't need to end with USDA doesn't have the authority to do pre-harvest. A discussion could continue with what if they did?

MR. PAYNE: Thank you, Ms. Klein. We'll continue in order. Maybe there will be some responses to your proposed language there. Next is Mr. Warshawer.

MS. KLEIN: If we had the computer, we could -- that's still not working.

MR. PAYNE: They are still trying to get the projection working.

MR. ALMANZA: I wrote it down in shorthand.

MS. KLEIN: Oh, okay. You left off that

last part.

MR. WARSHAWER: Steve Warshawer. That's a great help for what I wanted to say because I like the language except I feel we're entering a time where authority is not always the answer because authority without resources isn't worth a whole heck of a lot.

So in this case, we've got an industry that's very interested and willing to engage this process. Instead of focusing on seeking authority from Congress, I would focus on collaborating with industry and other relevant stakeholders. And out of that process could come an eventual need for authority, but right now what we need is better data, better research, more information and we've got to find ways to get that without cost and without a laborious, burdensome, time consuming process which have their own sets of costs.

So again, this is the opportunity of veal, which is a smaller industry segment, very engaged with their process here with us as evidenced by participation here at this meeting, and that if we

want to make a general statement about be willing to seek additional authority, that's fine, but in this immediate instance, what we need is FSIS to work with industry partners to get at the data that would help support more specific requirements as needed.

And I don't know if it's appropriate or fair with the Committee process to ask other people in the room to comment, but I'm sort of volunteering based on conversations in the Subcommittee yesterday in which we brought industry folks right to the circle of the Subcommittee to be sure that we understood, you know, what their input would be, and I think we would be able to do a lot in this particular area with industry without needing to go for authority or time consuming external processes.

MS. DONLEY: Are you suggesting an in the meantime-like notion to what's there?

MR. WARSHAWER: I would say be willing to seek additional authority, not that we require that as an immediate step, and that in the interim, that we ask FSIS to work with industry stakeholders to get at the necessary data and information that would

help create better outcomes beginning at the receiving pen.

I mean I don't want to get sidetracked into the ideology of, you know, government versus industry. I want outcomes, you know, I want information and I think FSIS collaboration with industry or other stakeholders, it could be other groups with scientific and research capacity, but if we always push this back and forth to the regulatory approach, it's slow, it's expensive, and it skips the step of what can we do directly with the involved parties? And I really want to see that step followed first.

MR. PAYNE: Thank you, Mr. Warshawer. Next, Dr. Chen.

DR. CHEN: Fur-Chi Chen from Tennessee State University.

Yeah, I'd just like to point out one point in terms of the research capacity, you know. In the response, we pointed out the pre-harvest risk factors. I mean, maybe it will be an important contribution to the heavy contamination.

And, of course, FSIS doesn't have any research or authority into this area, but we can look at from -- I mean, of course, with ARS and other research funding, I mean I think we may be aware but we still need for every program. I mean, you know, if FSIS can communicate with the national program reader in the -- you know, especially in the animal area, in the pre-harvest program and we had the research priority in there and, you know, actually that will help out I mean to answer some of the concern.

MR. PAYNE: Thank you, Dr. Chen.

Next, Dr. Shaw, did you have a response?

DR. SHAW: I just wanted to say, from the point of view of the research recommendations, I think we're interested in those longer term research recommendations because we do have on our website now a list of research priorities that we provide to our various partners that conduct research, and so we'll be looking forward to assessing what we currently have on our research priorities list with what the recommendations of the Committee are, so we

can see where there are opportunities.

My mic, I don't know if it's working or not.

But I guess I would urge the Committee that from a policy point of view, as Steve talked about, I think in short and long-term, and so I hear the research, that's a long-term thing for us always. Research is long-term.

But I would urge the Committee to think along the lines I think of what Ms. Donley was talking about, in short-term, as to, you know, with the notices coming out, and in the shorter term, are there things at slaughter. So, you know, animals coming in the door at anti-mortem, at post-mortem, practical things that we know now that we can point out to processors and to our inspection personnel to look for in the actual practice of slaughtering the animal right now.

And so maybe I should have worded the question a little differently now that I've heard you all talk about it, but I think there's an opportunity for two things here, a short-term and a

long-term. And I'm hearing the long-term. I'm hearing it. And so maybe there's something that can be thought about more short-term, immediate.

MR. PAYNE: Thank you, Dr. Shaw. Dr. Lorenzen.

DR. LORENZEN: I just want to respond to Sarah about getting Congressional authority for pre-harvest. If we do that for veal, it's going to be for all classes of livestock and poultry, and not all those animals are destined to be inspected. I just don't even see how that could be possible because we have all different classes. We have state inspection. We have federal inspection. We have custom exempt. They would have authority over everything because you as a producer don't have to decide until you take it to the plant how it's going to be inspected, until you decide where you're going to take it.

MR. PAYNE: Thank you, Dr. Lorenzen. Next is Ms. Buck.

MS. BUCK: This is Pat Buck, and I appreciate your comments about the long-term for

research, and I appreciate the comments that Nancy made about we needed to specifically answer that. So, we may, Dr. Shultz, be interested in modifying our guideline a little bit.

As far as what Sarah has proposed, I think it's really, really important when we look at food safety, as has already been noted, it is a farm-to-fork continuum. And we have a unique opportunity with this NACMPI Committee to actually suggest that FSIS have authority to go further into pre-harvest.

It's going to be very rare that you're going to have four consumer groups sitting on NACMPI at the same time, and all of us that work in food safety, and I'm sure many other people around this table as well, recognize that this has been a huge limitation that USDA does not have the authority to go on the farm.

And while it's very clear to me what Carol has said, if we do that, we are expanding it hugely, and we don't have the resources actually to do the jobs that we have been already assigned to.

So while I would like to go to Congress and

say, we need to have pre-harvest recommendations for FSIS, like we do for, you know, FDA food, I think it would be a good thing to have the recommendation that FSIS could talk about it. I see the obstacles for security that is going to be very, very large mostly because we don't have the resources, but because we don't have the resources to do the job does not mean that we should not make the recommendation. We're supposed to be helping FSIS achieve what it needs, and I think you need authority to go into the farm.

MR. PAYNE: Thank you, Ms. Buck. Next, Dr. Tilden.

DR. TILDEN: So I think our discussions have brought up again a multiyear discussion of acknowledging the reality of limitations of authorities and resources, and that we revisit that from time to time. And I think a number of us do recognize that this is an opportunity to not let the pre-harvest food safety issue drop.

But I do think we have to be careful about not wandering too far afield from the charges that

we were given, and so I think at the very least what we could do is we could say that there was a number of members who felt strongly that the importance of pre-harvest food safety needs to be not forgotten, and we can include that in the report.

But I do think, again going back to my point about resources, is more important things that could have a more direct impact could get lost if we diverted our focus, and that's my concern.

I think in the short-term, what we could do is we could say in this Question 4 response that, yes, there are differences to Nancy's point, and I think what FSIS can do is keep it on the radar screen in the rollout of whatever materials they do, that pre-harvest needs to be addressed. You work with ARS for the research. You work with industry to develop the best practices but recognize that that's outside the framework of regulatory mandate, and I think trying to push for regulatory mandates for pre-harvest at this point might be premature.

MR. PAYNE: Thank you, Dr. Tilden. Next, Ms. Klein.

MS. KLEIN: So I obviously still think that the inclusion of language that says, if necessary, USDA should be willing to seek additional authority. It doesn't say this Committee thinks that you have to. It just says let's not take that option off the table prematurely. So I still think that that should say that.

But as a more immediate first step, kind of adding on that, I would put as a first step, FSIS should convene a series of stakeholder meetings with veal stakeholders specifically, with the stated goal of reducing contamination of veal samples with pathogens at slaughter to levels comparable with the beef by 2014.

So giving a timetable for this collaborative discussion that Steve is mentioning for this, working with industry and talking about ways to improve pre-harvest without regulatory authority, okay, that's all well and good, but let's say that this Committee thinks that that shouldn't be theoretical, that we're envisioning a series of stakeholder meetings that occur, you know, within

the next 6 to 9 months with the goal of instituting these changes and seeing what happens.

To me it's a slightly more specific approach that could be included in part because I'm not sure that the members of this Committee have the exact language that they're looking for in response to Question 4 of, you know, here's what exactly you should do at the door of the slaughter plant. I certainly don't, and so there may be members of the Committee that do, and they should offer those, but to me the meetings or working together would be a medium term goal, not long-term like Congressional authority, not short-term like what should producers do at the door of the facility.

So I'm offering that concrete language for inclusion in the document.

MR. PAYNE: Thank you, Ms. Klein. Dr. Rybolt, you were next.

DR. RYBOLT: So one of the things that was brought up was the data Dr. Shaw's group presented to us, or that Bill presented, and then his group followed up on. In the dataset, there were two

plants that were part of the STEC I believe, and then, I mean of the O157, the veal plants, and three. So it was a limited dataset, not saying that there's not a potential problem, but the data was just broken out last fall I think is when it actually started being broken out. And the industry, to commend them, the group that we had here with us, they've actually started to address or, you know, maybe they were doing some stuff before, but they indicated that they've gotten together and they're working on some stuff.

So I like Sarah's, you know, suggestion that they have stakeholder meetings, things like that, at the same time we have the follow up that's going to be done. That's what the Subcommittee discussed, is continue with the 90 days, collect more data, because we do have limited data. You could visit 9 of the 32 facilities. I don't remember the sizes. We did talk about that.

So there is a little bit of a data gap right now. We need to collect that data. So I think in light of, you know, asking for additional

regulatory authority, we need to understand exactly what is going on first because it may be with these follow ups and filling that data gap, that the issue is actually addressed.

MR. PAYNE: Thank you, Dr. Rybolt.

Ms. Gapud, you're next.

MS. GAPUD: I want to say that I really agree with Patricia Buck's opinion. If we are sincerely after food safety, this is the best opportunity for us to move on. This opportunity seldom comes and here we are on this veal issue. If we want to really do something from farm-to-fork, this is the way it should be. So again, we should not let that opportunity go away. So I feel that we should move on.

And, I also agree with what Sarah said about doing something. We cannot just forget about this, you know, but we have to move on and we have to have a follow up on what is really happening and not just talking and discussing it without knowing after our meeting today.

MR. PAYNE: Thank you, Ms. Gapud.

Ms. Harvey.

MS. HARVEY: I think this Subcommittee has done a great job considering all this. However, I just sit back and looking at these recommendations, and I feel as though they're really just not concrete as they should be. The language is sort of a problem. The recommendations and the options given are not as specific as I think they should be. I feel as though it's pretty much sending the Agency on a wild ride or at the least a U turn instead of offering more realistic short-term and long-term goals. Definitely Congress I feel as though is time consuming and is not what it should be of a solution, but just more specific and more work-driven goals I would say.

Just to put it simply, honestly I don't know, but I feel as though we should have more short-term and long-tem goals and something should definitely be done, more resources and information. Working with the Agency I think is a great route to go as Steve pointed out. Thank you.

MR. PAYNE: Thank you, Ms. Harvey.

Dr. Reinhard?

DR. REINHARD: In the interest of trying to move forward, I'd like to go back to what Dr. Shultz has as potentially language that could be considered by the Subcommittee and the whole Committee to go in here, and so I want to go back to what Sarah stated the last time and ask her to restate it, just the last sentence because it doesn't sound like for a lot of the other there's necessarily consensus. But the stakeholder meeting being fairly specific, stating what needs to be done, giving FSIS an objective, consider it. We would then see about moving on. A lot's been put on the record, and that's appropriate for FSIS to review that to see what's important but maybe we could do that.

MS. KLEIN: So the sentence I had was FSIS should convene a series of stakeholder meetings with veal stakeholders specifically with the stated goal of reducing contamination of veal samples with pathogens at slaughter to levels comparable with beef by 2014.

MS. BUCK: Would you repeat that?

MS. KLEIN: Also I just want to ask Phil if that kind of directive is useful for you all or that kind of advice is useful? I like when you guys nod. That makes me feel like I'm on the right track.

UNIDENTIFIED SPEAKER: It's lightning speed. That's a short-term goal really.

MR. DERFLER: Okay.

MS. KLEIN: Right, that's a short-term goal.

DR. REINHARD: I mean like I've said a number of times, yeah, we're interested in whatever input, but certainly that would be, you know, we're going to consider what we get from you. So, yes, yes.

UNIDENTIFIED SPEAKER: Sarah, could you repeat your last sentence please?

MS. KLEIN: Sure. FSIS should convene a series of stakeholder meetings with veal stakeholders specifically, there's probably a better way to say that, with the stated goal of reducing contamination of veal samples with pathogens at slaughter to levels comparable with beef by 2014. I'm looking specifically at the chart on page --

where was that chart that had those startling samples? On page 2 of the PowerPoint that was given yesterday that had the startlingly high samples of STEC in veal. We can wordsmith it certainly. I was just jotting that down.

MR. PAYNE: This is Keith Payne here. My suggestion, during the break, we will bring in a laptop with an overhead projector. Whatever the consensus of the Committee is here on the revised language, we'll make the revisions to the document and then we can show the revised draft to the whole Committee.

Next in line, Dr. Tilden.

DR. TILDEN: I think actually I like the idea what Sarah's proposed, but I do think we have a sparsity of data for decision making, and we said on day one, that the whole purpose of the focus is better use of data for decision making.

So Dr. Rybolt had made the point of, if we coupled what Sarah's talking about with a commitment to increased focus on data gathering so that those are informed discussions, I think that would be

helpful.

MR. PAYNE: Thank you, Dr. Tilden. Next, Ms. Donley.

MS. DONLEY: Thank you. I'm sorry. I'm going to keep coming back to this and coming back to this. We as a Committee here have been asked a very specific question that should be given a specific answer, and the other things that have come up for discussion, I think are really terrific and should be included in our response.

But I would suggest that we kind of come up with either a four pronged, four bulleted, ranked 1 to 4 with the first one being FSIS should articulate the differences in classes of veal in its policy documents. That specifically answers the question.

Then number 2, FSIS should work with ARS on additional research for pre-harvest factors.

Number 3 would be Sarah's stakeholder meeting language.

And, number 4 is FSIS should seek pre-harvest authority from Congress.

MR. PAYNE: Thank you, Ms. Donley.

Mr. Waldrop?

MR. WALDROP: I agree with Nancy's suggestion that we do need to answer the question, and I think the way you have worded it is sort of half the answer, but part of the other half is that we don't have, as we were discussing in Subcommittee, I didn't feel that we had sufficient information to say this one, this one, this one are exactly different but that the data was showing that both of them pose the same risk.

So I think part of what the stakeholder meeting that Sarah's proposing could actually also inform that same question, provide the Agency with the different information. So kind of the way you've phrased it, I think then allows FSIS to gather more information to be able to answer that question and articulate those differences in the document because I think if they do have more information and they can then articulate them, I do think those need to be noted. I just don't think we had that information in our Subcommittee to be able to make that determination which also may explain

why we kind of punted this question.

And then I'd like to wordsmith some of Sarah's stuff, but I can do that either now or I can do it when we get a laptop.

Just a couple of quick things. I don't think we want to reduce contamination of the samples. I think we just want to reduce contamination of the veal itself.

MS. KLEIN: Right.

MR. WALDROP: And I don't think we should make it levels comparable with beef. I think we should drive the levels down to protect the public because, you know, I don't think the beef levels are all that perfect.

MS. KLEIN: Right. Okay.

MR. PAYNE: Thank you, Mr. Waldrop. Dr. Shaw.

DR. SHAW: I guess I just wanted to ask the Committee a question because we haven't talked about Question 5 yet, and I'm just wondering if Ms. Klein's comments are more appropriate for Question 5 or should they stay in Question 4?

DR. SHULTZ: Okay. Question 5: What innovative strategies can the Agency use to help industry (comprised of small and very small establishments) and FSIS personnel better understand the needs for slaughtering animals used to produce veal products?

Our response was the Subcommittee recommends that the Agency works within its small and very small plant outreach division to develop communications targeted to veal slaughter establishments. The material developed should be short and concise where possible. The guidance and tools should include visual materials, plain language such as non-regulatory guidance documents.

FSIS should also develop webinars, DVDs, regional meetings and partnering with State Extension Services and other appropriate venues to deliver this information.

MR. PAYNE: Any comments or responses? Ms. Klein.

MS. KLEIN: Honestly, I think that the statement that I read before about the stakeholder

meetings should be an introduction to the entire issue of the Veal Subcommittee, and I think that these specific answers are what the Agency's seeking on these specific questions and I think the suggestion of having a series of stakeholder meetings with a stated goal but that the meetings themselves are designed to elicit more information and have these discussions in more depth, is a threshold issue. So I would propose putting that sentence at the beginning of an introduction to this issue, and then answering these specific questions, in part strengthening the answers to Number 4 as Nancy stated, but I don't think that the response to Question 5 replaces the vision that I had.

MR. PAYNE: Thank you, Ms. Klein.

Dr. Shultz is the Chair of this Subcommittee. What I propose --

DR. SHULTZ: I believe what we would propose is that we meet at some point, some designated time, and rework the language for the answer to Question 4.

MR. PAYNE: And we can do that very shortly

if everyone is ready for a break. We will get the laptop set up so we can combine notes from the various committee members, notes that we've taken to make sure it reflects what the consensus is and then repost that after the break.

DR. SHULTZ: Okay.

MR. PAYNE: So I propose -- Mr. Warshawer.

MR. WARSHAWER: Other than it be strictly Subcommittee, could we do that wordsmithing with open invitation to anyone who's interested in helping like draft it or does it have to be strictly --

MR. PAYNE: Yeah, I think we would need Sarah's and other person's input.

MR. WARSHAWER: Okay.

MR. PAYNE: Okay. So what we'll do is take a break. We are probably 10:30. So we'll reconvene at 10:45.

(Off the record at 10:35 a.m.)

(On the record at 11:00 a.m.)

MR. PAYNE: Okay. If we may have everyone's attention, we'll resume our meeting. And

Subcommittee 1 has made their collective revisions to their position paper here, their recommendations, and I will turn it over now to Subcommittee Chair, Dr. Craig Shultz to lead the discussion on the revisions to the document. And we'll open up for discussion, final, you know, consensus from the whole Committee and voting from the whole Committee on the final document.

Ms. Williams will be up here at the podium to make any wordsmithing or do any wordsmithing or edits. So with that said, I'll turn it over to you, Dr. Shultz.

DR. SHULTZ: Okay. So we're discussing Question 4, our response to Question 4, and we've also added some language at the end of the document. So this is currently what we have for our response to Question 4.

And then maybe if you could drop down, Natasha, and this was some of the language that was introduced to be added at the end of the document.

MR. PAYNE: Mr. Gapud and Mr. Winchester, Mr. Warshawer, Ms. Klein, those of you on that side,

feel free to come up, walk up. We do have a roving mic. We have two roving mics, you know, for you to use to make any comments.

DR. SHULTZ: Okay. All right. Let's go back to Number 4, and we'll just read Number 4.

The response to Number 4, the Subcommittee recognizes there are specific challenges that impact slaughter with each veal classification, but the data currently provided by FSIS is insufficient to define risks among the various classes.

The Subcommittee recommends that the Agency confer with ARS and other research providers to conduct research into pre-harvest risk factors associated with STEC in veal slaughter. The Subcommittee also recommends that the Agency promote research into the development of industry best management practices. As a long-term goal, the Agency should address the animal drug residue challenge in bob veal calves.

This is the current response to Question 4.

If we're okay with that, we'll go down to the end of the document and this is still going to

require some revision, but we'll go through what was in there. There we go.

Okay. The Subcommittee recommends that the Agency works with the small and very small plant outreach division to develop communications targeted with veal slaughter establishments. The material developed should be short and concise where possible. The guidance and tools should include visual materials, plain language documents including plain language non-regulatory guidance documents. FSIS should also develop webinars, DVDs, regional meetings, and partnering with State Extension Services and other appropriate venues to deliver this information. That was the language that was there previously.

Okay. Language that we finally came up with and we realize that what struck up there on the top, we have to incorporate some of the language from that into the language here at the bottom, but additionally, the Agency should plan and conduct a series of stakeholder meetings to facilitate knowledge sharing and capturing to more fully fill

the data gap that exists for this specific class of beef. So we need an S on exists.

Okay. The Committee recognizes the need for pre-harvest interventions and should, in addition to the above stated research plan, ensure discussions at stakeholder meetings, and there we need to add multidisciplinary -- multiagency, multidisciplinary meetings, in front of stakeholder meetings. Multidisciplinary, multiagency stakeholder meetings on this topic.

Further, the Committee recognizes the potential difference within the veal class and as such, should likewise focus efforts at stakeholder meetings on this topic with the intent to capture best practices in both plant and pre-harvest.

MR. PAYNE: That was multiagency after multidisciplinary, right?

DR. SHULTZ: Correct. And multiagency. Comments?

MS. KLEIN: I'd like to capture the phrase that's struck out, recognizing that pre-harvest is a critical control point for pathogen contamination,

and then ditch the additionally. So it would be recognizing that pre-harvest is a critical control point for pathogen contamination, the Agency should conduct a series of stakeholder meetings.

DR. SHULTZ: Go ahead.

MS. KLEIN: Take the first phrase that is struck out there, the recognizing -- through the comma, yep, to grab that, and drop that in, in place of the word additionally below, and I also don't think it should say plan and conduct. I think we could just say conduct.

Yeah, before the should, it should say, comma, the Agency should.

MR. PAYNE: This is Keith Payne. My suggestion, since we're having comments, we're not around our table, and we're spread out. If you're spread out, just raise your hand. We do have a couple mics, if you have a comment to make and identify yourself please.

Dr. Tilden, you have a comment?

DR. TILDEN: Yeah, I think the term critical control point has an awful lot of very

specific meanings to many of us, and there's a huge amount of data that's got to be looked at to say, really do believe that is a critical control point. I think all of us agree the importance of pre-harvest food safety, it needs to be addressed, it needs to be considered, but to use the term critical control point, I think might be beyond what I can support. I'd just say recognizing the vital importance of pre-harvest food safety and leave it at that.

MR. PAYNE: Dr. Liang, you have a comment?

DR. LIANG: This is more words, or can be an important or critical determinant of, but anyway, I'm not going to go to the mat for words.

MR. PAYNE: There was a request from Ms. Buck to have Dr. Liang repeat what he said.

DR. LIANG: Maybe the phrase, pre-harvest can be a determinant of the rest of it. It's just a suggestion.

MR. PAYNE: Mr. Warshawer, you have a comment.

MR. WARSHAWER: Just some words,

recognizing that pre-harvest practices can influence or impact pathogen contamination. Take out the word, for. There you go.

MR. PAYNE: Dr. Reinhard, you have a comment and your microphone is not working.

DR. REINHARD: I would like to look at, in front of impact, pathogen contamination. Say impact potential pathogen contamination.

MR. PAYNE: Dr. Shultz, how are we looking?

DR. SHULTZ: It looks good to me. Does anyone have any additional edits?

MS. KLEIN: I have kind of a question. This is Sarah Klein. A question for Phil. Do we need to specifically delineate all the topics that we think should be discussed at this meeting?

MR. DERFLER: No.

MS. KLEIN: No. So just because it isn't stated there, we can still have a discussion on, for example, hypothetically authorities.

MR. DERFLER: Yes.

MS. KLEIN: Okay. Thank you. Then my only other suggestion would be where this goes in the

document. I don't have a specific wordsmithing on this paragraph, but where the paragraph goes in the document, I'd like to address when we get there.

DR. SHULTZ: It was suggested that we put it at the end, but we can move it or the beginning.

MR. PAYNE: Are we ready to move to that, Dr. Shultz?

DR. SHULTZ: Yes.

MR. PAYNE: Okay. And there is a comment from Mr. Waldrop.

MR. WALDROP: I had a comment on Number 4, just whenever we get to that point.

MR. PAYNE: Dr. Tilden?

DR. TILDEN: So I think getting back to the original charge, both 4 and 5 get to what FSIS can do within their existing framework, and so we're focusing on what veal slaughter operations can do to improve food safety and as part of these stakeholder meetings, they would talk about what regulators and veal slaughter operations can do to incentivize best practices. Is that correct? I think if we focus it on that, everyone would agree that that's the sweet

spot that we can all agree on, that these meetings can focus.

If you broaden it out, those are very legitimate issues that may need to be addressed, but I don't think we're going to reach consensus to say we're going to cover all the topics of veal pre-harvest food safety in these series of stakeholders and make it's something that's doable. So I think it's helpful. To make it doable, focus on veal slaughter operations, what they can do and then how they can influence pre-harvest food safety, you know, the operations, when they're receiving. I would not try to make it an all encompassing topic.

MS. KLEIN: It might be enough of an argument for FSIS to help them when they're planning a meeting. If they say we're going to have three meetings and first two are going to be focused on -- today and the last one is going to be focused on next steps, I mean I don't want to limit the Agency in here if what we're supposed to be doing is just telling the Agency we want you to convene these meetings to cover a variety of topics within this

important issue. I don't know. I'm not comfortable with saying and only cover these topics.

MR. PAYNE: Okay. We have comments from Ms. Buck and then Mr. Warshawer.

MS. BUCK: Is this on? Okay. I would agree with Sarah that limiting by listing what the meetings would be about is probably not something that NACMPI should do, okay.

I also think that since this pre-harvest practice as a potential pathogenic contamination is really sort of an overarching thing in response to all our questions.

So I don't know where, Dr. Shultz, you would want to put this statement. I don't know if at the end is the best spot for it. It's certainly a key spot, but we could also put it at the beginning. Sarah, do you have any suggestion?

MS. KLEIN: For the reason you just stated, my preference would be that it serves as a preamble, kind of framing the issue and then dealt with the specific questions below. So my preference would be that it's a preamble.

MS. BUCK: It seems that Dr. Shultz --

DR. SHULTZ: Any objection from the Committee? No objections from the Committee, Subcommittee. Okay. Also Nancy pointed out to me that we should change Subcommittee to Committee under response there. Natasha. Yeah. There's an extra S in -- oh, yeah, after works, the Agency works -- work. Okay.

So we'll move the last paragraph to the top of the document as a preamble. Above the questions, yes.

Okay. Additional comments? I think we're --

MR. PAYNE: Is that the last revision, Dr. Shultz?

DR. SHULTZ: I believe it is.

MR. PAYNE: And we have a comment here from Mr. Waldrop.

MR. WALDROP: Go back to Question 4 please. So for the first paragraph in our response, we say that we recognize there's specific challenges but that the data currently provided isn't sufficient to

determine risk among the various classes. I think we need to give FSIS the ability to, if in the next 90 days as they're going through this process, verification process, or as they're getting information from these stakeholder meetings, to be able to address any differences that they identify.

So it's not, you know, we're saying that we don't have enough data but that as FSIS gets data or gets information that makes it clear there is a difference, that they should be able to take action as necessary.

You don't have to put a 90-day timeframe in there.

If FSIS identifies the need to take specific action based on identified differences, they should --

MS. DONLEY: Can I say something?

MR. WALDROP: Please.

MS. DONLEY: If FSIS identifies areas in its policy documents where more specific language is needed, in the subclasses of veal, the Agency should include that language. Something. It's not very

elegant but --

MR. PAYNE: As stated yesterday, if we are good with the content, we can finesse the words after the meeting and send it back out to the Committee but content-wise is what we're after for the whole Committee to have a consensus on.

Dr. Shultz?

DR. SHULTZ: I think we have a working document with acceptable responses at this point.

MR. PAYNE: Is the whole Committee in agreement? And Mr. Warshawer, you have a comment?

MR. WARSHAWER: Hello. I just want to be sure of one thing on the preamble. Okay. There's two different connected but distinct items being described, a series of stakeholder meetings to facilitate knowledge sharing and capturing. And then in additional to the above stated research plan, multidisciplinary, multiagency stakeholder meetings.

And the reason why I'm emphasizing that is that the first, the easiest piece to facilitate is that first sentence which would be FSIS and

industry. The ability to gather and convene a multidisciplinary, multiagency meeting is a more laborious, time consuming process and is necessary but that the way that this is worded, I'm hoping is because we intend that Sarah's original 2014 timetable for some kind of industry-FSIS interaction is doable. That multidisciplinary, multiagency, et cetera, is not necessarily something that would be done by 2014.

MR. PAYNE: Dr. Tilden?

DR. TILDEN: Exactly, and I agree. Leave it up to FSIS with the discretion to see what we can get done by a specific timeframe. Like Sarah's saying, get something done by 2014, and I think there have been 15 years plus of multidisciplinary, multiagency pre-harvest food safety meetings, and so I think the idea of targeting it to what can practically get done and result in something different within the next year, or year and a half, is important not to lose.

MR. PAYNE: Thank you, Dr. Tilden. And then, Ms. Klein.

MS. KLEIN: I think this one works. So we've lost the 2014 language from the preamble is the first point that if we like that kind of immediate action step, we need to put that back in.

And the other thing is I'm uncomfortable directing the Agency to have meetings to which I'm not invited. I'm sorry. Just to be honest, I think it is difficult to be in a position as a consumer group where you say you guys should have a meeting and, you know, and it's not important to us that we be allowed to attend. So I would not be comfortable with the premise being that the Agency and the industry should go ahead and have meetings on this important topic and our presence is not important. So I don't feel comfortable with that.

But I think either way, we need to go ahead and add back in the specific language about the 2014 goal if the consensus of the Committee is that we want the Agency to have that goal.

MR. PAYNE: Thank you, Ms. Klein. We have Mr. Warshawer and then Dr. Rybolt.

MR. WARSHAWER: Okay. That's easy. The

delay and turning a short-term possibility into a long-term project isn't a consequence of involving the consumer groups. It's a consequence of involving multiple agencies. So can we add in the shorter term, the first sentence, can we put in something that says that the first round be inclusive of whoever, however we language it, to be sure that you all are there, and that we don't get trapped into a government agency tangle that prevents us from doing anything? That's what I'm concerned about.

I never imagined excluding consumer groups from the conversation. I'm just really keenly aware that if we're trying to get enough different government agencies involved, it will take that much longer until anything happens.

MR. PAYNE: Dr. Rybolt?

DR. RYBOLT: I think the intent was -- is to be inclusive of all interested stakeholders. So maybe that's the language that's used, and you can change the multidisciplinary, whatever, all that up there and take that out and just put interested

stakeholders. And actually I think the intent, too, was it's one and the same. So the first sentence and the last one, they're all really the same stakeholder meetings or whatever.

MR. WALDROP: Not two different meetings.

DR. RYBOLT: It's just a series of meetings, yeah, for interested stakeholders. So that should cover everybody. Sarah will get her dance card, too.

And I did want to go back to Number 4. I had a question with Chris' suggestions. I don't know if I have a -- where was that edited? Would that be within kind of their existing tools?

MR. WALDROP: Yeah.

DR. RYBOLT: That's what I was trying to understand, is that within or are we asking for something else?

MR. WALDROP: No, I just didn't think we really answered the question to some extent with that first sentence, and I wanted to make sure that within their existing tools, FSIS could, if they identify that there is a problem, they could address

it or, and this is really looking at changing the language in the notice and the directive.

DR. RYBOLT: Yeah, so they would issue a notice or something like that like they've done before.

MR. WALDROP: Yep, exactly.

DR. TILDEN: And so at that sentence, is it okay? And, Natasha, you don't have to add anything yet. We can just see what people think. The Committee encourages FSIS to increase sampling as needed to better define potential risks, you know, and that way we're not waiting in the future. If they see there's a data gap, but they know about it, and it's within their ability to fill that data gap, that that's a possibility, on this response. So that's one suggestion.

The other suggestion is just add the 2014 to the end of the preamble, so that we get an end in sight for that. So if you go back up to the preamble. So you'd capture best practice, both in-plant and pre-harvest by 2014. That's one way to get the 2014 in there.

MR. PAYNE: Dr. Lorenzen.

DR. LORENZEN: Since we struck the multiagency, are we considering that that is in the interested stakeholders up in the preamble? Sorry, because the other agencies are the ones that have responsibility for pre-harvest food safety, and you're considering that interested stakeholders and FSIS considers them as interested stakeholders. Okay.

MR. PAYNE: Dr. Tilden, do you still have or, Ms. Buck, you have a comment?

MS. BUCK: Yes. Could we scroll down to Question 4? The same sentence that has been added, that last sentence in the first paragraph of the response, if FSIS identifies areas within their existing tools where more specific language is needed in the subclasses of veal, I would put if more specific action is needed, I would think would be better than language.

UNIDENTIFIED SPEAKER: They're talking about policy.

MS. BUCK: They're talking about policy.

UNIDENTIFIED SPEAKER: Yes.

MS. BUCK: The Agency should -- okay. I'm sorry. I missed that point.

MR. PAYNE: Dr. Shultz?

DR. SHULTZ: I think we've arrived at an end.

MR. PAYNE: In consensus from the whole Committee on the recommendations?

UNIDENTIFIED SPEAKER: Can you go back up and --

MR. PAYNE: Go back up to the top and start from the start from the top and go down through them.

MS. KLEIN: I just want to clarify. This is Sarah Klein. I just wanted to clarify that initially the discussion that we had was about achieving a specific pathogen reduction in this product by 2014. It was not in an exercise of capturing best practices by 2014. Those are very different goals.

So my preference would be to state a pathogen reduction but --

UNIDENTIFIED SPEAKER: (indiscernible).

MS. KLEIN: With the intent to capture best practices both in plant and pre-harvest, and to achieve -- what do we want it to say?

UNIDENTIFIED SPEAKER: A measurable. Measurable.

MS. KLEIN: -- measurable and significant pathogen reduction by 2014.

MR. PAYNE: Ms. Buck, do you have a response?

MS. BUCK: I think this is great, but significant has statistical overtones, and I think we need to have any type of pathogen reduction, whether or not it's statistically significant.

MS. KLEIN: Okay. Yeah, I didn't mean statistically significant. I was using it --

MR. PAYNE: Are we okay with that?

MS. KLEIN: I'm done.

MR. PAYNE: Do you seek consensus from all Committee members?

DR. SHULTZ: Yes.

MR. PAYNE: Raise your hands. Voting in

favor?

DR. SHULTZ: Any opposed?

MR. PAYNE: Motion carries.

DR. SHULTZ: Thank you.

MR. PAYNE: Thank you very much.

Okay. We can go ahead and move into Subcommittee 2's recommendations and resume our place around the table.

Okay. We're moving onto Subcommittee 2 with the recommendations, and Ms. Sarah Klein is the Madam Chair of that Subcommittee. So once we get the document up on our laptop. I think everybody has a hard copy of Subcommittee 2's recommendations. If you'd like, Ms. Klein, you can go ahead and start, and we'll get this brought up on our laptop.

MS. KLEIN: Okay. So this is the report from the Subcommittee on Review of Criteria for Public Health Related Noncompliance Records.

All right. So we started with the preamble, a very brief preamble. The Data Analysis Subcommittee recognizes, actually we'd have to wordsmith that for the full Committee, recognizes

the work of the Agency in updating the regulatory criteria by which focused inspection activities such as FSAs are prioritized. This type of data-driven science-based approach is critical for addressing risk. The issues delineated below represent additional areas for consideration or issues of concern to the Subcommittee.

So then we answered Question 1, which I don't actually have the question here.

DR. SHULTZ: What comments does the Committee have regarding the approach used to select the PHR list?

MS. KLEIN: Okay. Thank you. So our responses were that data dilution is a concern, that the mixing of performance-based and public health criteria may misclassify items and their significance.

Second, it may not be reasonable that all data is randomly distributed. Positives may suggest clusters or links relegating it all to the larger data sphere. And assuming randomness does a disservice to the data. This may require secondary

sampling to tease out the additional data.

Third, FSIS has made an assumption that there's a link between NRs and pathogen findings even though there may not always be cause and effect, for example, in specified risk materials. Notwithstanding the recognition that an NR is indicative of a general loss of control, the Agency may need to provide a better foundation for the use of NRs as an indicator significant to trigger an FSA, for example, if the overall NR count was high enough above the cut point even without sampling positives, that could be enough to trigger a FSA.

FSIS still needs to clarify its intentions in process control and public health control and protection. Statistical significance does not necessarily equal practical significance. The Agency may be missing the public health benefit by focusing on the processed NRs. The Agency should provide its reasoning on this issue including whether it intends for PHR monitoring to be a performance-based evaluative tool, whereas the FSAs result from that monitoring are the public health

risk analysis.

Thus, on a continuous basis, the data gathered from those FSAs should be reviewed for relevance to public health, i.e., was the Agency looking for the right things, and should inform the development of the PHR list going forward. Similarly, the Agency should consider which of the candidate elements may be showing up later in FSAs and thus should be added to the list.

The information gained through ongoing data analysis should be shared with extension and used to update training for industry, regulators, and others as appropriate.

So let's tackle Question 1 before we move on.

MR. PAYNE: Any comments? Mr. Waldrop.

MR. WALDROP: Can you talk a little bit more about the discussion you had for the first two, just to provide a little bit of background. I'd just like to understand kind of what those issues mean.

MS. KLEIN: Yes. And actually I'm going to

ask somebody else on the Subcommittee to do that because that's not my area of expertise, the data dilution questions and the random distribution questions.

DR. TILDEN: I'm sorry. I was having a sidebar conversation.

MS. KLEIN: The first two bullet points, can you give the Committee a little bit of background on how we reached those first two bullet points and what we were intended to capture there.

DR. TILDEN: Okay. This is John Tilden. So there's a long list of regulations that are proposed to be included. Some of them have hundreds of thousands of observations associated with them that are related with performance-based criteria, how well the HACCP plan is being implemented in comparison with regulations.

We talked about how the hypothesis is that process control using a HACCP system will have either a direct or indirect link with microbiologically safe foods, but some of those write ups and NRs may or may not have direct or

indirect links with microbiologically safe foods. They have more to do with implementation of the program as written.

So we applauded FSIS in the direction they're taking and they've got better data for decision making now than before, but we encourage them to continue to try to separate out for whatever regs are created, to better define to what extent they help implement the program as written versus identify. Do they help us better and better focus on the public health risk in creating microbiologically safe foods?

And then misclassification is that if you are including things and saying we are marking these NRs for public health reasons when they're actually performance based, and they have more to do with process implementation, to the extent they aren't directly linked with public health outcomes, you misclassify them and then you're taking actions on things that aren't directly related with public health outcomes. We recognize this is a long-term debate, and we're moving forward, but we want to

continue to press the Agency to better and better define and use the data to characterize which of those regulations is most directly related.

And we said basically that the FSAs might be your best opportunity to intensively evaluate the actual in-plant conditions and how observations and NRs most directly impact microbiological safety.

MR. PAYNE: Dr. Shultz?

DR. SHULTZ: I question that I would have is in the process of doing this, is a key component of collecting this data also training those who collect it of the significance of it, and the functionality of it in the broader spectrum of overall plant compliance.

And I'll use the example of zero tolerance in beef, where we really worked hard over many, many years to associate a finding of fecal material on a carcass with microbial results, in-plant microbial results, generic *E. coli* results and other pathogen results from that product.

And what happened was, as a result, that we spent a few years defining what fecal material was,

and rather than just documenting it as fecal material, we had to describe it as fibrous and brown or green, so that we were sure that we had fecal material as opposed to hair or as opposed to dirt, rail dust from the plant, which has a different level of significance in terms of food safety, and at the inspection level, where all that data is collected, we often don't see the big picture. That's just one example, if anyone would like to speak to that.

MR. PAYNE: Thank you, Dr. Shultz. Any responses? Mr. Alvares?

MR. ALVARES: So I'll just say very briefly, and I think maybe some of the Committee members can weigh in, too, but there was some discussion about a feedback process. How do we know that what we're implementing is working and how do we translate what we learned from that feedback process into potentially better instructions to the field, better training, and so we see that as a component. Certainly some of the feedback we received in the discussions yesterday is a component

we need to incorporate.

MR. PAYNE: Thank you, Mr. Alvares. And, Dr. Shultz, your tent card is still up. Do you have a comment? Ms. Buck.

MS. BUCK: This is a question for Chris. In your estimation of the response given by the Subcommittee, since you were present at its deliberations, do you believe that this will have the level of statistical quality to give you the types of information that you need to move forward with not only selecting the PHR list, but with making new evaluations as you move forward?

MR. ALVARES: I'll just -- I'll use -- you know, start with this. So I think it's kind of a -- it's a tough question. On the one hand, I think we definitely have better data and we have better information to be able to make these kinds of decisions. And so I think we've seen from a data analysis, a statistical perspective, I think we've definitely had advancements through the data we're collecting from PHIS.

With that being said, I still think there's

opportunities for improvement. There's always, you know, opportunities to collect better data. As I mentioned in the feedback process, if we are learning things about how regs are being documented or cited, I think that we want to look at that both in terms of regulatory enforcement but from this process, also in terms of how it's informing our decision making for FSAs.

So I think we're making progress. I think we've made some good advancements, but I certainly don't feel like we're done in terms of an approach to analyzing NRs and making decisions based on them.

MS. BUCK: This is Patricia Buck again. And based on that statement, would you have any or this Subcommittee, should it be making any recommendations to have a subgroup to look at some of these data analysis issues? I mean, would that be something that should --

MS. KLEIN: Well, we do offer that as suggestion later in kind of a --

MS. BUCK: Okay.

MS. KLEIN: -- separate section, not as a

direct response to Question 1, but we do. So when we get to that point, tell me if that captures what you're envisioning.

MS. BUCK: Okay. Thank you.

MR. PAYNE: Thank you, Ms. Buck. Thank you, Ms. Klein. Next, Mr. Waldrop.

MR. WALDROP: Also based on Chris' response, and perhaps it will be captured later, but I think the Committee should emphasize the importance of revising this. I know that you've indicated that that's your plan and that that was in the slides, but I think considering the fact that you're working with this first 7 months of data from PHIS, since you got it started, we know there have been problems with the data. You recognize the need for more data, and that you will be getting more data.

We know that there have been problems with uploading some of that data from inspectors. I think it's going to be important to revise this continually when you have more data available to be able to make, you know, better assessments of really

where are the important public health related NRs.

So I would suggest that is the importance of revising this on a regular basis as an amendment to this document.

MR. PAYNE: Thank you, Mr. Waldrop. And, Ms. Klein, I'll turn this back over to you. I'm sorry. We have a comment from Mr. Alvares.

MR. ALVARES: So maybe more of a question because I heard something about not just using the NRs in addition to sampling data, but also by themselves. I just wanted to make sure, maybe I had miscommunicated or misheard what the recommendations from the Committee are, but the public health reg approach isn't -- the decision making that we do, as we go monthly through our process of prioritizing FSAs, doesn't incorporate sampling data. It's looking strictly at reg citations in the inspection tasks. The sampling data was used as outcomes to support the analysis for what we selected as regs, but as we implement, the focus is on just the inspection activities.

I guess maybe it sounded, from the

Committee write up, at least as drafted, there's an impression that we're going to be using sampling data as one of the inputs to this process.

MR. PAYNE: Dr. Reinhard?

DR. REINHARD: I think it's important what Chris has stated be included, and I think, Chris, for you, if you got to a point where an input could be the sampling data, and it drove to better decisions and science-based decisions, you should pursue that. And so I think it's more of a keep it open, work on a continuous improvement process to drive the Agency in the correct direction. So I think just culling it out with the data point would be appropriate, and then you'll have the flexibility, understanding that with the first process that you went through, specifically PHR, the output, right, you used the output of sampling results to figure out what your assumptions were.

MR. ALVARES: Okay. Thanks.

MR. PAYNE: Thank you, Dr. Reinhard. Dr. Tilden?

DR. TILDEN: Yeah, I think I'm saying the

same thing, that the goal is we're moving from visibly clean to microbiologically safe. So public health regulations should be linked to microbial counts recognizing that's going to take time and so that's the goal and you're moving towards that goal. I think that's in line with what we were discussing.

MR. PAYNE: Thank you, Dr. Tilden. Ms. Klein.

MS. KLEIN: Does somebody want to propose specific language that captures this concept of continuous improvement and updating that we can wordsmith in? Chris?

MR. PAYNE: Mr. Waldrop?

MR. WALDROP: Okay. I'll draft something while you guys continue with your discussion.

MS. KLEIN: Okay. So continuing on to Question 2. Does the Committee have comments on the four criteria used to select a candidate PHR list?

Our response, within the frame of continuous improvement, this was a question for the Agency, how does the Agency intend to drive change and advancement of HACCP? The Agency needs to

identify areas within the framework of HACCP systems that are still not being fully controlled. The Agency needs to identify gaps in existing practices and then we had, for example, where early adopters can share with capable learners how to close those gaps and more fully realize the goals of HACCP. Once those gaps are closed, the Agency can consider the next generation of HACCP principles.

The CDC's EHS-Net is a methodology for doing environmental assessments, and it's an example of the type of assessment that can provide additional data for decision making.

Then we need to strike this bullet that says enforcement. That's it.

MR. PAYNE: Thank you, Ms. Klein. We have Dr. Liang.

DR. LIANG: This is really sort of a small technical issue but probably important, and that is if you will allow me, maybe not now but soon, to find the appropriate EHS-Net is really a program, and I think the methodology that John alluded to was one of the activities within that program. So with

your permission, I'll at some point in time, I can do it now if you want, but I don't know if I'll be successful. I'll find the right, you know, label for referring to the methodology --

MS. KLEIN: Yeah. That's fine.

DR. LIANG: Okay.

MR. PAYNE: Thank you, Dr. Liang. Dr. Shultz.

DR. SHULTZ: If someone on the Subcommittee could define for me --

MR. PAYNE: Sorry, Dr. Shultz, your mic is not on.

DR. SHULTZ: How about that?

MR. PAYNE: It's on now.

DR. SHULTZ: Okay. Could someone define what next generation of HACCP principles is?

MS. KLEIN: Essentially we have to remember that these conversations we're having about identifying what is the next HACCP, that HACCP isn't the end of the road, and I think we were trying to capture that there is a HACCP 2.0 that hasn't been developed yet or explored yet, but that there are

still remaining gaps in the first generation of HACCP that we haven't gotten everybody doing all parts of. Nancy.

MS. DONLEY: I think it's a continuation of the discussion of continued improvement and that it's looking to constantly evolve, was kind of the general sense of the conversation.

MS. KLEIN: Does that answer it?

DR. SHULTZ: I would just think that it would evolve under one HACCP continuum. I think the principles are the same, that they shouldn't change.

MR. PAYNE: We have Dr. Rybolt or is that Dr. Marcy? I'm sorry. I can't see.

DR. MARCY: That's okay. I was going to speak to that, HACCP principles, that the principles probably do not change but, you know, the correct thought process, you know, HACCP is, you know, always improving and it's part of the validation process that, you know, as new practices come about, you know, they can be incorporated as part of that HACCP principle.

MS. DONLEY: Just as kind of an addition to

that is we had a terrific example in this first presentation that we had with problems with veal, how it's being, with HACCP and not being implemented very well and not being, you know, problems with inspection as well. So that's kind of, you know, we had the fact that HACCP isn't perfect. We're not questioning the principles of HACCP but we just need to have continuous improvement within the various industries.

MR. PAYNE: Dr. Tilden, you had your tent card up.

DR. TILDEN: And one of the things we talked about was immediately following implementation of HACCP in the late '90s, we had a drop in foodborne illnesses that related to some of the enteric pathogens and that plateaued off in the early 2000s.

What does it take to take it to the next level, so we get the next level of reductions? And, how do we identify the existing parts of our programs that are inefficient or less effective? And then if we can focus more clearly on those

areas, make them more efficient and more effective, then that could drive the next round of reductions.

MR. PAYNE: Thank you, Dr. Tilden. Ms. Buck.

MS. BUCK: Patricia Buck from CFI. I likewise sort of take some exception to the use of principles in that last sentence of the first bullet. There's seven HACCP principles, and I think one of those HACCP principles is you keep relooking.

So maybe what the Subcommittee would like to consider is instead of principles there, say the next generation of HACCP practices within various industries.

MR. PAYNE: Ms. Donley.

MS. DONLEY: Yeah, I see the concern there with the word principles. I really do. What if, you know, if we were to articulate, the goal of HACCP is to reduce foodborne contamination. So if we were to add, after realize the goals of HACCP which is to reduce foodborne contamination, once those gaps are closed, the Agency consider the next generation of maybe performance standards. Is that

what we're saying, is to get the performance, you know, or microbiological standards.

MR. PAYNE: Dr. Reinhard.

DR. REINHARD: I would like to propose and so what Nancy said, I don't know that it goes there where it was typed.

UNIDENTIFIED SPEAKER: Oh, I'm sorry. I was just putting it there.

DR. REINHARD: Oh, you weren't typing what she said.

UNIDENTIFIED SPEAKER: Yeah.

DR. REINHARD: Okay. For that last sentence, we could change it to say once those gaps are closed, the Agency can continue to make improvements in their HACCP regulatory system, and it broadens it to all the different things that the regulators potentially could look to, to make improvements in. So HACCP regulatory system. I think that covers what Pat had asked for, too.

MR. PAYNE: And that works for the whole Committee. I see affirmative.

Okay. Ms. Klein?

MS. KLEIN: Okay. The last two bullets of Question 2, FSIS could consider using the outcomes of PHRs to determine tasks that should be performed when an inspector completes an HAV. FSIS should consider providing a flowchart that more specifically explains the process of getting to a FSA. A second chart could be devised to explain the feedback loop described above. Questions? Comments?

MR. PAYNE: Mr. Waldrop?

MR. WALDROP: Is the intent of the flowchart for the general public or for inspectors?

MS. KLEIN: I forget who wanted the flowchart. Tom, was that you?

MR. PAYNE: Dr. Shultz.

DR. SHULTZ: I think that gets back again to the concern that I have about a coordinated effort in compliance once a FSA is implemented, that there is an understanding at the field level of the gravity of that and the direction of that, and that we all in the field, as a former field person, need to understand our role in that, and the criticality

of the data that we provide in moving toward that. In my experience, having been involved in FSAs from the field end, is that sometimes I felt I wasn't ready and I was being sprung upon, that I wasn't part of this early enough. Just a suggestion.

MR. PAYNE: Thank you, Dr. Shultz. Ms. Buck?

MS. BUCK: This is a question for the Subcommittee that worked on this. Is it your intention with asking for a diagram, so to speak, of the outcomes and the process to make it more widely understood? And is there a problem with being too hasty with that type of communication when sometimes some of these data collection problems may take longer than what is anticipated? I mean, was that type of thing discussed?

MR. PAYNE: Dr. Reinhard.

DR. REINHARD: So I don't recall, and I was on the Subcommittee, what specifically we were working on, on the flowchart, but that's okay. Would we just like to say and it should be FSIS should consider because I think that's leaving it up

to them, that we didn't tell them anything, we should just say FSIS should provide notice and directives on how this process is going to work because that's what this is really asking for, as a simpler way of just saying, everybody needs to know what we're doing here. And then the inspector gets the opportunity to understand how and what it means when things are going on through a system that he's not familiar with or she.

MR. PAYNE: Any responses to Dr. Reinhard's suggestion there? Dr. Tilden.

DR. TILDEN: Yeah, I think the point was that the PHRs would be one level of surveillance that would trigger a second more focused level of surveillance, and I think Dr. Shultz's comment about ensuring that we have a coordinated effort where everyone knows how the one level triggers the next level and then what our roles are in a coordinated compliance effort, I think that makes a lot of sense, and I think the intent here is try to make that more transparent, how the PHRs will be used to trigger both HAVs and FSAs, and then how the

information gathered in the FSAs and HAVs can be used to feed back into the process. I think that was the general intent of what we discussed, and the other Committee members can mention their understanding.

MR. PAYNE: Thank you, Dr. Tilden. And, Dr. Shultz?

DR. SHULTZ: I agree that that's the direction we need to go in, and I would say that from the field standpoint, what has made that process difficult is that there are these triggers out there that once a certain catechistic event occurs, we have a FSA whether or not we're ready for it or whether or not the field has been prepared for it, and then very often we are in a situation where we don't have the data that we need and we haven't done the homework that we need to do.

MR. PAYNE: Thank you, Dr. Shultz. Ms. Buck?

MS. BUCK: This question is directed to Chris, and I was wondering if during the deliberations of the Subcommittee, was there some

consideration given to how long it would take to get sufficient data on any of these PHRs to provide you with some validity for taking action?

MR. ALVARES: Okay. The analysis that we did for the Committee, for the report to the Committee, was based on 7 months worth of PHIS data, and we did talk about how much data we would need as we go through kind of our update process.

And the feedback I provided to the Committee in terms of where I think we would be likely to go is that if we were doing an annual update process each year, we look at this data and revise it, that we would look at that year's worth of data. So we would be looking at essentially 12 months worth of data and updating our public health regulations based on that.

There's another maybe scientific question, and so I'll try and answer both. The other kind of aspect to it is how far in time, what time window should we look at when we analyze PHRs in making a decision to schedule a FSA or prioritize a FSA? We've settled on a 90-day window or a 3-month

window, and it's not so much through, you know, a statistical decision making process.

It's more about what we felt was a reasonable period of time. We want something that is short enough that we can respond in a timely way, and if we need to compute an average from a year's worth of data, I would feel that that's going to really just delay our responsiveness.

At the same time, we don't want such a short window that there's insufficient data to make a decision, and so based on our kind of judgmental opinion, we selected the 90-day window, but as far as reviewing this process and making updates to the regs, it would more likely to be an annual process and therefore a 12-month set of data that we would analyze.

MR. PAYNE: Thank you, Mr. Alvares. Dr. Shultz.

DR. SHULTZ: I agree that the time period is critical, and I've experienced a number of situations where the amount of data that was used and the time period that was considered was so

short, that we were making very heavy decisions on a very limited number of tasks with limited observations by one individual, and I know that's a problem especially as we move into very small plants, that we would be talking about under veal, that we have one individual or perhaps two individuals in a plant that are making all the observations but the more observations that are made by a larger number of people, the greater the validity of that data is, as you progress in a regulatory mode.

MR. PAYNE: Ms. Buck.

MS. BUCK: Based on this conversation, would the Subcommittee consider adding some of the language that Chris just identified or is that not the type of things that would help with answering the question? I mean FSIS should consider using the outcomes of PHRs to determine tasks that should be formed when a inspection completes a HAV seems, I hate to say, a little vague to me. Okay.

So could we include some direction to FSIS, the rationale of using the 90-day window and the

annual review or is that something the Subcommittee does not feel we should specify or the Committee?

MR. PAYNE: Any thoughts from the whole Committee? Dr. Shultz, your tent card is up. Mr. Waldrop?

MS. BUCK: Maybe Chris has a comment on it.

MR. WALDROP: I was going to provide language on an at least annual revision of the PHR list. I wasn't getting into the 90-day window. So I'll leave that up to the Committee if folks want to get into that level too.

MR. PAYNE: Dr. Tilden?

DR. TILDEN: So maybe that second to last bullet could be revised to be FSIS should regularly reassess the validity of the PHR list and the guidance used to implement it. And I would recommend that they would, in light of the data gathered, the PHR data and sampling data. Look at both of those, assess the validity and then make revisions as appropriate.

MR. PAYNE: Does that work for the whole Committee?

MS. WILLIAMS: Can you repeat it?

DR. TILDEN: If we can say it right. FSIS should reassess both PHR and sampling data to assess the validity of this system and make revisions as appropriate. The process, however we want to describe it, with the idea that this is part of continuous process improvement.

MS. WILLIAMS: Can you repeat the part about validity? I'm sorry.

DR. TILDEN: To reassess the validity --

MS. WILLIAMS: Okay.

DR. TILDEN: -- of the PHR. I guess it's a surveillance system. To reassess the validity of PHR and sampling data.

MS. WILLIAMS: Gotcha.

DR. TILDEN: Access -- assess. So it's reassess. We'll look at it with spell check.

UNIDENTIFIED SPEAKER: To reassess the validity and the correlation of --

DR. TILDEN: Yeah. So our assumption is that PHR is correlated with microbiological sampling. So on an annual basis, FSIS should

reassess PHR data and microbiological sampling data to assess the correlation. Is that a more specific way? To evaluate the degree of correlation.

MS. WILLIAMS: To evaluate?

DR. TILDEN: To evaluate the degree of correlation between the two.

MS. KLEIN: That one's a separate bullet.

MS. WILLIAMS: Okay.

MR. PAYNE: We have a comment from Dr. Vetter and then Mr. Waldrop.

DR. VETTER: The last part of that sentence, I like the revisions that are going on, but the last part of that sentence, to determine tasks that should be performed when an inspector completes a HACCP, that's a totally different topic and thought process to the portion that you're revising right now.

MR. PAYNE: Dr. Tilden.

DR. TILDEN: I agree. So maybe we can take a stab at taking that fragment and making it a separate bullet.

MS. KLEIN: Okay. Sorry. I've got to get

to the computer here. Okay. So on an annual basis, is that what we're talking about?

DR. TILDEN: Yep.

MS. KLEIN: FSIS should reassess the validity of PHR and sampling data to evaluate the degree of correlation between the two. Yes?

Next bullet. I didn't want to lose the notice and directives piece. Can return to what that was?

UNIDENTIFIED SPEAKER: FSIS should issue notices and directives to explain the process.

UNIDENTIFIED SPEAKER: That negates that last bullet point.

MR. PAYNE: We have a comment from Dr. Vetter.

DR. VETTER: What Dr. Rybolt was saying, that statement basically negates or leads to that last bullet point where we're talking about the flow chart.

MS. KLEIN: It would remove the --

DR. VETTER: The notices and directives to explain the process. The flowchart would be part of

that or not needed because of that.

MS. KLEIN: I didn't strike it out yet I mean formally, but are we ready to delete that flowchart? Yes?

MR. PAYNE: Do we see an affirmative reaction form the whole Committee?

MS. KLEIN: Okay. But what is this fragment here, outcomes of PHRs to determine tasks that should be performed. What was the intention of that?

DR. REINHARD: The intention of that, because it came from me, HAVs are there to reassess some different things that may be getting out of control based off of data that is coming through this system. Whatever those things are that get looked at by the inspector, the Agency should consider the results of this analysis, i.e. which regulations matter for public health as it related to sampling results, and potentially incorporate the verification that those regulations into the HAV because I think they play together.

It's just that we state or the Agency

stated we did an analysis and these regulations matter if we're going to get to controlling the contamination of product. If you're doing a HAV because something says you're getting out of control and you want to avoid contaminating product, well, that just logically means to me this outcome you came up with needs to be looked at as part of the HAV test.

MS. DONLEY: The HAV or the FSA?

DR. REINHARD: I'm sorry, Nancy. What?

MS. DONLEY: The HAV or the FSA?

MR. PAYNE: There's a question from Ms. Donley about the HAV or the FSA.

DR. REINHARD: They're two different things. So it could be used in the procedure, but this was specifically at the HAV because it occurs before the FSA and it's earliest on.

So the inspector would know when to perform a HAV because PHIS is going to tell them to, okay. That's already what they're working on, correct, Chris?

All this is saying is whatever you have

them go work on, have them work on the things that lead to not contaminating product. The regulations that are most important for not contaminating product.

MS. KLEIN: Does the bullet that I put up there capture what you're trying to say?

The Agency should consider incorporating the outcomes of PHRs to determine tasks that should be performed when an inspector completes an HAV.

DR. REINHARD: Correct.

MR. PAYNE: Mr. Waldrop, your tent card's been up for a while.

MR. WALDROP: Yes. I'm looking for a little bit more clarity on that one and then I have another one on the reassessing.

So are you saying that FSIS should then, whatever the important regulations that they identified in the HAV, are you saying that they should consider those as important ones for their whole PHR system?

DR. REINHARD: The PHR are the important regulations. That's what they determined. If those

are the important regulations, they should put those in the procedure when an inspector performs a HAV. And I would ask, Chris and Phil, do you guys understand that?

MR. ALVARES: This is Chris. I mean I think I do understand it. In one context, I mean the HAV task is sort of defined and envisioned, but I understand what you're saying in the sense that if this task is being done because it's being triggered by PHRs, it could also be triggered by some of the other decision criteria, but I think it's important for the inspector to know what's triggering that task, you know, if it's, you know, either for the HAV or for cause FSA, and that may help them in focusing their activities to address, you know, that trigger.

MR. PAYNE: Mr. Waldrop?

MR. WALDROP: And then going back to this, the second bullet on the annual basis reassessing, so this bullet right now says that we should reassess the validity of combining the PHR and sampling data, but we also I believe were talking

earlier about, and I was suggesting earlier, that FSIS also needs to reassess all the regulations they're using and whether those are the appropriate ones to be considering in this as part of their public health regulation, and that I believe is something that FSIS was already considering doing, where they're reassessing all the regulations available and making sure they have the right ones that really have a public health impact.

So I would suggest that they need to, in addition to what you have up there, also do that type of revision, something along the lines of FSIS should analyze and update the PHR list annually based on all available data and information collected by the Agency.

MR. PAYNE: Dr. Marcy.

DR. MARCY: Yes. I'm confused now about the HAV. Is that not a task that is going to be done quarterly by the inspector? Now the PHRs may trigger one in advance through PHIS. Too many acronyms. I apologize.

MR. ALVARES: That's one possible outcome

that we had described in the decision report from 2010, and I think that's still, you know, part of the plans for implementation but I think this process of defining PHRs wasn't to define the HAV task. It's sort of to define when the task is being performed or maybe when it needs to be performed more frequently than the quarterly schedule.

DR. MARCY: On that task, and I haven't seen what that task entails but it's my assumption that what the inspector will do is look at the plant's hazard analysis.

MR. ALVARES: Yes.

DR. MARCY: And it's really not regulatory, you know, not looking at separate regulations per se? Just the hazard analysis.

MR. ALVARES: It is focused on the hazard analysis.

DR. MARCY: Okay.

MR. ALVARES: That's correct.

MR. PAYNE: I think we had Ms. Buck and Mr. Waldrop and then Ms. Gapud. Ms. Buck?

MS. BUCK: This is Patricia Buck. Given

that the question asks about how the PHR list should be selected, Bob, are you saying that one of the things that FSIS should consider using the PHR list is to incorporate it into all routine HAVs that are performed?

DR. REINHARD: I'm sorry. I'm struggling to explain it, and I wish I could do a better job. This is the issue I see. I'll try to re-explain it simply.

Potentially my understanding is that the PHRs could trigger a HAV, okay. If we agree to that, if the PHRs trigger a HAV, it wouldn't make sense to me that the inspector go work on the hazard analysis which may or may not have anything to do with the noncompliances that were in the PHR that initially sent them to do that task in the first place.

MS. BUCK: I've got you.

DR. REINHARD: That is the challenge that we were trying to deal with here. So if the PHR triggers a HAV and you could name it something else, they should work on the things that were identified

as being noncompliance that triggered another task in the first place.

MS. BUCK: Yes, I agree.

DR. REINHARD: That was the point.

MR. PAYNE: Ms. Gapud?

MS. GAPUD: But isn't it that this PHR, your ultimate thing here is like it's just an indicator or something that will trigger ultimately if you need to do FSA. Am I correct?

MR. ALVARES: Yes, that's correct. It's a trend indicator. It's a trigger for conducting these tasks, but I also want to make sure we understand, it's one of several triggers. So there's a set of decision criteria which includes the sampling results that can inform these tasks, but that's correct, yes.

MS. GAPUD: So if there's something in the PHR that you identified, and then that can trigger HAV, but then ultimately you're looking more, on a bigger one which is the FSA. But that's not the only one that can trigger whether you have to do FSA or not. Am I correct?

MR. ALVARES: That's correct. There are other things that can trigger a FSA.

MR. GAPUD: Thank you.

DR. REINHARD: Just to clarify one more thing, it doesn't mean that you wouldn't look at the hazard analysis, too. You can pick everything. I don't want it to be limited. All I'm saying is use the data you have. The hazard analysis may be critical, too, but also try to incorporate those things that were the noncompliance itself.

MS. DONLEY: Did I mess it up or make it better? Do we need to be adding, you know, it's not the regulation. It's the noncompliance to the regulation. Would that just make it a little bit more clear?

DR. REINHARD: It potentially could be outcomes of PHR noncompliances, right?

MS. DONLEY: Right.

DR. REINHARD: Because that's what it is.

MS. DONLEY: Right. It's not the validity of the PHR. It's the validity of the noncompliances of the PHR.

MR. WALDROP: And I think it is to determine the task performed in a HAV. I think that's --

MR. ALVARES: This is Chris. I don't have a good angle for reading what's up there, but just to make sure I understand some of the comments. I mean I understand the idea of the validity of the PHR approach, sort of the general approach of selecting these regs and applying them, but I want to make sure because one way to interpret the validity of the NRs is whether we're actually determining whether the inspector wrote the NR correctly, and that's not the approach that we're --

MS. DONLEY: Yeah.

MR. ALVARES: Okay.

MS. DONLEY: Yeah, that's not the intent.

MR. ALVARES: That's not the intention. Okay.

MS. KLEIN: So here's how it reads right now. The Agency should consider incorporating the outcomes of PHR NRs to determine which tasks should be performed when an inspector completes an HAV as a

result. Good. What time's lunch?

MR. PAYNE: Well, question from Ms. Klein about lunch, and we are I believe past the time. We were due to take lunch at 12:15. It's now 12:24. This is something to put forth before the whole Committee. We need a lunch somewhere. So if you'd like to work on through this, that is up to you, but we do need to take a lunch break, but we need to make sure we start our public comment session at 2:15. So that's the timeframe we have to work with.

MS. KLEIN: Can we bring back food?

MR. PAYNE: And you're certainly welcome to bring back food.

MS. KLEIN: Would people want to take some portion of lunch as a break, and then come back and finish a working lunch just to ensure we get out of here on time with the weather and blah, blah.

MR. PAYNE: Yeah.

MS. KLEIN: So how long is lunch supposed to be?

MR. PAYNE: Well, we had slated an hour for lunch, to reconvene at 1:15, which only gave us an

hour to the public comment session.

MS. KLEIN: Right. So what time is it now? It's 12:30.

MR. PAYNE: It's 12:30.

MS. KLEIN: So why don't we say let's try and be back here with something to eat in 20 minute? Does that feel right to people? No?

UNIDENTIFIED SPEAKER: No, it takes 20 minutes to get through the line.

MS. KLEIN: Oh, okay. What do you guys want to do?

MS. KLEIN: FSIS, order us pizza. I'm not joking. Go and get a bunch of pizza. I mean we've got weather coming, and I think we want to finish up, but we don't want to short trip ourselves. So whatever the will of the Committee is. This is your problem. This is not my problem.

MR. PAYNE: Okay. We got from our designated Committee Chair, Mr. Derfler, 30 minutes to go get food, bring it back, and we will continue to work through the issue. So in 30 minutes.

(Whereupon, at 12:30 p.m., a lunch recess

was taken.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:00 p.m.)

MR. PAYNE: I believe we left off with Question 3, correct?

MS. KLEIN: Yeah.

MR. PAYNE: We finished Question 2.

MS. KLEIN: Yeah, was there any last -- did John have a suggestion? Was there any last minute wordsmithing that needed to be done on that final bullet of Question 2? Yeah, Dr. Chen.

DR. CHEN: Fur-Chi Chen. Yeah, I just quickly have some comment on the question. Could we tie original question back to the document of this?

MS. KLEIN: Um-hum.

DR. CHEN: In terms of Question 2nd, I think -- original asked for -- is the four criteria there for selecting the PHR and our comment on that? I think, I mean, yeah, we are still missing on that part. So we -- I suggest we add some -- add -- and you know, Committee agree and basically on the four criteria is appropriate in selecting a narrow -- on PHR list. And in addition, then we added a comment

there.

MS. KLEIN: Okay. So before these bullet points, you would want an introductory statement that says the Committee agrees with the --

DR. CHEN: Four criteria, I mean list there, I mean like establish and maintain HACCP and maintain sanitary condition and prevent adulteration and implement effective corrective actions. That's the four criteria could use to narrow -- balance the first stage on the regulation. So, and I say we haven't met any, you know, except the HACCP part, we haven't -- I mean, we haven't made a comment on other criteria.

MS. KLEIN: Oh, I see. Okay. So --

MR. PAYNE: Is that clear to the whole Committee? Dr. Tilden, you have a comment?

DR. TILDEN: Yeah. You asked about the last bullet, and I've got some suggested alternative language that might be more understandable. And that is, the Agency should consider the regulations that triggered the PHR increase, noncompliance increase when determining the scope of for-cause

HAVs. And I think that gets to our whole idea of just evaluate what's triggering it and what components and to what extent we've got linkage between those specific health regs and microbial.

MR. PAYNE: Thank you, Dr. Tilden. We have a comment. Please identify yourself.

DR. SERRATOSA: Yes, Jordi Serratosa. On the first line that you have been writing, the Committee agrees that the four criteria used to establish the PHR are appropriately used, I wonder if is understood the Committee are saying how these PHR are appropriately used which is a judgment or that you wish that are appropriately used. I don't know if this is my misunderstanding or it's clear.

So if the criteria, the four criteria are appropriately used, you are evaluating or judging that those criteria are well used while I don't know if you are doing the exercise. You maybe want to say that these four criteria are correct in your view and should be appropriately used. I don't know if that's the meaning.

MR. PAYNE: Dr. Tilden, your tent is still

up.

DR. TILDEN: Sorry.

MR. PAYNE: Any further comments on that bullet?

MS. KLEIN: Dr. Chen, does that work with what you were trying to say. The Committee agrees that the four criteria used to establish the PHR are the correct areas to be considered, provided they are appropriately used with regard to hazard analysis, specifically colon?

Okay. We can always revisit. Let's move on just so that we get further on, and then we can always pick back up if somebody says, you know, I didn't have a chance to consider that.

Okay. The part that I struck out though about final bullet, are we comfortable with that being deleted? We're now replacing it with John's language, the Agency should consider the regulations that trigger noncompliance increases when determining the scope of for-cause HAVs. Any dissent? Okay.

MR. PAYNE: I see no dissent.

MS. KLEIN: Question 3. I'm sorry. I don't have the questions in front of me. If someone else could read the question.

MR. PAYNE: I can read the question. I'm sorry. I don't have the question.

DR. TILDEN: I have it. Does the Committee have any comments on the public health outcomes (pathogen test results) analyzed to select the final list of PHRs? *Salmonella, E. coli* O157:H7, *Listeria monocytogenes.*

MS. KLEIN: Okay. So the Subcommittee's first comment was that FSIS should include non-O157 STECs and *Campylobacter* for analysis.

Second comment, FSIS' sampling program may not be robust enough to serve as the only data source underpinning this determination. The Agency should consider including alternative, possibly non-pathogenic profiles in their decision making. This may include further sharing of industry generated data up to USDA beyond the local inspector, for use in data analysis, scheduling, enforcement, et cetera.

FSIS should look closely at the timing of how data is transmitted to the decision makers to ensure that the data is used contemporaneously for risk reduction activities. Delays in the transfer of data may weaken its usefulness.

MS. GAPUD: I know the timing here is very, very important. That last bullet point on Question 3 that we put as a Committee, I know the timing here is very, very important, but should we not put something in there to cover how long we will allow because, you know, again if it's delayed, it will be useless. But do we have to put something? I think we have to put something in there, a maximum time that we can allow. We cannot wait for two years. It will be useless. One year will even be useless, you know. I think it's got to be stated in there.

MS. KLEIN: Well, okay.

MS. GAPUD: I don't know. What's the opinion of the Committee.

MS. KLEIN: I don't --

MR. PAYNE: Dr. Reinhard has a comment.

DR. REINHARD: I think as long as it's

clear to the Agency and, Chris, you were involved in this discussion heavily, and it's for your procedure, when you develop a notice or a directive, what was being said here was that when the results dictate a FSA needs to be performed, if that's the task that's getting triggered, it doesn't make sense for that FSA then to be scheduled 6 weeks, 8 weeks, 10 weeks later, that it needs to be timely so the data that they're reacting to is still the accurate data of the circumstances that's occurring. And I don't know that we need to go beyond and further describe it, as long as FSIS understands what was being said as it relates to this bullet point.

MR. PAYNE: We have a comment from Dr. Marcy.

DR. MARCY: Not to argue with Bob, but I think the point that was brought up I think was, you know, Dr. Vetter, that in-plant folks could use the data, you know, as it's trending up, that could possibly to see if there wasn't things that the in-plant personnel could do to, you know, had discussion points with the establishment, you know,

even without reaching a cut point.

And too, you know, Veny, I think this data supposedly comes out every month on a 3-month rolling average. You know, so it's fairly timely.

MR. PAYNE: Dr. Shultz, you have a comment.

DR. SHULTZ: Just a question. Possibly non-pathogenic profiles and decision making, are you talking about indicator organisms?

MS. GAPUD: Say it again.

DR. SHULTZ: When you're referring to indicator type organisms.

MS. KLEIN: I think, Nancy, you had a specific thought there.

MS. DONLEY: Yeah, it was the whole idea of using, you know, the plants currently, they do their own, you know, whole plate counts and various types of sampling all the time, and that we can share some of that to be used in addition to pathogenic organism testing.

MR. PAYNE: Mr. Waldrop?

MR. WALDROP: Also on this particular point, was there any discussion in the Subcommittee

about or with FSIS about sort of the reason for the second cut when you're looking at PHRs and whether or not, it sounds like you may have been thinking of those sample programs weren't robust enough to be the only source to be able to make that cut. So was there a discussion of why the second cut, what purpose that serves and whether the data is robust enough to allow that second cut?

MR. PAYNE: Dr. Reinhard?

DR. REINHARD: So that is correct. In context of making the results more powerful, the question was asked what other data is potentially available and initially it was passed on there isn't any, and then we went further into the discussion of there potentially is a lot more data that could be of great value and very powerful in determining how and what gets done.

MR. PAYNE: Thank you, Dr. Reinhard. Mr. Winchester?

MR. WINCHESTER: I'm still unclear with this second bullet, following Craig there. The Agency should consider including alternate, possibly

non-pathogenic profiles in their decision making. If this is related to pathogenic test results, as the question starts out, I'm still not clear what you're wanting them to look at that's non-pathogenic that we would -- it's just unclear. I mean, I don't think that's the direction that this is going, but other than opening up to any test results. So total plate counts or what are we looking at?

MS. DONLEY: We're kind of looking at, you know, just the fact that, you know, that FSIS is currently using pathogenic sampling to determine PHRs, and that that may not be enough. The question is, is that enough data to be able to be the sole determinant for determining a PHR within their list of other regulations?

MR. PAYNE: Ms. Gapud.

MS. GAPUD: I think what Nancy is trying to say is about not just looking at the pathogens but also the high total plate counts. Sometimes there's no pathogen in there but the counts are so high, that could indicate some sanitation issue, and I think that's worth looking at. I think that's what

she wants to say.

MR. PAYNE: Dr. Shultz?

DR. SHULTZ: As I understand it, FSIS has authority to review plant records regarding standard plate counts, whatever, associated with sanitation, and basically determine whether or not the plant has acted appropriately in their sanitation standard operating procedures in response to whatever their findings were, but I don't know if that data, because we don't necessarily know the standards under which that testing was performed, we don't know whether and would that data therefore be of any value in a national database compared to data that's been delivered under a very strict standard.

MR. PAYNE: Ms. Buck?

MS. BUCK: I was wondering about the non-pathogenic as well. Would it be more appropriate to say perhaps microbial, you know, give a specific example as opposed to non-pathogenic. Microbial plate counts. I mean, I could see a value including that, but I just wonder about the term non-pathogenic.

MS. GAPUD: But I think it has value because what was said, you not always see the pathogen, but it indicates some unsanitary conditions in the plant when the total plate counts are so high.

MR. PAYNE: Dr. Marcy.

DR. MARCY: Yes, thank you. Just a follow up question for Chris related to the microbial data, the pathogen data. You know, you're not using that to select your public health regulations. You're using that to select the establishments by which to gather NRs for comparison, right?

MR. ALVARES: So just to clarify, we're using the pathogen testing data as a second cut for selecting the public health regulations. So the first cut is do these regs, you know, do noncompliances with these regulations indicate a loss of control relative to the four criteria that we had in Question 2.

And then we're trying to further narrow that down to say, can we tie them to quantitative outcomes like pathogen test results?

So the testing data is used in our PHR selection process.

Now when you go to apply the PHRs in our day-to-day or month-to-month operations, we aren't using the pathogen testing data there. All we're doing is calculating the NR rate, comparing it to the cut points and making decisions based on that. And that's a way of trying to identify an issue before maybe the pathogen test results, you know, result in recalls or outbreaks or things like that.

MR. PAYNE: Thank you, Mr. Alvares. We have a comment from Dr. Vetter.

DR. VETTER: I understand where Nancy was coming from with her initial comment during our discussions. Her concern was that in selecting the PHRs that maybe our sampling wasn't robust enough to use to do that, and that's where she said, are there other things that we could use?

Having said that, I would agree with Dr. Shultz in that it's not a standardized process within the industry on how that's done, collected and analyzed and also being able to gather and input

that into our system in a timely basis would be something that's just not practical at this point.

So I think that FSIS has taken what it has and done something good with that which is narrow the scope of the PHRs.

Then I think there's a separate thing that's being discussed which is what Dr. Gapud brought up, and we do look at the non-pathogenic or the other microbial results and they are indicators of sanitation, and that is part of what we're doing in daily inspection in the plants. So it's not that that's being ignored and not being used in that manner, but I don't think that it applies very well to this purpose.

MR. PAYNE: Thank you, Dr. Vetter. Dr. Tilden.

DR. TILDEN: So I think part of where we're coming from is, and we said right up front, that we think these are the appropriate indicators species for the purpose. So short-term, that's the answer. Long-term, we identified that we all want to get to the root cause of what creates positives, and to get

at that, it takes a deeper understanding of the dynamics of what's going on within the facility, and so from my standpoint, I thought the discussion was going that we wanted to encourage FSIS to look beyond just reacting to the positive, focus on the root cause dynamics and, you know, this can be part of the FSAs of what is contributing to that, what were the factors and then part of that would be looking at these other alternative data sources.

MR. PAYNE: Thank you, Dr. Tilden. Our next commenter is Mr. Winchester.

MR. WINCHESTER: After hearing some more comment, this entire second bullet actually comes to a question. How and/or when would a plant offer this data and how or could USDA input it into the system that they have and what relative value would it have if it wasn't created and/or generated in a systemic way that would help or derive the same outcomes?

I'm just trying to say, I don't know if asking for other information from a plant or from a facility and then say, well, we'll feed that into

USDA and they'll figure out how to analyze it and put it into their database so that we'll have more information, and to be non-pathogenic and to look at total plate counts or other things. I just don't know that this, one, could even be done, first off. I mean it's great to get that information I think if a plant is willing to share that, but I don't know how much they're willing to share that to go into a database that would recognize them as finding, hey, these are the results that we're finding in our own plant that USDA may or may not have observed.

So I'm just questioning this entire bullet. I don't know if anybody else has questions to that level or not, but I just -- I'm not sure that this can be done and maybe that's a question for the USDA.

MR. PAYNE: I see a response coming from Mr. Alvares coming here.

MR. ALVARES: I mean I think I understand the main point, the main theme that the Committee is trying to drive at which is to use as much data as possible in decision making.

I realize, and I agree that there are some real challenges with using establishment testing data, and I think the recommendation is purely focused on that, that it will be a challenge for the Agency. If it's a broader kind of recommendation to use data, for example, you know, serotype data that we get from ARS, then I get the point of let's get as much data as we can in a timely way, incorporate it and make decisions based on that. And it could mean, you know, test data from AMS or other types of, I mean there's a number of different sources where we can get testing data and maybe get it in a more timely way and utilize it.

If the recommendation is really just about plant data, you know, that takes it down to sort of a one thought process. If it's more broadly about utilizing a full scope of data, that probably takes us down a different process.

MR. PAYNE: Thank you, Mr. Alvares. A comment from Ms. Donley.

MS. DONLEY: I just remembered that when I originally brought this idea up of, you know, maybe

using total plate counts and things like that. It was that FSIS would be doing that within their sampling, and that that be used along with the pathogens. And then the discussion kind of veered into, well, the plants are doing all of their own, and so that's how my initial concept kind of got dropped.

MR. PAYNE: Thank you, Ms. Donley. Ms. Buck.

MS. BUCK: This is a question for the Subcommittee. Did you consider in your deliberations whether or not there should be a suggestion made to FSIS that when they do their analysis of the pathogen test results, that they have that analysis reviewed by an external group to ensure the quality of the analysis?

MS. KLEIN: I don't think we discussed that. Does anybody on the Subcommittee want to respond to that?

MR. PAYNE: Ms. Donley.

MS. DONLEY: Yeah, I guess and maybe, Pat, you can elaborate a little bit more, I guess I don't

see the point of that. I just think that that would just cause delay and I think FSIS has the scientific expertise to be able to do it. I just don't know if you can elaborate more. Am I missing something in your question?

MS. BUCK: I think in the past when we have looked at some of the information that FSIS has provided us, and it has happened even in the recent past, one of the questions that always has come up is why wasn't this reviewed by an external group. And I would think that Chris might have some input for us to why this is not done because most scientific efforts demand this type of external review.

MR. ALVARES: This is Chris. I guess there's certainly activities that we do that merit peer review, you know, risk assessments that drive policymaking, I think is one good example, and anything where we're commonly submitting articles for publication are peer reviewed.

We also do a fair amount of analysis that informs internal Agency decision and to submit each

and every one of those to a peer review process I think, and I'm just speaking personally but, you know, it would really kind of hamper the Agency's activity.

So I think a balance needs to be struck there, and I mean, you know, we're open to the peer review process and we're perfectly happy to do that either beforehand or even as, you know, a follow up so that we can continue to get feedback and improve the process.

MS. BUCK: Thank you. There may be some reports that come out of your pathogen test results that you very much would like to follow up with using an external to USDA FSIS peer review process.

MR. PAYNE: Thank you, Ms. Buck. And before we go to Mr. Waldrop, next is a time check. We have approximately 45 minutes to our scheduled public comment period, just to gauge our progress on getting to a consensus on this issue. Mr. Waldrop?

MR. WALDROP: Thanks. Going back to this bullet and going back to the difference between whether we're talking plant data or we're talking

Agency data, I would say that this is the second cut of the PHRs and as we suggest, FSIS will have 12 months of data to put into that and help make that decision. So that could include the data, Chris, that you mentioned which again you may not get immediately but you have in that 12 month period, and that we should just make this broader so that FSIS could consider that type of data to inform that second cut. So they could also collect additional data, the plate count, FSIS could collect that if that seemed like something that could help inform their decision.

So I would say make this broad so that the Agency could bring in additional data that is relevant and useful to make this second cut.

MR. PAYNE: Thank you, Mr. Waldrop. And, Dr. Tilden, you're next in the queue.

DR. TILDEN: I agree with that, and again, I think we're all affirming that you're moving in the right direction, but you're going to be gathering data from these FSAs in the next year, and if you can standardize that and open it up so that

you're looking at a range of data sources, whether it's in-plant data that they've already got or stuff that you could generate, if you can build that in, then you're going to be that much better off, and that's why we went through it for Question 1 talking about better standardizing the investigation because there are intensive evaluations that will really help inform what are the in-plant dynamics that are contributing to these positives.

MS. KLEIN: So -- I'm sorry. Go ahead.

MR. PAYNE: Did you have a comment, Ms. Klein?

MS. KLEIN: No, I was just going to suggest that we look at whether we've captured any of what people are thinking in this language here.

MR. PAYNE: Let's take this opportunity to make sure we've captured everything thus far.

MS. KLEIN: I tried to make it bigger so that it would be easier to read up there.

FSIS' sampling program may not be robust enough to serve as the only data source underpinning this determination. The Agency should consider

including alternative testing data such as total plate counts in their decision making.

Wait. We're redundant here.

The Agency should consider including -- should consider, how about, the Agency should consider gathering and accessing total plate count data, serotype data and other sources for use in data analysis, scheduling, enforcement, et cetera.

UNIDENTIFIED SPEAKER: Instead of sources, put data.

MS. KLEIN: And other data.

UNIDENTIFIED SPEAKER: It should be other sources of data and other data.

MS. BUCK: And other data.

MS. KLEIN: Other sources of data and other data.

MR. PAYNE: Mr. Warshawer, you want to recap that?

MR. WARSHAWER: There were two questions. One is external data and then other is additional data FSIS gathered, and those seem like two different conversations. I just wanted to be sure

that the position was finalized in the language.

MS. KLEIN: Right. I was trying to capture those two concepts in the phase gathering and accessing because that would suggest that either FSIS could decide that they need to start generating their own data from sampling of total plate counts, for example, but also accessing captures this idea that the Agency may decide that it's easier to work with industry to figure out a way to use the industry generated data or to work with ARS to use the serotype data. So that's what I was trying to do.

MR. PAYNE: Dr. Reinhard.

DR. REINHARD: I feel like I have to clarify because I feel like I know what the Subcommittee was saying, and what they said is that we have a limited source of data, and with that limited source of data, there is a potential that the decision of which regulations are PHRs could be totally wrong.

And as you continue to go forward and make improvements to the process, you should always look

to include more data from more sources and continue to expand the ability to be confident in the decisions being driven by the analysis.

And there is data available, and I think this now gets us to that point where we're saying there is data available that could be used, and we're not making any kind of assumptions of what would be of value, but it could be CDC outbreak data. It could be industry data. It could be serotype data, you know. I mean there's lots of data and you'll have to continue to work to drive it because there is that potential that the NRs and the PHRs with the limited dataset you have aren't driving to what your goal is.

I mean I vote we go to Question 4.

MR. PAYNE: How does the whole Committee feel about the language here?

MS. KLEIN: So what we've got now is FSIS' sampling program may not be robust enough to serve as the only data source underpinning this determination. As the Agency moves forward with the PHR analysis, it should seek to expand the pool of

available data to ensure confidence in the decisions being made. The Agency should consider, for example, gathering and accessing total plate count data, serotype data and other sources of data and other data for use in data analysis, scheduling, enforcement, et cetera.

UNIDENTIFIED SPEAKER: I'd get rid of other data. That seems to be pretty redundant.

MS. KLEIN: Really.

MR. PAYNE: Does this look good to the Committee?

MS. KLEIN: Okay.

MR. PAYNE: All right. Ms. Klein.

MS. KLEIN: Okay. So we've answered the three questions, and then we had some other kind of lingering orphan type issues that we wanted to deal with.

One of them was enforcement, and here we made a statement, the Committee acknowledges that there is a need for information gathering to improve the scientific basis of the program without limiting the capabilities of regulators to enforce current

regulations.

I think there was some discussion about improving that language, and the second bullet, we need to combine these two somehow. These are not distinct thoughts. So we need to work on this enforcement piece.

MR. PAYNE: And we have a comment from Dr. Tilden.

DR. TILDEN: The point here was that not every public health activity of importance could be captured by linking it to an increased microbial count on a test. For example, in-plant personnel may identify something that requires immediate action, and by effective enforcement in plant, they can correct the problem before it results in a positive test result.

So while the focus here is on a data driven system, it was important to recognize the in-plant activities that need to happen and prevent positive test results. And Sherika was helping us to make sure that we didn't lose that.

So it might be helpful to include the

comment that not every important public health activity can be linked to increased microbial levels.

MS. KLEIN: Okay. Hold one second. Not every --

DR. TILDEN: Not every important public health activity can be linked with their impact on microbial levels. And then, for example, in-plant personnel taking actions to address unsafe conditions in preventing increased microbial test results. Does that do it?

MR. PAYNE: Ms. Klein, if you would like to reread the revised statement for the Committee's approval.

MS. KLEIN: Yeah. It is the understanding of the Committee that not every important public health activity can be linked with its impact on microbial levels. For example, in-plant personnel may take action to address unsafe conditions and thus prevent increased microbial test results.

Thus, while the Committee acknowledges that there is a need for information gathering to improve

the scientific basis of the programs, such as by gathering and analyzing data, the capabilities of regulators to enforce current regulations should not be limited.

MR. PAYNE: Dr. Shultz?

DR. SHULTZ: I'm just not quite sure what the nuance is with data somehow or the availability of data or the use of data limiting regulators to enforce current regulations. I would think if you took an action on an unsafe condition in a plant, it would result in a NR and that NR could trigger the whole regulatory process anyway. So I'm just not sure how data would limit it.

MR. PAYNE: Mr. Warshawer has a response.

MR. WARSHAWER: I'm just guessing that, and Subcommittee members help me if I'm totally off, that we want to avoid creating a culture where we wait for the data as opposed to acting on what we see. Is it that simple?

And so we're saying the in-plant personnel will act on what they see to enforce the regulations, and the data will help them do so

rather than the reverse where we can't do anything because we didn't get the data yet.

Is that what the Committee was trying to deliver?

MR. PAYNE: Dr. Tilden.

DR. TILDEN: Yeah, I think one of the Subcommittee members brought up the point that some of the health regs that were taken off of the list could result in unsafe conditions. And so, you know, there's the potential that something that's not on the list could be of a signature public health concern, and the way we have discussed it was, yeah, that's why we have in-plant people there and we need to focus and target. And so it's just acknowledging that there are other conditions that need to be addressed by in-plant people.

MR. ALVARES: This is Chris. I think I'm interpreting the recommendation from the Committee very similar to Dr. Warshawer, in that, you know, this isn't intended for the inspector to now say, okay, I don't have to do anything until enough NRs have been -- if there's a significant enough issue,

they should issue the NR, they should take actions. If that leads to, for example, a NOIE, although not in the PHRs, a NOIE is one of the other decision criteria that can then lead to a FSA.

So if it's significant enough, I think it's still, you know, the inspector should be enabled to take those appropriate steps, and I think that even that process is incorporated into our overall decision making criteria.

MR. PAYNE: Ms. Harvey has a response.

MS. HARVEY: Yes. Dr. Tilden and I did have a revision to that section on enforcement, which would address the part about inspection personnel, in-plant conditions can be dynamic. IPP may observe conditions that may lead to contamination and need to address it immediately. That was one of the statements that we had in there as well and can be put back in there if the Committee --

MS. KLEIN: Sorry. Say the second part. Plant conditions may be dynamic.

MS. HARVEY: IPP may observe conditions

that may lead to contamination and need to be addressed immediately. We may need to add something else to that, but we definitely had that as well.

MR. PAYNE: Thank you, Ms. Harvey. And our next commenter is Dr. Vetter. And just a time check, we have approximately 30 minutes before our public comment period starts.

DR. VETTER: This is just my opinion, but this bullet, what we're doing here with the PHR regs doesn't affect in-plant inspection. It changes nothing. So all of the daily inspections steps, the observations that are made whether they're scheduled or unscheduled, all the noncompliances that will be seen, that will go on and continue regardless of any recommendation that the Committee makes regarding these PHR NRs.

So I personally don't think this is necessary because it's not changing, there's no changes to that daily inspection system and what's expected of IPP in-plant. That hasn't changed.

MR. PAYNE: Thank you, Dr. Vetter.

DR. RYBOLT: I was just going to echo that.

I mean, I was reading it as well, and in the presentation, I think there was some confusion and Danah hit on it, but I think there was confusion that this changed the activities of the inspector, and it doesn't. So this implies that it does.

So I agree. I don't know that this necessarily needs to be here. I do get the mis-confusion and the fear that it's going to change the inspection activities, but none of that's changing.

MR. ALVARES: That's correct.

DR. RYBOLT: The activities in-plant is what I'm saying, yeah.

MR. ALVARES: Yes.

MS. KLEIN: So I think in the interest of time, we should kind of come to a consensus about whether we want to include this and move on. So it seems like we've had a suggestion that we not include this information. Is there a compelling argument to leave it in?

MR. PAYNE: Ms. Harvey?

MS. HARVEY: I forget exactly how we came to that yesterday but obviously we were making our

points, and I just forget the direction we were in, but we all agreed upon that.

MR. PAYNE: Mr. Waldrop?

MR. WALDROP: It does seem though that that sentence that says it is the understanding of the Committee that not every important public health activity can be linked with its impact on microbial levels, sort of comes out of that discussion we had at the previous one, where we talk about how the sampling program may not be robust enough to serve the decision making.

So I like that sentence and that seems to flow from what we were discussing earlier. We may want to keep that sentence, put it up in the earlier paragraph but then the rest, I agree, it seems to just be restating what is already happening in the plants.

MR. PAYNE: Dr. Tilden?

DR. TILDEN: I'd go with what Danah says.

MS. KLEIN: Okay. Sorry. Where did you think that should go, Chris?

MR. WALDROP: Question 3, second bullet,

second sentence.

MS. KLEIN: Right here?

MR. WALDROP: Yes. Because I think that's what you're really trying to talk about.

MS. KLEIN: Okay. All right. So let's go back down. Okay. I wish we were doing like Robert's Rules here.

So the motion has been made to delete this section.

MR. WALDROP: Second.

MS. KLEIN: All right. Okay. And it's good we have some time left because this might take a while.

Okay. So this was an additional area that we thought was important to discuss about data.

Data should be available for IPP personnel whereby they can easily determine whether noncompliance is trending upward so that they can use PHR analyses to be proactive rather than reactive. Facilities should similarly be able to review that data so that they can react internally. Consideration should be taken to ensure that this

data does not lead to selectivity wherein compliance activity is calibrated to remain below the cut point or alternatively push above a cut point to trigger a FSA.

The second bullet, prior to implementing the data posting plan, the Agency should convene stakeholders to identify the message for sharing PHR data that serve the goal of rapid and effective risk mitigation and process transparency while remaining contextually appropriate and not providing disincentives.

Did a lawyer write this?

MR. PAYNE: So any comments on either of the two bullets in the data section? Ms. Buck?

MS. BUCK: This is Patricia Buck. Is this -- was it the intention or discussion within the Subcommittee that the data plan would be part of the larger strategic plan that USDA is putting together? It's the first time you mentioned a data plan. So I didn't know where, you know, can you give me some guidance as to what you were thinking?

MS. KLEIN: Does someone remember? I don't

remember where the data posting plan language came from, but I know that the intention of this section was to discuss whether there was a way to be sharing data more publicly.

DR. REINHARD: Chris presented the data posting plan earlier in the day, and so this just references that the PHR analysis results, what information comes out of it, flows into that data posting plan, and I think the Subcommittee was saying that FSIS needs to, before they rule it out in that data posting plan, make sure that they go through the process of making sure all the stakeholders are together on what should and shouldn't be in there and how it works.

MS. KLEIN: Yeah, I mean this was an extensive area of discussion in the Subcommittee, and I think we've fairly come to consensus on a number of other items today, but if there's ever an opportunity to use the some members of the Committee agree language, we may want to do that. Some members of the Subcommittee felt strongly that NACMPI should be making a statement that public

sharing of data is important. Notwithstanding that, the data needs to be contextualized and not provide a disincentive to companies for participating.

So we may wish to wordsmith this so that it says some members of the Committee or we may wish to try and reach consensus on it, but I'm just trying to give you a little bit more, that this was a lengthy discussion in the Subcommittee yesterday. And this is the last thing that we have to discuss I think before the thing, so we can massage this if we need to.

MR. PAYNE: Mr. Warshawer.

MR. WARSHAWER: Has there been any indication that data public posting is not considered beneficial? I'm just confused.

MS. KLEIN: Yeah, I think the discussion that we had yesterday, and maybe somebody can help refresh my memory was we were talking about real time trend data so that not just the in-plant personnel and the particular plant would be aware of what's happening, but that outside stakeholders could also say, wow, have you noticed that it seems

that that plant is going up on this issue. And we were talking about whether that data could be made publicly available, and if so, whether you'd have to make it anonymous or whether you'd have to, you know, what you'd have to do to clean the data sufficiently so that it wouldn't be gathered and aggregated and delivered to the public 6 months later, but that it would be fairly contemporaneous with what was going on visible to the Agency and the industry.

MS. DONLEY: And I'll just add to that, that we saw it as kind of very win, win situation for everybody, number one is that the inspectors can see, to say, uh-oh, is there a trend going this way in some other plants that maybe I need to be looking at that particular issue, and that, two, industry within industry, that they can be saying that, uh-oh, there are some plants that are dealing with more of these, you know, just kind of focusing in on what's trending out there, and then they can zero back to their own processes.

MR. PAYNE: Ms. Harvey, you had a comment.

MS. HARVEY: Actually there were a couple of members on the Committee that were for this, and the only concern I saw was inspectors and other officials within the Committee not having access to the information as Ms. Donley pointed out, but with access to certain information, we agreed that it can be dangerous. And I recommended that it be left up to the administrators.

MR. PAYNE: Thank you, Ms. Harvey. Dr. Reinhard.

DR. REINHARD: First, I appreciate Sarah's position and where she stands and why she states it. I think that based off the fact that this Committee actually dealt with that issue the last time we met, and those recommendations have been turned into the Department for them to go forward and work on, it isn't necessarily beneficial for us to go back through and re-say what was said before about either all or some of the Committee members' position on data sharing in and of itself.

So I think if this language, and we worked on this a little bit, is close enough for us just to

go ahead and move on, because I know the Agency's already working on last Committee's recommendations. I think that the point has been made for the record actually very well by all parties.

MR. PAYNE: Thank you, Dr. Reinhard. Ms. Buck?

MS. BUCK: This is Patricia Buck, and I would tend to agree with Bob. We did look at this issue the last time around. I think it's really important that we have access to all different types of data.

I think though when you're dealing with data, from what I understand, you have to have it in context and it certainly has to be in sync with the strategic plan that USDA has put out for improving its data collection, analysis, the whole shebang.

So if this language is acceptable and if the Subcommittee thinks it's important to draw more attention once again to the importance of data as we move forward with improvements in food safety and food safety inspection, I'm all for leaving it in there.

But, as Bob pointed out, we pretty much looked at this and we definitely need to have the stakeholder meeting that the recommendation is calling for. I mean that was suggested in the last comments from NACMPI, and we haven't heard anything. This comes back to that issue of the follow up is really important I think for this Committee.

MR. PAYNE: Thank you, Ms. Buck.

MS. KLEIN: I have a horse in this race. So I don't hear what the will of the Committee. Is it to leave it in as it is or take it out? I know I would vote to leave it in, but --

MR. PAYNE: Dr. Tilden.

DR. TILDEN: I think what I heard is it's okay as is, leave it in but let's not belabor the point because we spent a whole meeting on it before.

MS. KLEIN: Yes.

MR. PAYNE: Does this represent the consensus of the Committee? It shows affirmative.

MS. KLEIN: Great.

MS. BUCK: You might bold convene stakeholders.

MS. KLEIN: Right. Okay.

MS. WILLIAMS: Do you want to make all the corrections?

MS. KLEIN: I want highlighted the CDC, that one. Okay.

Do we need to scroll through this again and make sure that we're okay with everything?

MR. PAYNE: Just on final check for Committee consensus.

MS. KLEIN: Is this large enough? Do people want me to make it larger? Good.

MS. DONLEY: I'd just ask that FSIS, whoever it would please, before they print this out for everyone, insert the questions, the actual verbiage of the questions onto this document.

MR. PAYNE: The questions will be inserted. So we will have copies of this coming soon, of the Committee's final recommendation on issue number 2.

And we are at 2:00. So I'm looking to the Committee Chair, do we do a break or shall we start the public comment period?

UNIDENTIFIED SPEAKER: Break.

MR. PAYNE: Break. Break is the consensus. So resume at 2:15, 2:05, 2:05.

(Off the record at 2:05 p.m.)

(On the record at 2:12 p.m.)

MR. PAYNE: What we're doing now is for the last Subcommittee's recommendations, that the whole Committee had come to a consensus to, we've added the questions to that document. We will have that printed out, copies made before you leave.

So, Mr. Almanza, I think we can start our public comment period, and the last I checked, which was about a couple of minutes ago, we don't have anyone who signed up to make a comment.

Okay. We have Scott Goltry. You had signed up --

MR. GOLTRY: This morning.

MR. PAYNE: Okay. Mr. Goltry, feel free to come up.

MR. GOLTRY: I'll stand right here.

Hello, I'm Scott Goltry with the American Meat Institute. Thank you for allowing me to provide comments to the Committee.

My comments will focus on the Veal Sanitary Dressing Subcommittee. We appreciate the realization by the Committee of their limited technical expertise related to veal processing.

I applaud this Subcommittee's request to have industry members participate and provide technical input that was pertinent and within the scope of the charge of the Committee.

In the future, if technical expertise outside of the Committee is needed, invitations should be made in order to aid in the Committee's deliberation.

Even though there is a perceived issue based on the limited data, there has not been a known outbreak related to veal. This could be related to the unique, intended use of veal products. Although based on new data that was requested by the industry, this data now highlights the differences between within the beef market class. AMI members which produce over 90 percent of the veal in the United States, continue to be engaged to continue the concerns of this data.

Thank you.

MR. PAYNE: Thank you, Mr. Goltry. Any other comments? The floor is open.

Any comments from the Committee members?

Mr. Almanza, I'm not seeing any comments, further comments. I'll turn the meeting over to you.

MR. ALMANZA: Okay. Thank you.

Okay. Well, I have some prepared remarks but before I go into those, I want to talk a little bit about the exchange that I saw here and just the importance of what this Committee does because some of the difficult discussions that you all were having are difficult discussions that we have in the Agency. I look over at Dr. Shultz there, and he's probably more familiar with that than most of the other Committee members and certainly I was watching just the body language between Dr. Shultz and Chris and they'd nod at the same time and shake their heads at the same time.

But, it's one of those things that when we set these charges out, we know the dynamics that are

involved, and so the things that you all bring, you know, it's kind of like light bulbs go off, and we're thinking, huh, well, yeah, that sounds like a good idea, and then the more you discuss it, you get to the point to where we were when we were discussing it within the Agency. And so I would say that this is extremely valuable, and how Dr. Hagen and I and certainly everyone that looks to this Committee for guidance, we thank you. We thank you for your participation because we know that you have lives. We know that while you're away from what you're doing, like your inbox is going to be just a little bit bigger when you get back to your office, and somebody isn't doing your work for you. So we appreciate that. We appreciate you taking the time to do this for us.

And as I said yesterday, these are difficult issues, and we don't expect everyone to agree with everything. In fact, if you did agree on everything, we'd think that there was something wrong with how we put the Committee together.

And so we asked you to have an open and

honest discussion, and by all accounts, at least what Phil tells me, that happened, and sometimes the discussions like while I was here, can be just as important as the recommendations that you make because everything that's said here is captured and that is relevant to the decisions that we make going forward.

I hope the process has allowed you to come to a better understanding of these issues. These problems aren't going to be solved overnight, and we're going to continue to grapple with them. Some of them may be revisited in future NACMPI meetings, and it's important that we're all on the same page, so that we continue to have a well informed discussion.

So it's through this discussion and the debate that we really hash some of these things out, and I hope that you all found this to be beneficial as we do.

What will happen next is my team and I will review the recommendations. Taking a quick look at them, I think there are some very constructive

suggestions. Some of the research on pre-harvest risk in veal, building on existing partnerships, developing clear, concise guidance material for small establishments, using data to fully realize the goals of HACCP and making sure that data is transferred in a timely manner so that it's most useful.

And, that was really one of the things that struck me in the discussion that you all were having about data, and the different data sources and the different data streams and how the challenges that we have and how we can utilize that in a way that is uniform and consistent and that means something to or the same thing to everyone because I can tell you, I mean you go in some of these plants and some plants are very good after the amount of testing they do, about the data that they keep, and then you have another extreme where they just don't have a lot of data, some of them for very good reasons. Some of them just can't afford it. They're very small plants, but there's some that when they know that we're going to be looking at their data, they

just don't test. So we have everything in between, right.

And so it was interesting, the discussion that you all were going, well, here you have this but we need that data but how do you know that the data that Plant A and Plant B and Plant C are generating is going to be able to be captured in a uniform way for us to be able to do anything with so that it means something to each one of you or what you want it to mean to you in a way that protects public health and is really aimed at food safety.

So very, very good discussions. I'm really pleased that I heard that.

So in closing the meeting out, I want to thank you again. I think we've made some real progress here, and I look forward to building on this in the future.

So on behalf of Dr. Hagen and I, thank you all.

(Whereupon, at 2:21 p.m. the meeting was concluded.)

C-E-R-T-I-F-I-C-A-T-E

This is to certify that the attached proceedings in the matter of:

NATIONAL ADVISORY COMMITTEE ON
MEAT AND POULTRY INSPECTION
PLENARY SESSION
Washington, D.C.
January 17, 2013

were held as herein appears, and that this is the original transcription thereof for the files of the United States Department of Agriculture, Food Safety and Inspection Service.

_____

TIMOTHY J. ATKINSON, JR., Reporter
FREE STATE REPORTING, INC.