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NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

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SUBCOMMITTEE 2

ISSUE 2: DATA ANALYSIS

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Patriots Plaza III
355 E Street, S.W.
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I-N-D-E-X

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

(1:25 p.m.)

MS. KLEIN: Do people feel good about that? All right, set the timer for 20 minutes. Let's go.

MR. ALVARES: Okay. So I'll keep my answers short, so we can get as many questions asked as possible.

When we implemented PHIS, there were some changes to how we got the mandates. One of the basic ones was some of the mappings of regulations to tasks changed a little bit in the system, so I talked about how -- on a higher level, things like that.

And because of that change in the data, it didn't make sense to keep calculating the same way because of some of the regs -- and so we had to, at the very least, kind of re-map everything in terms of the data analysis. But I think they're also written and part of that is the process-- the Committee took a Committee Review in our strategic data analysis in 2010. And this is the time when we should have a Committee Review, as well, or -- for

an expert group to come in and weigh in on this, so we decided this was the right time to also meet with NACMPI or whoever, and the review will be done.

And then the other part, I think what sort of led the way to doing this is that with the data we have now we feel that we can conduct better analysis. The first time that we did this, when we looked at the 62, we weren't very successful at being able to narrow down on this to the most informative ones, so we had -- what we kind of relied on was correlation analysis, Quality 62, or associated with *Salmonella*.

Now I think we've got more data and more -- analysis to look more at regs individually -- as well as *E. coli* and *Listeria*, we can narrow it down. So there were some modifications to it, but -- to our process and our methods, but in a lot of ways, it's an update that needs to be done driven by changes in --

MS. DONLEY: And just as a comment to the Committee and the audience is that -- and I understand what you did. You know, I would just

offer that I would feel more confident if FSIS frankly had a more robust sampling program and was working from a more robust sampling program.

I'm a little concerned about just working off of these -- PHRs that can be kind of documented back, if you will, to a positive sample, because I just don't think our sampling program is robust enough. That's my concern.

DR. TILDEN: And one thing that might be helpful, too, is I think all of us maybe have some -- minutes of where we're at on these. They might be able to get that out on the table and then we can figure out where to follow up. Because it will come out sooner or later, so it's like it might be more efficient just to get everything done, to put it out there.

MS. DONLEY: Each are high-level things.

DR. TILDEN: Yeah. What are the top three things that you want to say?

DR. REINHARD: Okay. I think it's great that FSIS is trying to use the data that they have to make improvements, that's my high-level. And I

think the important thing is you draft out what the Agency is going to do and you go forward as you're going to need to use what you find to change what you do continuously. That will be an ongoing process.

And so, you know, there will come a time where you don't want to be just doing it one way and whether three months' data is sufficient, and when you do the statistical analysis, I have some concerns around that. And what you put together to determine which NRs you wanted to, at this point, call public health regulations that you're going to monitor -- for resources. But that being said, it's a great start, it's a process, and we'll get through it as we go.

DR. TILDEN: Generally, to what Bob said --

MS. KLEIN: Remember to say your name.

DR. TILDEN: Oh. John Tilden, Michigan Department of Agriculture.

I do think that this is a form of public health surveillance, so I would recommend that we can benefit and strengthen the program by using many

of the criteria that are used to determine the usefulness and cost effectiveness of other public health surveillance systems. And there are defined criteria that CDC has established and updated over decades of work that I think could help inform FSIS as they move forward.

I think one of the critical things is to define to what extent are we using this system to improve implementation of the existing program versus to prevent human illnesses. So that's why I asked the question about performance-based programs versus risk-based.

Performance-based, as I understand it, is trying to make sure that the program is being implemented as envisioned. And so non-compliance means it's not happening the way we want the current program to work.

Public health-based would say how do we get at what's really causing unacceptable contamination levels. And those two may not be the same. And the same non-compliance may be better at one than the other.

And I applaud FSIS for trying to start teasing that out and as you say, failures (ph.) will help over the time, but we can start that process at better defining which of those NRs really helps us with implementing the existing program versus which of them can we say really help us prevent contamination.

DR. MARCY: John Marcy with the University of Arkansas.

I'm glad you've reworked, you know, from the 62. I know it's a lofty goal. I hope, going forward, that you have plans for validation.

I can see in your Step 2, where you took your public health regulations and talk about how they relate to control of those four steps, but it's not clear from your work how it relates to the pathogens of interest. Now, particularly, the *Salmonella*, as it crosses all species and then the O157:H7 or other pathogenic *E. coli*s, you know, that may be more species specific, and the *Lm*-specific ready-to-eat.

MS. HARVEY: Sherika Harvey.

I would also like to say that I'm happy and I'm proud of FSIS for coming together and getting this done. And I think all of the scrutiny behind this is really -- it's like we're here for nothing. But obviously, FSIS is coming together and definitely making strides, so I commend the Agency on that.

But with doing all this, I'm hoping, as well, that there is a plan in place to make sure that this is followed out and this plan is definitely executed because, I guess, it was big to go from the 64 to the 32, but making sure that 32 is where, you know, it needs to be and that the check system is there, pretty much, just to put it simply.

MS. GAPUD: Veneranda Gapud, Process Management Consulting.

Again, I concur with everyone, again, recalling you for doing lots of stuff already for us. In fact, you have -- you know, this is really a lot of work for you to do and again, that's great, you know. And again, we are here, we're talking about this thing, but again, you laid down the

foundation already and how -- where we can go around and that's really wonderful.

Again, I think there should really be a follow-up. In fact, to me, I'm quite concerned when you talk about modernization -- you know, the proposal that you have, which I, myself, of course, I used to be with a poultry company and I don't know exactly what is really happening with that now, so hopefully, later on, there will be more follow up, or asked to be more engaged and we learn more on what is really happening with the Agency.

But again, thank you so much for all of your great work.

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

Yeah, I just echo what Dr. Tilden just said -- in the regulation is seldom and it should be performance-based or it should be public health-based. You know, either way, we have -- on that.

And the second comment I have is, basically, the criteria for the public health outcome, there's definite need, I mean, more

specific in terms of different species or product.

MS. KLEIN: Okay. Yeah, I don't know that there's anything new to be said, so I think we have identified, actually, a couple of good jumping-off points for our discussion now. We still have time left on our clock for -- if there were specific questions for Chris on the data, if we want to do that, and then we can --

DR. VETTER: I just wanted to specify that I have permission that --

MS. KLEIN: Sure.

DR. VETTER: Representing -- I just had a couple of quick questions. The sole purpose of this is to be one, and I say one, of the triggers for scheduling FR typing (ph.) FSAs, right?

MR. ALVARES: Right.

DR. VETTER: Is there any other purpose that they are thought about being used for the in the future or is that the intent?

MR. ALVARES: Well, the other purpose that it will be used for, when it comes online, is for Hazard Analysis Verification. So that's a new task

at the Division for PHIS. It's not being used right now as far as decision criteria informing. There are some pilot tests going on with it, you know. But we haven't fully implemented that task and so we're not applying this criteria at the time. But I think we had stated, back in 2010, when there was a lot of integration on -- that was one of the other tasks that was -- they're the only two we've identified.

DR. VETTER: I only have two other -- one question, one comment. You're looking at *Salmonella* in raw.

COURT REPORTER: Can you keep your voice up a little bit?

DR. VETTER: You're looking at *Salmonella* positives in raw product samples, correct?

MR. ALVARES: Yes.

DR. VETTER: What about RTE product samples?

MR. ALVARES: I'll double check, but I think that they left it in --

DR. VETTER: I don't see any mention of

that. I see *Lm, Lm, Lm,* but --

MR. ALVARES: Yeah.

DR. VETTER: -- I don't see any mention of *Salmonella*.

MR. ALVARES: I'll double check and I'll see if I can get you the answer --

DR. VETTER: Because I know it happens less frequently, but we do have it.

And then my last comment would be that you definitely need to consider bringing the non-STEC into this criteria because the current expectation is that if a plant does receive a positive non-STEC, that they reevaluate their HACCP plan, because most of them are not sampling for that; they are sampling for one toxin in an indicator, so to speak, and that's what they're using to verify and validate their HACCP plans.

But should they have a non-STEC positive, they're expected to ensure that those would be infected against that, as well. So I think, because of those expectations,that must be definitely brought into this.

MR. ALVARES: Anyone else?

MS. HARVEY: Can I respond to that?

I don't know how much you were speaking of *Salmonella* in RTE, well, *Listeria monocytogenes* -- and the focus isn't on RTE products, but -- because of how they have to be controlled and carried, that's the reason that it is final, so I don't know how much you'd be able to get from the analysis of *Salmonella*. It's pretty much just --

MS. GAPUD: But I concur with Dr. Vetter about *Salmonella* also in the fully cooked product.

DR. VETTER: We sample --

(Simultaneous speech.)

MS. HARVEY: I just -- they didn't get that far with it.

MS. DONLEY: I have one question. It's an easy one, I hope.

Chris, when you say with the four criteria, establish and make a HACCP plan of critical control points, is the hazard analysis included in that? You don't specifically say that but, you know, it's critical that the plant, the establishment, has a

good hazard analysis done for the HACCP plan to address the hazards.

MR. ALVARES: I believe that it is included in that part of the HACCP.

MS. HARVEY: Yeah.

MS. DONLEY: Okay, all right. I just wanted to make that clear because what you said and what was in the earlier materials, is you refer to the hazard analysis specifically at times, but -- and for purposes of our discussion, when we talk about HACCP related things, it means a hazard analysis has been done.

MR. ALVARES: Yeah. And in terms of regulations and non-compliance, if there's a non-compliance related to hazard analyses, that could inform the public health regulations -- that way a trigger has called a hazard analysis verification, which isn't -- we need to call it a mini-FSA, but it's not the scope of an FSA, but it's -- system and individual task.

DR. TILDEN: And since we're talking about FSAs, have you guys looked at, Chris, the impact on

the number of FSAs that would be scheduled if you move to the system?

MR. ALVARES: We have to some extent. So once we get to a set of public health regs, we need to define cut points and use that for the selection process. We have a finite amount of FSAs that we can schedule in a month. It's a lot more than what we can trigger before -- a lot of it is routine FSA.

But we want to make sure that we're not overwhelming the system with for-cause FSAs, so we are really trying to pin the limit of our resources, identify the highest priorities. We don't have a quota or anything like that where we want to schedule, you know, just for example, 20 FSAs for this criterion -- but what we want to do is try and define cut-points that identify -- in a manner that allows us to actually act on that to decide --

DR. MARCY: John Marcy from the University of Arkansas.

Following up on that, when these for-cause FSAs are done, will you have a mechanism in place to follow up to see, you know, if they correlate with

what you expected them to find or if there is no, you know, direct relationship?

MR. ALVARES: In terms of corrective actions or --

DR. MARCY: You know, you had a certain reason for it to come up for a for-cause, which are -- you know, because the NRs there are substantiated.

MR. ALVARES: The analysis of FSAs is pretty complicated because that's just the nature of the FSAs. They're big. Text is kind of -- they're sort of NRs on a much, much greater scale, as far as documentation.

We are moving forward with converting our FSA process to PHIS, with -- now would you believe that that's going to allow us to do a much better link, the findings in the FSA, with other outcomes and plants, and monitor it on an ongoing process.

So I think the mechanisms are coming into place to do that. I don't know that we have ability -- I can't tell you that this is our process for evaluating each FSA to determine whether it has the

intended effect in terms of correcting maybe PHRs, but I think that that's something that we'd be interested in analyzing.

DR. MARCY: Would your goal be to put the FSA on a more objective versus subjective basis for data analysis?

MR. ALVARES: We would. Well, it's still -- on the one hand, my perspective is -- I would like as much quantitative, categorical types of data as I can.

DR. MARCY: Right.

MR. ALVARES: From an enforcement regulatory perspective, they need to document, in their own words, what they're observing and that's hard to do in the check list, so we're trying to strike that balance between documentation and analytical information.

DR. MARCY: Okay.

MR. ALVARES: But yeah, to the extent that we can identify things that can be translated into categories, that's -- it's not, kind of, a PHR-related project, but it's a more general --

DR. REINHARD: So Chris, you told me in here, I know, but I don't remember seeing small type, I think. When you did the analysis of the NRs for plants that had a positive -- and let's take *Lm* as an example.

MR. ALVARES: Okay.

DR. REINHARD: You used NRs and positives at six months, January through June, and in that you would compare NRs across establishments. The first can only produce ready-to-eat products, correct? Or would it be across all establishments?

MR. ALVARES: I believe that the analysis was actually all establishments.

DR. REINHARD: Okay.

MR. ALVARES: I think where the analysis -- is sent in and those -- I'm seeing *Listeria* is only in -- they're the ones that are likely to be selected for that outcome. I think the other outcomes reach the other types of operating characteristics. But in the end, what we envision is that the set of public health regs compasses the multiple pathogens -- those are going to apply to

all establishments and so in some ways, it's all coming back to sort of a national level of comparison for analysis.

DR. REINHARD: Yes. But I think one suggestion we probably can make is the data would be more accurate in determining whether or not *Lm* is likely to occur, right? If you look at the plants that are kind of -- what NRs are they getting and did it include the entire population? Because it actually dilutes, right, potentially, the significant NRs that are driving the *Lm*. Use that example.

I want to continue on *Lm*. Off the top of my head, I don't know, but the Agency pulls, like, six or seven thousand samples for *Lm*, annually, right, something like that? And you get about 25 positives annually. Those positives could be from the same plant and often, they are. Multiple positives, one plant.

So in the six-month period, the first -- the January to the 30th of June, do you remember how many plants had an *Lm* positive? Because I'm

assuming the population that you're looking at as cause, is very small: eight, twelve, maybe. I don't know, fifteen it could be, I guess, depending. Do you recall?

MR. ALVARES: I don't.

DR. REINHARD: Okay. And you might have said that in here, too. I read it so fast. I didn't --

MR. ALVARES: I don't think we have in the report anything about how many plants are in this, sort of, positive -- but, you know, the Committee recommended the best information that we could.

DR. REINHARD: Okay.

MS. HARVEY: Yeah, I agree with him. That would be very helpful.

DR. VETTER: Just to piggyback on what you said. The other thing about *Lm*, even more so than *Salmonella* in RTE, because they represent two different types of product, loss of process control, but are you looking at, like, *Lm* totals or are you separating that out as far as environmental kin**ds** -- because sometimes we just get plants that have

environmental positives and don't ever have any product contact with --

MR. ALVARES: So I'll double check that. I think it was just the product process.

DR. VETTER: Just the product process.

MR. ALVARES: Yeah. But I'll double check that.

DR. REINHARD: I thought I read it, product to contact positives, too.

MR. ALVARES: Okay.

DR. REINHARD: I thought I read product and to contact --

DR. VETTER: I didn't get any of this stuff beforehand, so it's in here.

DR. REINHARD: I don't recall exactly, because there was a lot of -- but I thought that was in there. But the environmentals are. You can't use them because you composite them. And so I'm going to stand on my soap box. It would be a lot better if you didn't composite the environmental samples. We would get better information, trying to look for causes, et cetera, et cetera.

MS. HARVEY: Yeah.

MS. KLEIN: Okay, let me take a moment just to kind of tell you what I'm hearing.

It sounds to me like we are identifying three broad issue areas that might be a useful way for us to kind of dump our buckets of information to give to the Agency.

In no particular order, the first appears to be a data bucket and that would be concerns and suggestions that this Committee has with regard to the way the analysis, the data analysis, was done and the way that it should be done going forward. And so in that discussion, we would decide where we come down on issues such as the ones Bob just talked about.

The second bucket might be kind of these -- the bigger issues that John identified of what is your goal here, are we doing public health, you know, public health-based versus performance-based and what is our recommendation around that.

And then the third bucket would be looking ahead, what are the plans for validation, what are

the plans for, kind of, execution and how do you intend to fold in changes to the regulatory system that are occurring, such as poultry? Because I agree that that's going to be a huge change and we need to know how do you intend to fold that in here.

So those are the buckets that I've kind of identified, but tell me if that doesn't feel right or if something significant has been left out or doesn't fit neatly into one of those buckets. Obviously, I wasn't -- I didn't name everything that would go into each, but that was just kind of the frame that I thought made sense.

MS. HARVEY: Can you repeat that last point about folding in? How would that --

MS. KLEIN: Oh. You know, how they intend to, once new regs are announced, for example, like the poultry proposal, once that's finalized, what effect will it have here and how will that be -- what's the word that I'm looking for? Folded in.

MS. GAPUD: What will be the impact?

MS. KLEIN: Yes, the impact of the new regs on this, that's being compiled now. Does that make

sense?

DR. TILDEN: There's another way of saying that. It's part of how is this part of a continuous process improvement?

MS. KLEIN: Yes, thank you.

DR. TILDEN: So you have to anchor it in something to make sure that your evaluating, is it working as you go forward?

MS. KLEIN: Yes, yes.

DR. REINHARD: And I have someone -- who wants to do that with the reviews annually, et cetera, et cetera.

MR. ALVARES: Yeah. And I think, just to use the proposed rules for an example, I think what we would have to do is go through the same kind of process that we laid out this morning. We'd have to use our criteria, compare them to the regs, select the regs that we think are good candidates based on our understanding of non-compliances and then analyze, in that case, probably, most likely, *Salmonella* and hopefully at that point -- and then use that to select the relevant regs and implement

that in the next --

MS. DONLEY: I just kind of noted and -- this hole through the bucket of the performance standards versus public health standards. Actually, your Step 1, Chris, says four criteria have been identified for selection of, well, public health regs.

But do we want to -- really, that's a big issue is what is the purpose of this? Is it performance standards or is it public health, really? Is it for regulatory purposes or -- is the goal regulatory purposes or public health purposes?

MR. ALVARES: So I guess maybe I'll make just a brief comment and it may be something more for the Committee to talk about.

To be able to link it directly to public health outcomes, I think it's particularly -- I'm not sure we know or have identified a good way to do that, particularly when we're talking about -- I think, at a very broad level in terms of estimates -- so for example, estimates of prevalence of *Salmonella* in poultry relative to illnesses in the

population of *Salmonella*. But how do we link it, then, to which establishments do we go and do FSAs at; that, I think, is something that's really hard to do right now, just based on CDC data.

Although that's our, kind of -- our endpoint is public health and preventing food borne illness, the way that we're trying to get at that is to identify the regs and define bacteria that define or that they point to loss of process control, that we think often leads to product that could result in food borne illness.

So I think what we've tried to do is focus more on what are the regs, what are the criteria that are more about loss of process control. That's, I think, something where we could look at in the establishment and get a better of understanding of when we should go there and whether we should go to this plant versus that plant.

MS. DONLEY: Okay.

DR. REINHARD: NRs contain multiple regulatory sites, potentially. Did you look at all of those? And so that NR could have five sites, so

theoretically you looked at it as five NRs and what's the regulated -- is that correct?

MR. ALVARES: Sort of. It's more like that than it was in the first W3NR version. So in terms of calculating W3NR regs, the old way we were doing it was if the non-compliance cited any W3NRs -- and it could be one or it could be multiple -- that counted as a non-compliance to the new reg, one non-compliant task.

And if it's not entered as one task performed, where the public health reg was pathable (ph.) to that task. So it was really counting of the tasks done. If they perform a task where they could verify the W3NR and was there non-compliance, and the ratio of those two.

The problem or maybe the challenge in the original is that when they performed the task, we just assumed that, in verifying all of the regs that were applicable to that task, therefore every task where a W3 reg was applicable was counted. Now with PHIS, when they go to perform a task, even if the task is fully compliant, that no non-compliances

were identified, they still check off which regs they verified.

And so now we know that if 310.22 is a PHR, we can say okay, they verified it this many times and they found a non-compliance in that specific reg this many times, so we can calculate the ratio at the reg level.

DR. MARCY: So you're saying they're tracing the denominator?

MR. ALVARES: Yes. Well, so now, let's say they do a task and they verify three W3 -- or PHR regs in that task.

DR. MARCY: Right.

MR. ALVARES: And one of them is not compliant.

DR. MARCY: But only one?

MR. ALVARES: One, yeah. Only one.

That it would be, for that reg, you count once. But for the other regs there would be, sort of -- I guess I'm not explaining it real well, but for the other ones, it wouldn't count against the plant because it was -- it will count is a zero

because it was verified but it was compliant.

DR. MARCY: But it's still going to the denominator?

DR. REINHARD: Correct. That's the way --

DR. MARCY: Okay.

MR. ALVARES: But if they do a task and there's a public health reg that's outgoing and they don't verify it, that's not going to count.

DR. REINHARD: Does everybody know what a task is, on the Committee?

MR. ALVARES: No. Can you do it, briefly?

DR. REINHARD: It's 10 seconds. So the Agency -- do you want to tell them?

MR. ALVARES: No. Why don't you tell them?

DR. REINHARD: Okay. The Agency --

(Laughter.)

DR. REINHARD: The Agency gives the inspectors a set of verification procedures to execute on a weekly or bi-weekly, however they do it, basis.

MS. HARVEY: Daily.

DR. REINHARD: Daily. It comes every day.

You have stuff for each day, but -- they send it every day now, too?

MS. DONLEY: There are daily tasks.

MS. HARVEY: Daily tasks.

DR. REINHARD: And weekly tasks, okay. And so they would go perform that specific regulatory oversight within the establishment that it was assigned to.

DR. MARCY: But they can do additional tasks, as well.

MS. HARVEY: Yeah.

DR. REINHARD: When they do that task, they then complete whether or not it was compliant, if an NR was issued, and they do the NR and all the regs get cited and that whole deal.

In addition to that, the inspector can do tasks that they have determined need to occur. And then they would enter that into the system, PHIS, and say they did this task and this was their regulatory finding. So it's almost like a specific point audit check. So go see that the light is on. Yes. Have they complied or not? But whatever that

-- it's that type -- so they would have a task to go review the plant's implementation of monitoring --

MR. ALVARES: Yeah, I think that's a good description and I think it may go to handling tasks as they're doing that activity, there could be a number of regs that are applicable to the handling and when they come back to document it, they would check off which regs they actually verified.

DR. REINHARD: And inspectors do hundreds of tasks, right?

MS. HARVEY: Yeah.

DR. VETTER: Yeah, there are a lot.

MS. HARVEY: There's routine and there's directed task.

DR. VETTER: Yes.

DR. REINHARD: Correct.

MS. GAPUD: And what are you going to do -- sometimes there are some NRs issued to the establishment and then I think the establishment, they are given the opportunity to challenge that NR, so what would we do with that if the establishment challenges the NR that was issued?

MR. ALVARES: So that's -- you're right. That's a difficult -- it's a bit of a challenge because on the one hand, if we were to exclude -- this is sort of the thought process that we went through with this.

When it comes to appealing non-compliance issues, if we were to exclude those because they're under appeal, there's a concern that that could be used to try and avoid it, so you appeal any NR that has a public health reg cited and that keeps your rates low and keeps you from getting an FSA.

So on one hand, we're concerned -- we want to try to prevent that kind of behavior. On the other hand, we recognize that if we include them and the appeal is upheld, that we may be counting something against the plant that -- so we don't know if there is a really clear -- I think we have to strike a balance between the two.

There's no -- to me, there isn't an obvious way forward there except to say I think we're going to try to count them and probably rely on the district and the inspector to make a final decision

as to whether to do an FSA. If they really feel that there's some -- NR is under appeal and let's wait and see where those play out and if they're upheld, they may get selected again in the next month. Those are the kinds of things I think may be more judgmental as we go through the process.

MS. HARVEY: I think it should be up to the DL (ph.), as well.

DR. REINHARD: I think it is a tough situation and unfortunately, for the establishment, I believe the Agency has to assume the NR is valid until the appeal is granted and use that in the process.

And I have tracked W3NRs since Dr. Raymond had his first meeting in 2005 and it doesn't have a huge impact as those appeals are in and they roll out. It doesn't directionally move the data. If it's a regulatory non-compliance that an FSA is already automatically scheduled, right, that can occur and there could be an appeal. But it isn't very often that that does occur in that manner. It's the way I think.

And so people -- everybody wouldn't be happy with that answer, but I think that is the appropriate answer.

MR. ALVARES: And I don't know the exact rates, but I think that the percentage of appeals that get overturned is --

MS. GAPUD: Not much.

MR. ALVARES: Yeah. It's not -- I mean, it's not -- it does happen, but it's certainly less than 50 percent. I don't know if it's in the 10 percent range or what exactly, but because I think the majority of them tend to be upheld, our sort of inclination is you've got to go one way or the other; let's include it.

MS. HARVEY: Well, I think -- yeah. Because it would be another problem if it's not.

MS. KLEIN: Okay. So do we want to start tackling the questions that were posed to the Committee?

DR. TILDEN: I'd recommend we do that first because we might be able to knock out a couple of them and then, if we get into philosophical

discussions, we've at least gotten some things done, yeah.

MS. KLEIN: Okay. So then let's just go in order.

So the first: Does the Committee have comments regarding the approach that was used to select the PHR list?

DR. TILDEN: And we don't have to pay to dump everything at once, right?

MS. KLEIN: Right.

DR. TILDEN: If we've got multiple comments, we just maybe do one and give everybody a chance to get one out?

MS. KLEIN: Yes.

DR. TILDEN: Because that's my case. I've got multiple -- I don't want to hog the conversation.

MS. HARVEY: Go ahead.

DR. TILDEN: My first one is I don't think it's a reasonable assumption that all the data is randomly distributed. So I don't think using it to test is appropriate for all the data.

So for example, taking *Listeria monocytogenes* from a firm, there's a reasonable expectation that anything from that facility is likely to be clustered or linked in some way. So you can't -- I think we've been doing ourselves a disservice by just dumping it into the greater pool and analyzing it like it's not linked data.

So I think you almost need -- and this goes back to the public health surveillance principles, is if you've got multi-stage sampling, make it explicit. Just say this is what we do at the program level and this is what we're treating as random data, and then this is data that we know, at the facility level, is likely not to be random compared to other facilities, so we have a second stage of sampling and this is how we handle that data.

And I've talked with a number of people. I think people would feel comfortable because then you say okay, that's how we're getting at that; we've got a problem facility that's got an issue and how do we not let go of that or lose that information.

DR. REINHARD: Other comments for this bullet, or for this question?

DR. MARCY: Yeah, I've got a comment on the assumption that, you know, you look at -- you know, take *Salmonella*, for instance.

You looked at comparing these NRs in plants, establishments, that had a single positive *Salmonella* in that period versus plants that had zero. Now, we can assume that they took a test from the plants in the control group, there was a test that was negative --

UNIDENTIFIED SPEAKER: Right.

DR. MARCY: -- versus they weren't tested.

UNIDENTIFIED SPEAKER: Correct.

DR. MARCY: Okay. That's not obvious.

The second part of that statement is that, you know, what I follow from that is you're forcing that assumption that there's a link between the regulations and these pathogens. I know you want to get there. Is that -- a correlation? You know, are you forcing correlation by that criteria? I understand you've got correlation and also, we all

know that that's not cause and effect. So I'm hoping that we can get to cause and effect.

DR. VETTER: To add to what Dr. Marcy said, I think we do have some instances of cause and effect but, for example, you've got specified risk materials --

DR. MARCY: Yeah.

DR. VETTER: -- that you're looking at in comparison to *Salmonella, E. coli* and *Lm* data and they have nothing with --

DR. MARCY: Yeah. One of your examples in your PHRs was --

DR. VETTER: And so that's where I think you've got --

(Simultaneous speech.)

MS. DONLEY: And that kind of links with what I was saying, too, was some of my earlier concern is that it's just relying -- is it relying too heavily on a sampling program? Does the sampling program identify all of the concerns and the SRMs are one where it won't.

DR. MARCY: Correct.

DR. VETTER: I think it's a definitely good thing to consider and would be a way to look at it, but I think you've got to have maybe a subset or an addition in those parts of that, possibly, and those that don't relate --

DR. MARCY: Yeah, I have no doubt you've got an object in mind, but --

MR. ALVARES: So I mean, certainly I think I want to kind of not count it too much just because I think the Committee just would like to get all the feedback. With SRMs, I think one of the thoughts there is not so much that SRMs in the product are going to result in *E. coli, Salmonella,* and *Listeria*, but that NRs related to SRM are indicative of either a failure to follow procedures or --

MS. DONLEY: Loss of control.

MR. ALVARES: -- yeah, loss of control. That, you know, if it's happening multiple times or it's happening over -- it becomes more of a systematic issue, then it can expand into other areas that will result in *E. coli*.

So it isn't necessarily that -- I mean,

maybe one of the things we need to do is better lay out why we think each reg has an association. But I think that it's maybe more indirect. It isn't so much that an SRM is going to cause these pathogens, but that it's an issue about how the establishment is processing.

DR. VETTER: So just to clarify, using SRMs as an example. If someone had a spike in SRM NRs, but they had no positive *Salmonella*, no positive *E. coli*, no positive *Listeria*, how would that trigger an FSA or would it?

MS. DONLEY: Not with what is laid out in here right now.

DR. VETTER: Or am I misunderstanding?

MR. ALVARES: If they had a spike in SRM NRs to the extent that your NR rate was high enough to be above the cut-point and it would be -- we wouldn't just look at SRMs, so it would be all EHRs (ph.). There are two or three that are SRM related. If the overall NR rate is high enough, they could get an FSA. And it wouldn't necessarily mean that they had *E. coli, Salmonella* and *Listeria* positive;

it could be negative for that. But what this is saying is we want someone to go in and do an FSA to make sure -- just to take a closer look at the overall process.

DR. VETTER: I guess what I'm saying is I don't understand how this works, exactly.

DR. MARCY: Well, good. Probably no one does.

(Laughter.)

DR. VETTER: It seems like what you're looking at is the rate in which they have that level of non-compliance compared to the positive. So it's like -- it seems to me if they're not having positives, you wouldn't be looking at that rate. So it's me. Am I getting that wrong?

DR. MARCY: I don't think they look at positives other than which ones to sample from to compare their comparative group and control group. Do you have data relating to the actual counts past that?

MR. ALVARES: You mean after the positive occurred?

DR. MARCY: Yes.

MR. ALVARES: I'm sure we do, but I don't think the -- it wasn't part of our analysis since it's after the positive.

DR. MARCY: Yeah.

MR. ALVARES: Where questions come in is to try and identify which regs we think are informative. So we're looking at a period of time and what we're saying is that if these regs are higher during that period of time, that those plants are at an increased chance of getting a positive of one of these pathogens. It doesn't mean they will, for sure. They very well may not. And the increase in risk is --

(Simultaneous speech.)

DR. VETTER: That is how you are trying to link performance to risk.

MR. ALVARES: But then when we implement this, we aren't looking at pathogen testing results. All we're looking at are okay, we've identified these, we know -- we believe, statistically, there's a link. We believe that, at least our understanding

of the regs, logically there's a link. And so now we're going to analyze them and if they're high enough, we're going to send -- an EIA has to do an FSA and just make sure --

DR. VETTER: And that has no dependence upon any positive results, at that point.

MR. ALVARES: Right, right.

Now, there are other -- you know, as I mentioned, this is one of seven decision criteria and some of those other decision criteria, if they get an *E. coli* positive or a *Listeria* product positive, those are also reasons to go in.

So they could have very low NR rates that don't trigger them in this -- public health criteria, and still get an *E. coli* positive and they'll still end up on the list to go, to send an EIA to take a look at what's going on.

MS. DONLEY: I think the thing that kind of concerns me, and that's kind of getting teased out here a little bit, is that -- my experience with manufacturers of all different kinds. I used to be in the apparel business.

So you don't -- your plants tend to -- you don't have your management. If you don't have control in one area, you probably don't have it in the other area, even though you may not be seeing it and especially if you're not looking for it. If you've got -- a plant is not going to say okay, because it's -- that's not a PHR, it's okay we go slack in here but we can't have go slack here because it's a different PHR. You know, one level of operating, typically.

So I guess that's where, with some of these -- and if they were to have a spike in SRMs, to me, that's going to say hey, there is a systemic problem here. The plant is not in control somehow. It may be something that -- I guess there is the -- technically, you could have a very isolated group of operators in one part that are just all no good but typically, I just don't think that's the norm.

MS. KLEIN: So Chris, just to clarify, you are saying that the Agency is using SRMs, for example, as an indicator of overall loss of control, if there are enough of them?

MR. ALVARES: Yes. So in the public health regs there are three SRM regs, that if they contribute to the rate being high enough, it could trigger an FSA, for-cause FSA.

DR. REINHARD: So for the Committee, I think it's important that this -- the way I understand it, this is an enhancement tool for FSIS to direct FSAs where potentially there is a process control issue. It doesn't take away any current inspection activities that already occur for any regulatory thing going on out there.

So as they go through the process and they get through it, you know, there will come a time when they'll say well, we want to put this in there, we wish it was in there, but it all doesn't have to be in there to start. They'll get there, right?

In the meantime, the rest of the process still controls SRMs, just like it always did, and an FSA would come, if they deserved an FSA, for not performing properly and having the process controls for that specific thing. Just like if a facility was misbranding products, okay -- and that's not in

here -- an FSA has been triggered because they're having challenges branding, right. It's not considered -- but it would be something FSIS would take regulatory action on and still send an FSA, potentially, and do those things.

So I think that's the one part that we have to be a little bit careful not to go into too much of, because I'm sure FSIS gets this, as everyone in the room does, that you can add this, you can add this, you can add this. Eventually you will. I mean, right? You'll eventually get to where you go further and analyze more, and do NRs lead to potential cross-contamination from allergens? You know, there are a hundred things. I think it's the process. And I really want to get through having them --

DR. TILDEN: Exactly.

MS. KLEIN: So initially, just so that I'm not capturing things that we don't -- does the Committee agree with -- initially, what I captured was your statement, John, that there was kind of a forced assumption that the Agency was making and

that the suggestion was that the Agency should provide a better foundation for making that assumption.

Are we, as a committee, comfortable with that or do we feel that the assumption is valid and we don't need the Agency to provide additional information about why they're making that assumption? I just want to make sure I'm not capturing something here and -- I'm just trying to keep track, but I just want to make sure we're not --

MS. HARVEY: Well, as we agreed upon earlier, there needed to be some more information. And I do agree with Dr. Marcy. It is definitely forced here and so I think that would be helpful. What time allotted, I don't know if we can and we have to continue on, but anyway.

DR. TILDEN: I think this is something we've been discussing as long as I've been on this Committee and I don't see that it's -- I mean, I think we're moving forward, but I think we need to fast-forward it. And I would recommend that we get

very explicit on saying FSIS still needs to separate out process control versus public health protection because let's put it in scientific methods-speak.

That's a hypothesis that FSIS holds dearly to, that if you have process control, that's the same thing as public health control, public health protection. If you look through what's getting written up, you know, like some of those things that are on that list, I'm not convinced -- yeah, it's a loss of process the way FSIS implements HACCP.

Is it really public health control? I don't think so, you know, and there are -- if you go through -- and that's why I was very appreciative of the list you gave. There are some of those things which are purely human beings screwing up and making mistakes that human beings make when you make a detailed system. Does that mean people got sick because of it, every time? No.

And I think that's why we have to go back to public health surveillance systems because public health is pretty used to making limited resources maximize public health protection. And you have to

make tradeoffs. And so one of the points I wanted to make was that statistical significance does not mean practical significance.

And you've got lots and lots of -- if you go through your tables, most of your list, you've got huge chunks of your observations are related to things that I don't think actually gives you public health bang for the buck. They help you with process control and making sure that people are implementing the process as intended and they'll catch that, but by linking the two together, you can miss the public health protection while achieving -- implementing the program as is.

And I think it's essential, what I heard from Bob and others, is industry is just as committed to improving the process to keep people healthy. But what we're doing is; I think we have opportunities over the next couple of years to better define which of these things are generating tons and tons of NRs. They are not resulting in public health benefit. And maybe there's a simpler way to control process without -- and not jeopardize

public health.

MS. DONLEY: Chris, does this list also kind of control what type of tasks the inspectors are asked to perform?

MR. ALVARES: No, it doesn't change -- it doesn't do anything to adjust or prioritize any of the tasks that the inspectors would do. The only things that would happen is that an FSA could get scheduled, which would be indentifying -- or an HAV could get scheduled, which would be deducted by, I think -- I forget who -- so, I mean, those are really the only two things. It wouldn't change the frequency of any of the other tasks.

DR. TILDEN: Can I give a specific example, because I think it sounds so vague that it doesn't work. In your book that you gave us, on page 21 of the document that is from -- which one? Data driven inspection processes from September 2010.

MR. ALVARES: Okay.

DR. TILDEN: If I'm in Table -- it's towards the end of that path 5. Not exactly the last one, I don't think, but --

MS. HARVEY: Table 7?

UNIDENTIFIED SPEAKER: Table 7.

DR. TILDEN: Table 7 on page 21.

It looks like what's driving most of these FSAs is the NRs on the bottom. So by lumping in 120, 67, whatever it is, that's effectively making the decisions on what gets looked at. And I apologize if I'm overly simplifying the thing.

So that means if you've got a whole bunch of stuff that has a lot to do with HACCP process and it has questionable public health impact, then you are really focusing well on implementing the program as is and trying to bang people's heads to get them to do it as is, as opposed to looking at how do we make it better and how do we fine tune it and give the Bobs of the world the data that they need to make informed decisions.

And CDC, when I used to work for them, they made the point that sometimes you're better off collecting less data that's higher quality data, that's actionable data, that helps drive change rather than just flogging people and do more, do

more, do more. They're not going to do more. So what you got to do is figure out how do you get to the data that will drive decision making in the private sector and the public sector. And so -- for example, so that's one.

The other thing is -- and I agree with you. I'm not just blowing smoke when I tell you thank you for sending this stuff out. Except, like, a selection for public health regulations. And I went through it and I had to flip through a bunch of different places, but on your Table 4.4-1 on page 11, one of the things, you didn't include how many FSIS verifications are in that, each one of those things. You got percentages, but you got to have the denominators, as well.

So for example, the fifth one down, 416.16(a), I looked it up and if I got it right, that's maintaining records. So if you screwed up on your recordkeeping, you got kicked on that one. There are one million verifications on that one. One million verifications where if you screwed up on your records, that's logged in together.

MS. HARVEY: Which one was that? Repeat that.

DR. TILDEN: Page 4-1 on page 11 of the document called Selection of Public Health Regulations, January 2013. 416.16(a). And it's sanitation, okay. But it's -- I know.

If you talked to someone in the FSIS world, if you don't have those records, you've got nothing. You talk to someone in the FDA world and it's like the world will not end. But that's a cultural belief and it's a difference in regulatory paradigm. So I'm just saying you're putting a whole lot at stake that is sacred and that protects public health.

The other one is, down towards the middle of that thing, there's something called, I think, 417.2(c)(4), which is List of Procedures within your plant. And that's 400,000 observations.

MS. HARVEY: Was that 417?

DR. TILDEN: 417(c).

MS. HARVEY: Yeah, that's HACCP.

DR. TILDEN: Yeah. I'm not saying it's not

important, I'm just saying that those recordkeeping things -- the rest of this whole thing, a couple of them are a thousand observations, you know, a hundred observations, and then you've got some of these mammoths that boom, that's what's driving your program, as I'm looking at it.

DR. MARCY: Probably have no public health.

DR. TILDEN: Well, I don't know if they do or don't, but it's -- I believe it is a hypothesis that we still can't answer to what degree they do directly impact and maybe you can't say like you're saying, Chris, you can't get to how many illnesses did that cause. But it might, if we do the data collection correctly, five years from now we might be able to say to what extent are they correlated with increased counts.

MR. ALVARES: Yeah. So a couple of comments. I mean -- everything you got there, but I think that's part of why we need Committee comments and recommendations. You're right, there are huge variabilities in the tasks that are being verified or the regulations, I should say, that are being

verified. That's one of the things that we do want to look at, is whether everyone is verifying tasks to the same -- pretty good. Yeah, the frequencies would be kind of expected.

They're doing a task every day and this reg is applicable to that task. There may be some inspectors that are verifying that every time they do the task, some of them may not be, and that's one of the things that is the source of variability in this that we see as --

DR. MARCY: Are you collecting that data, too?

MR. ALVARES: Yes.

DR. MARCY: Cool.

MR. ALVARES: Yes. So we know when they verify -- we understand when they verify tasks. They are required to verify every regulation in a task. There are some that are mandatory and there's a larger set that are optional. So to some extent, they're not supposed to go through and verify every reg every time they do tasks. They're supposed to sort of cover the applicable regs. When you do a --

task, certain regs would be applied to this establishment -- so there's that -- it's the characteristics of the data that does, you're right, complicate how you count these, how you address them.

We think that rates are, sort of, the better way because rather than, sort of, totals -- because you're right. A million of these tasks and a thousand of these tasks, you know, Task B. Task B never will become an influencer of the overall rate, so we're trying to use -- grades for each reg and they combine that into a rate.

I think that tries to address some of the variability in the frequencies. There are other ways to do it, too, but I feel like that's kind of clear enough to follow that industry can kind of help with monitoring. I think there's that --

DR. MARCY: It's hard for us to do it right in that model. We don't know what has to -- what regs are tied in when they do a task. We may know they did a task, but --

MR. ALVARES: So I think one thing that

should be available now with the PHIS reports would be more detail of what regs would be verified and what's coming up as non-compliances or non-compliant.

The other thing that I just wanted to mention, and I don't know if we have a clear procedure on this, but one of the ways I envision, things like this reg maybe isn't quite as -- probably doesn't have the public health link association that we may be applying or assuming -- let's take an extreme, Sarah, where say that Recordkeeping 1 represented all of the NRs at the plant and pushed it high enough and -- it ended up getting selected purely on NRs for one type of -- one regulation.

What really happens is that they end up on a priority list for FSAs and that goes to the NIOs. The NIOs, they have some decision making to do there, too. So what they could do -- and I know some of them do this. They may look at the regs that triggered that FSA and they may review them and decide no, I really don't think that these are the

kinds of things that we meant by this process. They may decide what's -- I know that's not purely quantitative, it does put some subjectivity in there, but I think it gives us some opportunity to interpret what data is causing these -- to be triggered.

CDR TARRANT: Just to note that we're now at --

MR. ALVARES: And I'm not trying to either influence, kind of, the comments but I'm hoping I'm providing context, I think. And certainly feel free to --

DR. VETTER: I would just say that now that I understand a little bit better, what I see this as the -- NRs, is those are performance based. But then when you get to the point of the FSA, that usually gets into public health risk. That's going to hold that together. And then the EIOs go in and do a full three-four week FSA and pull the whole -- together. That's when you get to public health risk and then that determination could be an enforcement action or something much greater than an NR. But

this is one of those things that throws up a red flag: do we need to go in and do that type of assessment?

MR. ALVARES: And to that point and to the point you made about maybe doing less and getting really high quality data, it can be -- in some -- it can be a good way to go. The FSAs, for us, are the less frequent activities that generate really detailed comprehensive data.

And so this, in some ways, is a way to try to identify where do we go and do those FSAs, then that data gets up in our systems and so then we have to ask questions like okay, of the FSAs that were done because of PHRs, what were the findings of those? Are they finding non-compliances, are they resulting in NLIEs? Sort of, are we -- is the FSA confirming the indications from the inspection and that's an important detail.

MS. KLEIN: I think that's an important element that I want to capture. So let's try and capture that as a phrase that we can then fold into our final document and then we should break for five

minutes to refresh ourselves.

But what would be a good way to capture? Do you want to just restate what you said and I'll try and --

DR. VETTER: That the PHR monitoring is a performance-based monitoring system for evaluation and that the FSAs that result because of an increase in those -- non-compliant regulations. That is where the public health risk analysis comes in, is during the FSA process.

MS. KLEIN: So theoretically, on a continual basis, the Agency should be receiving feedback on whether the FSAs are proving the theory?

DR. VETTER: Yes.

MS. KLEIN: Okay. And do we, as a committee, want there to be some feedback mechanism for -- or how does FSIS intend to adjust the system if, for example, it turns out wow, in this particular area, none of these PHRs -- the results of an FSA also resulted in -- do you know what I'm saying?

MS. DONLEY: Yeah. You're trying to say is

that if there were a number of PHRs that resulted in an FSA, in doing -- assessments. And at the end of the day, the food safety assessment was very good, then were we looking at the wrong stuff that instituted that FSA.

MS. KLEIN: Right.

MS. DONLEY: Yeah.

MS. KLEIN: So what's --

DR. TILDEN: Verification. Verification that there was public health risk or not based on that FSA outcome.

DR. MARCY: That might certainly be an interpretation of looking at the wrong stuff. It might be a local interpretation, how it's being coded at the plant, what the inspection personnel versus what the FSA finds.

MS. DONLEY: It could, but that's a feedback going to FSIS, as well.

DR. MARCY: Yeah. I mean, I'm looking at the wrong things here.

DR. TILDEN: But if I can make a pitch? I think it's important for FSIS to make a cultural

change to differentiate process performance-based regulation versus public health and I think we still have the blending and it's not explicit how you assess either one.

And I think to emphasize the benefit from in your routine inspections and in your FSAs, because I have a feeling the FSA guys -- I know a couple of the folks that do them -- they're just as passionate about process control as anybody else and they might very well have a hypothesis that hasn't been tested and they perpetuate it.

MS. KLEIN: Okay. Do we want to take a five-minute break? Yeah? Okay, let's reconvene in five minutes.

(Off the record.)

(On the record.)

MR. ALVARES: And then some questions about who were in the comparison groups. For example, in *Listeria*, the only groups that were compared were -- and testing for *Lm*.

So if it's an RTE -- there was an RTE in the control group as well. We didn't include -- it

doesn't include a beef slaughter establishment. We never sampled for RTEs. We don't have any negative results to look at the 30-day prior to.

MS. GAPUD: So that's good, then, because the data is not being grouped in the way --

DR. MARCY: And my question on the control group was in the *Salmonella*, you know, if they were negative because they were negative or negative because they weren't tested.

MR. ALVARES: Right --

DR. MARCY: Because it could've been -- okay. But they were tested.

MR. ALVARES: Right. It does raise a point that not every establishment that -- STECs gets, you know, a pathogen sample of all it. I think in some ways most of them do, but not every single one.

And so a data-driven basis for selecting these is based on establishment sample. But then the application of those regs is --

MS. KLEIN: Given what Chris has just said and what we've just discussed, take a look at the highlighted question and tell me whether that

question has been answered and thus, we don't need to include it in our --

DR. TILDEN: My vote is it's -- include two different issues. One is data dilution, where you include a whole lot of non-public health-related things with -- and it's called misclassification bias in the epi world. For the first sentence.

MS. KLEIN: Yeah.

DR. TILDEN: The second sentence says it's not randomly distributed. That's a different issue.

MS. KLEIN: You data people.

(Laughter.)

MS. KLEIN: Tell me exactly how that should be, because that's clear --

DR. TILDEN: I'll tell you just my thoughts. So data dilution is a concern. And then hit return and separate bullet.

MS. KLEIN: Yeah.

DR. TILDEN: And then, instead of the data is not -- it may not be reasonable to assume that all data is randomly distributed.

MS. KLEIN: Okay.

DR. TILDEN: So that'll mean something to the folks that do that kind of stuff.

MS. KLEIN: Okay. Okay, and we can obviously add more. I'm just trying to make sure we're not missing things.

DR. REINHARD: The ones you call data dilution.

MS. KLEIN: Yeah, what are you --

DR. TILDEN: Data dilution is when you have a whole bunch -- it's that whole thing of you have a whole lot of performance-based criteria measures mixed with public health measures and you're calling them the same thing.

MS. KLEIN: Is that in bullet three --

DR. TILDEN: Data dilution is where I put that.

MS. KLEIN: Okay.

DR. TILDEN: Yeah, mixing of performance-based and public health criteria.

MR. ALVARES: And you're talking about in the sort of the larger set of setting criteria and this one seems to dominate as far as the selection

criteria.

DR. TILDEN: Right. And that goes back to your specified risk materials. It has not anything to do with the others, but you're assuming that process control in one is a problem for the other, which may or may not be true.

UNIDENTIFIED SPEAKER: There's a comment.

DR. BOOREN: Yeah, Betsy Booren from the Meat Institute Foundation.

I think this whole discussion really indicates that putting your data into context is going to be critically important, even within your own system. So all of these questions, I think, as I'm listening to it, we need to make sure, even for your use, it's very clear what every dataset is, what it's being used for and what it defines, because there was a lot of assumptions as to what this data was and where and how it was being used, and if you don't have that context, potentially over-assumptions or underestimations could occur and both of those could be disastrous.

So for what it's worth, as someone who

reviews your data a lot, and I always really appreciate those little footnotes putting everything into context, as much as you do that, over the next week I'll review it. It's great.

MS. KLEIN: So in terms of process, how do we feel about our answer to Question 1? Do we feel that what I have captured here in taking notes only addresses Question 1 or does it spill over into the other questions?

And we don't have to keep to the frame that the questions were asked, of course. But you know, we just kind of keep generating bullets.

DR. REINHARD: I think it can sit in one. And then if we think it spills over, we can then answer.

I have a question for the Subcommittee. If we're willing, I would like to put a data bullet first to state -- because I think we said it, you know, the Subcommittee, but the Committee will vote on it, that we're very appreciative that FSIS is trying to take a science-based and data-based approach to improve, right, the system.

MS. DONLEY: An introductory sentence.

DR. REINHARD: Yeah, something just that says you're doing good. Right, it's good.

MS. HARVEY: Data analysis.

MS. GAPUD: We have to give them credit. They have done so much work, I think they deserve it.

MS. HARVEY: Yes, that's what I meant.

DR. TILDEN: A good job. Keep going, guys.

MS. KLEIN: Okay, I'll just keep typing it all and you continue. Why don't we start discussing Question 2, and then I'll catch up to you.

MS. DONLEY: I just have a question. Do we want to just -- well, if you say it's just implicit that there's a hazard analysis included and that it's just that other times that's separating out from the hazard. It's understood that hazard analysis is already there, and I'm fine.

DR. REINHARD: The question, Chris, that you asked, are you asking -- I think this says, is the Committee okay that we used all the regulatory science associated with these four things, to then

narrow down, right, that's your population of potential regulations that affect public health, to narrow down to the 32, then that's statistically getting based off the methodology. Is that question?

MR. ALVARES: Essentially, yes. You know, also there are additional criteria. And I'm not trying to -- again, whatever the Committee wants to include is fine. If it's not clear that hazard analysis is part of this criteria, I think that the Committee should say so. I mean, it may be implicit just because I'm so close to it and I understand it. But if it's not clear to the Committee, that's -- I appreciate the kudos, but I also appreciate the criticism as well.

DR. REINHARD: Yes.

MS. HARVEY: So now I think I'm confused. What are we supposed to -- explain what you want us to answer.

MR. ALVARES: I mean, I think what we're looking for is do you agree that these four criteria encompass essentially what the areas of public

health concern that were not -- or are there broad areas of inspection or the regulations or the code that we missed in evaluating this? Or are there other ways, when we go through and read a reg, how should we decide -- are there other criteria that we use to decide whether it's -- and further analysis?

DR. MARCY: This is John Marcy from the University of Arkansas.

I think these four -- and I'll go back, you know, there again to your presentation, where you said step two and you linked these four to your process control. And I would say these four really cover the waterfront pretty well, in terms of public health. And if you accomplish all of these, then you should have a safe product. I don't see an issue there. You know, I think you'd have trouble for this Committee to say we don't believe that you need to have preventive --

MS. HARVEY: Yeah, these are the -- I'm sorry.

DR. MARCY: I don't think they suffice for that. But in terms of your process control part,

your linkage for process control to public health, there's the stretch.

DR. TILDEN: And that's my concern. So when HACCP first went in, there was a dramatic decrease in the number of human illnesses. Since early 2001-2002, flat line.

So if we keep reinforcing the existing system, why do we think that's going to change what's happened in the last five years? Or will we just be perpetuating flat line? How do we unleash a new dynamic that's going to help take it to the next level?

DR. MARCY: All those standards have been --

DR. TILDEN: Right, but the human illnesses haven't. I'm not a meat inspection person, so I'm speaking as a state regulatory official kind of a person. So it's an outsider's view of the world.

Yeah, down to about 2000, you know, but then it's been flat lined. So they say insanity is doing the same thing over and over again, expecting a different result. So what are we going to do

differently? And I think that's the challenge.

DR. MARCY: Yeah.

DR. TILDEN: If we keep looking at -- if we just keep more records, if we just do more of these 100,000 widgets, we'll get incremental changes. And it's like, is that true? What does it take to change the paradigm, to unleash the next round of innovations? And to me --

UNIDENTIFIED SPEAKER: HACCP -- is what you're --

DR. TILDEN: Well, or just to take HACCP from -- it's great. I'm not saying trash can HACCP and I'm not saying trash can records. But I'm just saying --

MS. GAPUD: What's the next level of HACCP version 2.

DR. TILDEN: Yeah, and how do we -- this is continuous process improvement. How do you get industry, universities and government all measuring the right stuff and having their fingers on the wheel that are going to drive change rather than just reinforce what we've already got?

MS. HARVEY: Well, as I stated earlier, there's more room for enforcement, enforcing all of this.

DR. TILDEN: We're all about enforcement in my department as well. But enforcing the same old same old, is that really going to drive change?

MS. GAPUD: We have to come up with something, the next level, that we make the HACCP more useful.

MS. DONLEY: I think that's true, but I don't think the existing -- this is just my opinion, but that there are some -- I think there are still some holes, that if there were some additional things that, in my opinion, industry should be doing and I think that can be required to do, and once those were in force, would we see some betterment? So I think we're missing some regulations.

MS. KLEIN: But HACCP isn't fully gestated, you know, like HACCP is still not a completed entity in your mind, as opposed to a completed entity that is ready to now move on to the next generation.

MS. DONLEY: Yeah, HACCP is just kind of,

you know -- and that's the framework that goes around everything. But there are additional things, I think, that government should be doing and that industry should be doing that would then lead to the public health benefits within the HACCP environment.

DR. TILDEN: So going back to the public health paradigm, one of the things that we do real hard is we try to identify the root cause for contamination during outbreak investigations. And we try to make the distinction between, when we go into a facility that's linked with an outbreak, regulatory compliance, which is usually just trying to bring them to a standard which may or may not control why they have the outbreak. And we say, step outside and say what went on in that firm. Take off the blinders of whether it was regulatory compliance or not and say, from a science standpoint, what were the factors, the root cause analysis, that could've contributed to that? Then you can step back into your regulatory paradigm and figure out, you know, whether we have legal authority to enforce or not.

But also that gives you the freedom to then evaluate how do we have to change our paradigm to make it better? And I think you need that freedom within FSIS, when you're doing these FSAs, to say we wanted to assess compliance with regulations, absolutely. But we also wanted to do root cause analysis and move beyond current requirements to say what's the best available science.

And I think I'll do a hyperspace leap here. The whole diffusion of innovation paradigm, you don't have to get rid of HACCP. What you have to do is you have to get the early adopters and the best practicers to share their toys and say, I can tell you, if you really want to know how to prevent contamination in our ready-to-eat facilities. My facility hasn't had them for five years, because we did X, Y and Z different. How do you make it so those early adopters and best practice people share, and then you take best practices and you make them average practices through the Extension? And that's where Extension could tell you what they could do better if they had what?

You know, if we didn't spend so much time running around the gerbil cage trying to just do 15 more iterations around the gerbil cage, but we started saying this is what we could do, this is the data I need to drive change, then you could get industry best practices being shared to the capable learner.

So you've got the three categories: the early adopters, the ones that got the best practices; the capable learners, so they're not opposed to doing it if you just tell them how; and then the resistant-to-change group, that's what us regulators are for.

And you can figure out how to make this whole -- the data FSIS gathers and the data that industry has, how do you make that more accessible and in a format that is information that can be used for decision making? And I think you're heading down that path. But I think being more clear in distinguishing performance based versus public health protection will, over time, help us and serve us well.

MS. DONLEY: I think those are all excellent points. I think FSIS's hands are a little bit tied right now, in that the food safety assessment is something they can only enforce to standards that are already in place. And I'll give you an example.

There is a real -- and I don't have the numbers. Someone else here in the room may have them. But there is a huge, huge -- something's happening in poultry plants, where you get your *Salmonella* numbers, where is it, just prior to the chiller? I'm not exactly sure. Post-chill, post-chill, post-chill. And then you go do some sampling in a grocery store and there the numbers are just off-the-wall different. Something's happening there. And that's an area, a real good area, for opportunity. And FSIS cannot now do anything past that post-chiller point.

MS. HARVEY: Sharika Harvey.

I'll keep speaking my magic word, enforcement. You even said legally enforce. It's more room for enforcement activity.

When we have all of this set in place, when it comes back, what are we able to do? What will we do so that it won't continue to happen?

MS. DONLEY: And to your point, I mean, it was made crystal clear this morning with the veal, what's happening in veal establishments and what's not getting enforced.

DR. TILDEN: So one thing. For example, FDA. When they went out to Chamberlain Farms, the cantaloupe place, or they went out to Rocky Forge, the standards weren't crystal clear exactly what regulations do you have to regulate a cantaloupe farm. They were still able to do what they called an environmental assessment.

And one place that I would recommend FSIS consider is CDC has a group called SNET (ph.), BHSNET (ph.), that has standardized -- they've looked over data from years and years of outbreak investigations and they are pretty close to standardizing a methodology for doing environmental assessments, to help you -- it's based on systems.

So it's an interaction of employees plus

equipment plus facilities plus food, and the interaction of those effects, that leads to food safety events -- food contamination events in a complex interaction.

But they're helping to build the science so that you can break it down into its component parts and try to isolate it and say to what extent was it employees, to what extent was it the facility, you know, and say it's the interactions.

So there are models out there that would help if FSIS, FDA, CDC, everybody was using the same intensive investigations. Whether you call them an FSA or FDA calls it an environmental assessment, you know, if the science is similar, then Extension people, whether they're supporting a meat-poultry outbreak investigation or a fruit-veg outbreak investigation, we can kind of get our heads around where are we going with this and how do we get good data for decision making?

And then, when you look at your reports, you have a standardized approach, that the waterfront was covered. And EIAOs, whatever they

are, yeah, those folks, when they're gathering information, it's standardized so you can make comparisons, apples-to-apples comparisons. You know, I think a lot of that work is out there. So in my mind, that's low-hanging fruit that would help.

So getting back -- Sarah's giving me the eye.

MS. KLEIN: Yeah.

DR. TILDEN: I like the four criteria. There's nothing wrong with them. It's just the specifics of how you implement them and tease out the parts that we talked about.

MS. HARVEY: I agree, John.

DR. VETTER: Danah Vetter, NAFV.

I just have one comment or recommendation. It's been a while since you did W3NRs and now you've got PHRs. How often do you anticipate looking at this?

Because I think that should be a part of the process and I think part of that should be a combination of recommendations, I guess, for two and

three, is that when you look at -- how do I say this? But you look at your candidates and whether you're having -- when you have enforcement actions, if some of those candidates that weren't part of that narrowed process are actually coming up as being noncompliant in FSAs. And so then, should they be considered to be brought back into that process?

And the same as if you were looking at those that triggered the FSA, but were not resulting in enforcement actions, would they be looked at being dropped out? So would that be part of that cycling evaluation?

MS. GAPUD: I think you mentioned that before, you know, that there will be continuous improvement or review.

MS. HARVEY: I don't know, because that's what I was thinking earlier and I'm glad she brought that up, because I was thinking that. And I don't know if there will be something or the trial will already have run when we meet in the spring or when we meet again or whenever. You know, when we can

look at it and crawl.

Thank you.

MS. KLEIN: I just want to capture again what was just said, that the Agency should consider which of the elements. I want to flip what we said before, so that we capture both of those things, and then I want to go to public comment or questions.

DR. VETTER: You have the two sets. You have the initial set of the candidate --

MS. KLEIN: Yeah.

DR. VETTER: -- PHRs and then you have the actual ones that were determined based on the statistical analyses these are being used to trigger FSAs.

And so not only should you look at whether those in the smaller category are validated as being the right ones, but you should also look at -- or some of the ones that were in that candidate category showing up in FSAs, who they were.

MS. DONLEY: If they came up when the FSA conducted, should they be added to the list of the -- to the 32?

DR. VETTER: Exactly. If it's coming up at an increased frequency --

MS. DONLEY: Yeah.

DR. VETTER: -- so to speak.

MS. KLEIN: Okay, Tony.

MR. CORBO: Yeah, I have a question.

UNIDENTIFIED SPEAKER: That's not loud enough to hear you.

MR. CORBO: This is Tony Corbo from Food & Water Watch. I'm surprised you can't hear me.

DR. TILDEN: Come up to the mic, on the right here.

MR. CORBO: The discussion here has been about triggering FSAs. And in passing in your presentation downstairs, you mentioned HAVs and it's come up here a couple of times.

Number one, why hasn't the hazard analysis verification process occurred yet? We were told it was going to be in 2010, in 2011, 2012, and here we are in 2013 and you're saying it's still not there. So that's question number one. Why hasn't that procedure come into existence yet?

And number two, when it does, how does that interact with this process with the FSA? Is that going to be an intermediate step?

MR. ALVARES: For an FSA, you mean, something like that?

MR. CORBO: Yeah.

MR. ALVARES: So the division is -- and what we described in the 2010 report is that this could also trigger more frequent HAV tasks. So I think this kind of standard frequency would be quarterly. If there's a reason to do one more frequently than quarterly, this is the trigger that would help decide that or determine that.

So whether that also leads to an FSA, I think, depends on whether they exceed the cut points and whether there's enforcement or maybe -- because I think in some ways you don't necessarily have the one lead to the other. It depends on what the outcome of the activities are. I'll explain that later.

The first question about why haven't we implemented, I'm not the right person to answer

that. I don't have an answer for you on that.

DR. REINHARD: Chris, do you know what is in the HAV task?

MR. ALVARES: So I haven't seen the task itself, in terms of how it shows up in PHIS. I know there's a pilot going on with our field office right now.

But essentially, the inspector is reviewing a set of plant records, they're answering a series of questions in the task about their hazard analyses, and probably multiple hazard analyses as well. And then that's kind of the basis. If there are non-compliances, those would be documented.

DR. REINHARD: And so that had a point. And so I was thinking, because this came up through discussions here as I've been listening, if these PHRs are the things that lead to product positives, then there's a process of control or public health, whatever. But you're saying it's public health.

I would think you'd want to look at the HAV task and look at these 32 regulatory cites as being the critical thing for that potential review in the

HAV versus I know what's in there to some extent and what they do. But it is worth considering, right? It's totally different thinking than we've got.

So here's your way of looking at it in a different way. But it potentially is worth looking at. So that's my comment on how HAVs play into this. We could look at whether or not these regs are the tasks needed for an HAV.

DR. MARCY: I don't understand.

DR. REINHARD: So if we say these 32 --

DR. MARCY: Yeah. Then what would you have --

DR. REINHARD: -- regulatory cites are --

DR. MARCY: What would you have the inspector do?

DR. REINHARD: Whatever task is associated with verifying --

DR. MARCY: The hazard analyses?

DR. REINHARD: -- meeting those regulatory requirements. So if one of the 32 is -- I don't know.

MR. ALVARES: So rather than just simply

saying you got flagged because of the PHRs, if we were to be able to provide information that says these were the regs that caused this flag and you should use that to inform where you go with this task.

DR. REINHARD: Don't go do a records review.

DR. MARCY: Okay.

DR. REINHARD: That doesn't have a public health impact.

DR. MARCY: I don't think they do, anyway.

DR. REINHARD: Go perform a task that is critical to public health.

DR. MARCY: Okay.

DR. REINHARD: That's the way I would describe it. So I don't have the regulations.

MS. KLEIN: Okay, I'm not clear. Someone dictate to me exactly what you want this bullet to read right now -- I'll just clear that one. Okay, go ahead.

DR. REINHARD: FSIS could consider --

MS. KLEIN: Um-hum.

DR. REINHARD: -- using the outcomes of PHR regulations to determine tasks that should be performed when an inspector completes an HAV.

MS. KLEIN: Okay.

DR. REINHARD: Does that make sense now?

DR. MARCY: Well, if you want to put in light of Question 2, it has to do with these four criteria, which you may want to relate it to that versus just the hazard analysis.

DR. REINHARD: It didn't have anything to do with Question 2.

(Laughter.)

DR. MARCY: Stay on point. Well, it's going up there as part of Question 2.

UNIDENTIFIED SPEAKER: It's part of Question 2.

MS. KLEIN: Okay. Well, we are going to put it, as long as it captured the thought.

All right, where are we? Are we still on Question 2? We have one hour left.

MS. HARVEY: I mean, those are all critical, so should that really be considered?

Don't you all agree, all of those points should be considered?

MS. KLEIN: Is there anything else we want to add at this point?

All right, let's move on to Question 3 and then see -- oh, yeah.

DR. CHEN: Okay, Fur-Chi Chen, Tennessee State University.

Yeah, I do get, I mean, the PHR process. I mean, is there any way we can have a flow chart to make it more clear and flow on the processing, development and processing, I mean, coupled to the public health decision criteria related to the FSA? I mean, if any relation here and the flow chart will make it more clear.

MR. ALVARES: We could, yeah. I mean, we certainly could try to put together a flow chart.

DR. CHEN: Because, I mean, from my understanding, the PHR here is one of the components only on the overall decision criteria. I mean, that's the only.

MR. ALVARES: Yes.

DR. CHEN: And of course you do have another six criteria listed there.

MS. GAPUD: So you're talking about a flow chart that leads to the FSA?

DR. CHEN: Um-hum, because that's only one of the criteria there, I mean, in the public health decision.

MR. ALVARES: I can certainly imagine a flow chart that talks about how do we get from the point we're at today to scheduling FSAs? There could also be in this flow chart of this feedback loop about how the results of the FSAs are better informing the PHRs and our data analysis there.

Are you talking about sort of the flow chart of implementation and procedural activities or more of the --

DR. CHEN: Yeah, and the -- related to the, yeah, the FSAs.

MS. GAPUD: A flow chart that leads to the FSAs.

MS. KLEIN: Okay, Question 3. We can always come back. Okay, comments on the public

health outcomes pathogen test results that were analyzed.

MS. GAPUD: We put some on there and now we put *E. coli* here. Again, I think it was mentioned, the STECs also, that we can do them. And also how --

MR. ALVARES: Those two, the non-O157s and the -- are probably at the top of our list. There was a question sort of before this -- something about residues and whether we would include those. I don't know. Right now we decided not to, probably because I think the residue tests are more about what's going on at the farm rather than in the plant. At least that's sort of where our thought process was on the residue tests.

MS. DONLEY: Does FSIS do any more generic testing, you know, plate counts and stuff like that, or is it just strictly pathogen testing?

MR. ALVARES: I'd say the majority of our sampling programs, it's just the pathogen in vitro. So O157 and *Salmonella* and *Listeria*. What we do are baseline studies. Usually they're a discreet period

of time and for a specific date. They tend to do more a larger panel of tests, like generic *E. coli* and some of the other indictor organisms. But that isn't a standard practice for most of --

MS. DONLEY: And the reason I'm asking this -- and it goes back to what I brought up the very first thing when we started the meeting -- number one, is I think that the FSIS's sampling program is not as robust as it could be to be having so much importance being placed on this test. I mean robust in terms of both frequency and in terms of -- I think N60 has got some very deep flaws to it.

So should there be another component added in, which could include total plate counts and things, to see that there is some sort of a process control that is to kind of show that -- because the pathogens, let's face it, O157 is like finding a needle in a haystack, in a sense. So is there a better way of looking at some non-pathogenic profiles in the testing program, at the same time, that could be helping to identify out-of-control systems?

You know, the plants do this all day long, all day long, but FSIS doesn't have that data. And obviously FSIS would have to conduct their own data. So I don't know, it's just --

DR. REINHARD: Why is that? Why would they have to conduct their own data?

MS. DONLEY: Would you share it with them?

DR. REINHARD: Well, from a regulatory standpoint, we do have access to data. They're allowed to review it and they're allowed to see it. The question is how would they use it? I think that's the question. What weight and value do you put on it?

DR. MARCY: Yeah, they have access to *Salmonella* data from the *Salmonella* Initiative Program.

DR. REINHARD: Right. So my environmental monitoring program may have access to my finished product testing and verification. My HACCP plan may have access to --

DR. MARCY: But Chris might not have it.

DR. REINHARD: Right. And right down

through the global inspector right on the site. It doesn't go anywhere, but it doesn't mean it's not there.

MR. ALVARES: So I think all of the statements are correct. The inspectors can and are supposed to review testing results at the plants. That data doesn't come back to headquarters and go to the database. We don't use it for things like those kinds of activities, scheduling.

But I think that the inspector, if they see things in the data, certainly they can bring that up to their supervisor. I think there's a process within -- to address issues on that.

DR. REINHARD: It's an interesting question, but there's no plant that takes thousands of finished product samples and they're negative for *Lm*, but the Agency comes and verifies them four times a year. There may be someone else who's taking none and the Agency's verifying once a year, right?

MS. KLEIN: Um-hum.

DR. REINHARD: So there's data that could

help, right, with FSIS saying, where we do apply our resources? Because you have a limited budget. And it is an interesting question. It's never, never been agreed to. For a whole list of these issues, right, they would have to be teased out, but it is theoretically possible.

MS. DONLEY: Yeah. And I certainly don't mean to suggest that it should be in lieu of pathogen testing.

DR. REINHARD: Right, yeah.

MS. DONLEY: Yeah, yeah, but to see if there some way to see in a particular plant. And I don't know how you do that, I don't know how you do that, to see if it's -- you have to look at trends.

DR. MARCY: Yeah, a lot of companies will do total plate count, you know, to look at their quality --

DR. REINHARD: Correct.

DR. MARCY: -- to see if their shelf life -- because total plate count will relate a whole lot more to their product quality or their refrigerated storage than it will in public health.

MS. DONLEY: Yeah, but it also does reflect to, you know, process controls, sanitation controls. It does, you know, present a picture.

DR. MARCY: Well, yeah, that was one of the reasons why the generic *E. coli* Biovac 1 was used and it's not proven to be very effective, but that's why it's there.

MS. DONLEY: Just in the slaughter.

DR. MARCY: Right, yeah.

MS. HARVEY: And if it comes back positive, you know, we have to kind of --

MS. GAPUD: But the inspectors, the USDA inspectors in the establishments, they have access to the that. You know, whether it's just a generic *Listeria*, they have access to that. In fact, when there is an issue or there's so much frequency of generic *Listeria* is so high, the inspectors are going to race by and say, what is going on in here? Although it's not specifically -- but they raise it here.

MS. DONLEY: So I guess we're not going to put together program here today. That's not going

to happen. For today it's wrong. But it's just something to maybe think about, and is there some way that some industry data could be helpful in analyzing what should be considered a PHR as one of these? Is there a role there, I guess is the question, is there a role?

MS. KLEIN: Do we want to go -- like, do we want to look at the way that I just raised that now or do we want to wait and go back again and look through everything I've written?

MS. DONLEY: I think that looks good.

DR. TILDEN: So Chris, how many actual samples is all this discussion based on? You know, in a year, how many *Salmonella*, *E. coli*, and *Listeria* samples do you collect?

MS. DONLEY: About 10,000 for *E. coli*.

DR. REINHARD: Ten thousand *E. coli*, 10,000 *Salmonella*, and maybe 12.

MR. ALVARES: Well, for *E. coli* in general, for ground beef it's about 12,000. Then add a couple thousand for a trim component. So it's probably about 15,000 for *E. coli*. For *Listeria*, I

think it's about -- I want to say like 20,000 for ready-to-eat product, for *Listeria* and *Salmonella* ready-to-eat. And then for *Salmonella* in raw products, I mean, I'd have to look it up. I think it's like 20,000.

DR. REINHARD: Thirty to thirty-five.

MR. ALVARES: Probably, yeah.

DR. REINHARD: Is that what it is, 35,000?

UNIDENTIFIED SPEAKER: Or it has been.

DR. REINHARD: Yeah, that is half a unit.

DR. TILDEN: Okay, so that's a boatload of data.

DR. REINHARD: Yeah.

DR. TILDEN: So I guess my question would be, are we doing everything we can to capitalize and get the most out of that data and convert that data into information for action?

And one of the public health criteria that's in those CDC guidelines I mentioned was the timeliness of the information. It doesn't get to the hands of decision makers in a time that they can do something about it.

So I think that might be a helpful thing, is I would recommend that FSIS look at how do they look at the turnaround time of when that information becomes available and who it's available to, so that it can be used by risk managers in the public and private sector, to make decisions to intervene.

You know, 10,000 samples, that's a lot of samples. So how do we make sure we're not losing any of the public health impact that could be benefited from that?

And my fear is that sometimes it goes into the system. By the time the laboratory comes out and the FSA comes out 2 months later and the inspector comes tripping into the facility two months later, well, what does he see 2 months later and how does that relate to what happened 2 months before?

MS. KLEIN: Sorry. What else?

MS. GAPUD: It's very good.

DR. VETTER: Danah Vetter, NAFV.

This has nothing to do with those three questions, but it has to do with the NRs and the

rate of noncompliance with those NRs. And I may get this wrong because I'm currently not in the plant using PHIS, but it's my understanding that it's very difficult for an IIC to do an analysis and know what the noncompliance rate is for these. They have to request that through that currently.

That needs to be considered, that they're able to do that analysis or pull that very easily, because it will help them know where they need to look at things that need to monitor in the plant. And they can also relay that information to the facility so that there can be a more proactive approach versus waiting for these things to spike to the level that they trigger an FSA.

So that needs to be a potential use of these PHR regulations, because I believe it's a way that they can be used proactively rather than reactively.

DR. MARCY: So what could gain access is the cut point.

DR. VETTER: No.

DR. MARCY: Right, yeah.

DR. VETTER: Right now they're not able to do an analysis themselves.

DR. MARCY: Correct.

DR. VETTER: They have to request that through that.

DR. MARCY: Right.

DR. VETTER: And that's a disadvantage for both the input inspection and for the plants themselves.

DR. MARCY: Yeah, they know how they're trending. They just don't know how everybody else is.

DR. VETTER: Exactly. And they don't, you know, versus if they were able to say oh, we can see the steady incline. Something must be starting to happen. And then in the weekly meetings they can have that communication and conversation and possibly catch something before it gets out of control.

MR. ALVARES: And I think just to maybe clarify, I think inspectors have a pretty good perspective on the tasks that they perform. I think

they have a little bit less visibility on the regs. Within a task, it's easy to open a task and see what regs are in play.

But we'll get the kind of scope of the last month's tasks. It's a little bit more complicated. We do have some reports now that summarize the non-compliances and the regs that were cited and provide some graphs to help prioritize. I think that's the feedback --

DR. VETTER: Yes, I believe there's a lot more than can be done there, particularly for it to be used by supervisors, supervisory personnel, to give feedback to their staff and then give feedback to the plants as well, so it can be used more proactively in that case, rather than reactively.

DR. REINHARD: So we should capture it.

MS. KLEIN: Okay, let's hear it.

DR. VETTER: Like I said, it doesn't really have anything to do --

MS. KLEIN: So let's put it, we have hanging out there also, that doesn't really fit nicely in here, enforcement.

DR. REINHARD: Yeah, we can just add it.

MS. KLEIN: So we'll just put a little category that covers it. And within that we'll at some point need to capture some language on enforcement. And now we are capturing Danah's point, which I forgot.

DR. VETTER: We'll call it, I think, the frontline and the IPP personnel need to be able to --

MS. HARVEY: IPP kind of covers that.

DR. VETTER: Yeah, I guess IPP covers the frontline, too.

MS. KLEIN: Give me a minute.

DR. VETTER: I don't want to say that they're analyzing, but they need able to --

MS. HARVEY: Have access?

DR. VETTER: No, trends and noncompliance trends over periods of time. So I guess analyze.

MS. KLEIN: Do they have access to this data already?

DR. MARCY: Yeah. Well, what they don't have is a cut point. They don't know how they're

tracking with the other folks, but they know how they're tracking.

MR. ALVARES: I would say, I think maybe not in a way that allows them to just kind of pull something up and see it and act on it.

DR. MARCY: Right.

MR. ALVARES: Just thinking about sort of what Danah's getting at, I think the question is, are we presenting information in a way that's -- you know, that they don't have to flip to this page and then got to this page and then go that page to kind of pull all of the --

DR. VETTER: To pull it all together where they can easily determine whether noncompliance is trending upward.

DR. REINHARD: Yeah.

DR. VETTER: Or in a negative manner, so to speak.

DR. REINHARD: Yeah, some kind of process indicator as to how things are running.

DR. VETTER: A process indicator so that they -- exactly, so that they can then use PHRs.

This is what it comes down to, so that they can use PHR analyses to be proactive rather than reactive. That's what it boils down to.

DR. REINHARD: And you should go ahead and just let that exact same information populate on the facilities. The PHIS, when they log in they can see their results, too, so then they can react, as that indicator data is telling them something may be moving.

MR. ALVARES: So I know I don't think I'm supposed to be asking questions, but I'll sort of -- because we had some of that discussion internally and it's kind of led to a conversation that maybe the Committee could comment on it, about can that introduce, maybe, a selection bias in the process that actually makes the data harder to determine? If the inspector sees that, if I write a couple more NRs, this plant's going to get above the cut point and get an FSA. Or if I write fewer, they're going to stay below the cut point and not get an FSA. That ends up in our discussions about how to provide information, who to provide it to, when to provide

it, and whether that can actually work against us.

Kind of the idea of pharmaceuticals, they do a double blinded, where you don't really know what you're getting or who you're giving it to, so that there's this separation.

DR. VETTER: I don't see that as happening. I'm not saying that it might not be of use. This is Danah Vetter with NAFV. But my experience has been -- because it used to happen with PBIS. With PBIS you had the ability to pull noncompliance for a period of time and you could look at trending of sanitation and of those types of things.

And at that point in time, if you started seeing it trend upwards, you would go the plant and say something's going on. This is trending upwards. Do you have any people? Do you have a sanitation crew? Do you have -- what is going on? And it would come out. If you keep going at this rate, you will have an FSA. That would definitely be said if we don't find the problem and fix it and do something about it.

So I can't say that that wouldn't be said

or that wouldn't be discussed or that wouldn't be a plant's motivation to fix the issue. But I still think -- I don't think it would be used to just fly under the radar.

DR. TILDEN: And I think -- John Tilden -- if we're talking about going to a transparent process that's data driven for decision making, then you've got to trust people, give everybody the information and let them use it. And then if someone is abusing the system, that will become apparent too, and then you can take corrective actions. Whether it's a regulatory problem or it's an industry, then you work everybody together to fix where the problem is. And I think that's how you unleash the next round of improvements.

MS. KLEIN: Is it everyone's collected vision that the data that's available for IPP and for industry would also be publicly available so that other stakeholders could also be doing this same sort of trend line analysis?

And that could serve as a useful kind of watchdog for whether in fact there is an abuse of

the system, where analyzing the data, an outsider might say that's fascinating. You know, these people seem to be trending up and then they never quite get the FSA or, you know, because they're not getting enough NRs and it seems like the NRs taper off as soon as the trend becomes apparent. Or alternatively, wow, this is really working, this system, because as soon as the NRs start trending up --

DR. TILDEN: Action is taken --

MS. KLEIN: -- action is taken and the problem goes away.

DR. TILDEN: -- or the problem goes away before it becomes a problem.

MS. KLEIN: Right. So I mean, I would propose to add that, you know, any data that is shared in this way should be publicly available for analysis as well.

MS. GAPUD: I see the benefits well in that thing, because that will get them motivated to really do something rather than,. you know, well, it's just NR. Who is seeing the NR anyway? I agree

with you.

DR. TILDEN: I think we have to be careful about not providing disincentives for sharing information.

DR. VETTER: It can be blind data. I mean, it could be as far as that, but it could be -- I mean, you could not specify so that you don't --

MS. KLEIN: It's only blind for the public, though, but everybody else gets --

DR. TILDEN: Well, let's go back to public health. So when HIV -- there was the whole thing. Everybody should know everybody's HIV test, you know, and they get to the point where they say, you know, that is not in the public health's interest because you're going to drive everything underground and you're creating -- humans are humans and that type of information would not be used appropriately by everybody. So in the interest of public health there were safeguards put in place.

I think that's the kind of conversation. You've got to talk with industry and have those honest conversations of how do you build trust and

how do you also acknowledge that there is information that it just may not be in everybody's interest to share?

MS. DONLEY: But if it was blinded by just being Plant ABC and unidentified and the public could still look at it, then it's up to them to go FSIS and say hey, Plant ABC is having some real issues here. I don't know where. We're watching.

DR. REINHARD: I think the question is a good question. I think the Agency needs to walk and then run and get through the process. And so if you come up with a way for it be immediately used at the facility, it then leads to how did this information then go to the next step or not. And I think that's a good question.

DR. BOOREN: Yeah. Betsy with AMI.

You know, we talk a lot about benchmarking and I think that's what you're talking about. You're looking at data and you're trying benchmark whether it's inspectors in-plant, are they doing -- where are they sitting in the inspection? Or is it within districts?

We hear all the time about differences in inspection between districts and facilities, and so we're benchmarking, as well as the plants get the information and let's say we have more than one facility and you would perhaps want to see how your different facilities sit or how it sits compared to your industry. Benchmarking is really important.

The problem we found is how that data is released. And to your point, who sees it and what does it mean? And what we've always struggled with is putting that data into context. I can give you data.

Let's say it's NRs and let's say it's NRs -- give me something from a public health-significant NR -- a non-public health-significant NR, something that, let's be honest, you've got --

DR. REINHARD: A facility and grounds?

DR. BOOREN: Okay, a facility and the grounds.

DR. REINHARD: Outside the plant there was --

DR. BOOREN: There are implications to

that. But if you saw that number spike, is that really -- are we seeing public health -- and balancing. And that's a blurry line, but figuring out how to do that and make it fit.

And I know we're getting into a weird area here, but we struggle with that data and how to put it in the right context to make sure the best decisions for public health are being made. And we've looked at it and we haven't found a good solution. But we have found, when we start sharing it equally, that's usually when change is made.

So I mean, for what it's worth, that context, like I said earlier, the context of what data and what it means and how it's being used in a situation like this would never be more critical, because you can make a lot of false assumptions.

DR. REINHARD: There is a key with non-compliances. And so as I look across multiple establishments, what I do with non-compliances is you're not always just chasing if you've got one it is bad, if you didn't, it is good. It doesn't lead you to the right answers.

And so the rate and the regulation, as it relates to, potentially, public health regulations and public health and NRs, it is a place where we could look and see if that sub-context level is a benefit. Just chasing a huge bucket of NR rates in the country to drive them down, you know, it doesn't lead to the best results, I will tell you that. That's not a behavior that comes out and then gets what we want it to.

MS. HARVEY: I think should be left up to administration.

MS. KLEIN: Okay. So just to this final point, I mean, how do we like this? Except that it's totally redundant. Do not provide disincentives.

DR. TILDEN: I think we need to clarify that it should be made it available to the public, that walk-run -- you know, crawl-walk-run. And I personally think a lot of people agree that transparent means better information sharing. But I think that there has to be some acknowledgement. But let's start and do something successful at the

beginning and then build on that, I think, that incremental kind of a thing, to do it right first and then build, rather than just say hey, let's put it out there.

MS. HARVEY: Yeah.

MS. KLEIN: Help me understand where the -- why other stakeholders can't be privy to the learning curve. Like why, for example, consumer organizations shouldn't see the data at the same time that the Agency and the industry are also seeing it, even if it hasn't reached its, you know, summit of usefulness.

DR. TILDEN: And I can't speak for others. I'm just speaking as a state regulator. I do agree 100 percent with what you're saying. In practicality, I've been burned lots of times by information that's gotten out and gotten into the hands of someone who didn't know how to use it, and it tied up weeks of my time trying to undo something that was a non-issue and it became a communication nightmare.

And so that's why I'm hesitant to just say

yeah, let's just put information out there without the caveats of make sure it's appropriately explained and a reasonable human being could use the information and make good decisions with it.

Some of the data, it's just that it's not intuitive. That sounds like patronizing and saying oh, you know, people aren't smart enough. I don't believe that at all. But I do believe, especially when you're talking about large amounts of data, it sometimes take an awful lot of work to know how to use it.

MS. KLEIN: Well, I mean, I agree with that. I guess I was just kind of thinking about like, you know, in the law, we talk a lot about the reasonable person standard and that's supposed to capture that if a reasonable person would know that it's dangerous to do X and they do it anyway, then you're not negligent. But I think there are degrees of reasonable person when it comes to data sharing.

DR. TILDEN: Right.

MS. KLEIN: A reasonable person on the street is not going to understand the data, and if

we wait until a reasonable person on the street would understand the data, we're never going to get there. But could reasonable people who work in the field of food safety, who analyze data as a matter of course, who are used to seeing it, to contextualizing this information, understand the data much sooner than average Joe on the street? Yes.

And so I guess, as one of the organizations, for example, that belongs to the latter category, I don't want to be lumped in with average Joe on the street. If I have to wait for him to understand it, I'm never going to see it. So it seems to me that, you know -- yeah.

MS. DONLEY: I think, too, if it's something -- particularly in this day of, you know, the viral age that we're in and how things can just get distorted and just blow up, that it would be important that it be blinded and also that there'd be enough context around it to be understood that there's it can't be just grossly misrepresented out in the public sphere. It's a big charge.

MS. HARVEY: Sharika Harvey.

I agree with John, and back to Sarah, if you really consider it a learning curve. But as I said, I think it should be left up to FSIS administration. But, however, I think that if there is an organization, what have you, that wants the information can request it or there's a particular site. Writing an e-mail, or what have you, to get on a particular list, maybe. I don't know.

MS. KLEIN: I guess that sounds to me like a FOIA. It sounds to me like, you know, the Agency is going to share information back and forth with the industry. But anybody else who wants to be privy to it, I think, is going to have jump through some hoops and that seems like I can't -- I'm not comfortable with that. I think that the Committee's charge generally, although this wasn't a particular question, is that we should be recommending to FSIS. Ultimately, FSIS will make the decision.

And so I think we should try and reach consensus on whether we are recommending to the Agency that this same data be available to everyone,

but perhaps in a blinded or contextualized manner so as to prevent its misuse or misunderstanding. But I think we should try and come up with what we think is a reasonable recommendation to the Agency.

And so I'm still pushing for this highlighted language, that it should be publicly available, but it's reasonable to consider methods for sharing it that don't dis-incentivize it. But just because I'm typing doesn't mean I'm going to win.

DR. BOOREN: You said, why we don't want to share it? I think, to go from a walk-step-run, I think one of the things to think about is, if you're putting some of this data out there and you talk transparency, there may be a lot of bugs in it. And if you had a washing period with the industry or the Agency, if they decided to share data in that way, in a washing period to get some of those bugs out so some of the errors weren't misconstrued and then there was a washing period where it would then become publicly available, you sort of got the kinks out of the system.

Well, I think industry could get into that, because they're working through this process in a system and it allows it -- it's not perfect, but it allows it to get better and then that data would be made available.

I think you could do that in a way, because I don't think it's going to be flawless. You know there's going to be errors throughout this whole process, and kinks to work out. But having sort of a washing period, where perhaps the data is not -- at least initially not available right away, it allows industry and FSIS to fine tune that system and whatever that system may be, to report it. And then once it's where it needs to be, once it's available, then it's a smooth ride. We found in a lot aspects that we can do that. That process is so smoother and more accurate on a long-run period.

MS. KLEIN: So is it your vision that once that -- is it a washing period?

DR. BOOREN: That's the term I'm using.

MS. KLEIN: That phrase. But you're just going phase in.

DR. BOOREN: From a phase-in, yes. So what you're doing is, let's say you pick an example, you pick one product or whatever dataset it is and you work out the kinks.

MS. KLEIN: Right.

DR. BOOREN: And you work it through and let industry and FSIS, through a time period -- it could be a year, it could be two -- work through all of those kinks.

MS. KLEIN: It could be 90 days.

DR. BOOREN: It could be 90 days. We'd like a little longer than that to be thoughtful and put comments out and get them reviewed.

MS. KLEIN: We like that process. It's like 60 days.

(Laughter.)

DR. BOOREN: When we have that process, though, we get better data.

MS. KLEIN: Right.

DR. BOOREN: And we get better consistent data. And I think that's where we want to be, is better consistent data to make decisions.

And so that would be my justification, when you say why aren't we doing it right away? Let us figure it out. Let us work with our regulators to figure it out and we want to share. I mean, I'm speaking just -- that's a scenario of why we do it. I don't know if our industry, where it would be. But that's why when we've done many of our sharing of data, we go through that process because it helps us eliminate errors and we're better at it.

MS. KLEIN: Once the errors are eliminated, would it -- like once the kinks are worked out, is it your vision that then it would be shared contemporaneously or that it would always be shared on -- you know, like CDC, I'm getting 2010 data now.

DR. BOOREN: No, I think we're to an agreement with data. As long as it's accurate, as timely as possible is where we would be. I think we've all said that getting data too late is worthless. But there needs to be a process where we can initiate it and do it right.

DR. REINHARD: So we had a presentation on data sharing. Oh, sorry.

DR. CHEN: Go ahead.

DR. REINHARD: And I don't know what happened last time with this same question, right, with some on the Committee or whatever we did and we end up writing something like that. And I don't know if you want that or if we can do something where we all can agree.

DR. CHEN: Yeah, this is the question I tried to bring up. I think that's one of the long questions we had for the data Committee back in 2010. We had a long deliberation just on what type of data we should publish and in what format.

So yeah, it's in the previous report already. Maybe we should look at it from there, I mean, yeah, related to this discussion.

MS. KLEIN: Yeah, we don't have to reach consensus, necessarily, to include it because we can just say some on the Committee believe, you know, which --

DR. REINHARD: But could we word around it? So that would be my question, since we did that last time. We have a couple choices that I see that

potentially we could word around it and that would be -- one would be just state that we believe FSIS needs to take the information from this system and consider or just use it as they go forward with the initiative they went over earlier, blah, blah, blah, blah, blah, right?

And so that's the process that's going to get data out. We tell them to take this data over there, right, and then it potentially goes into that process and comes out. And it comes out however that process will be. Anyhow, that's how it's going to be. So we could just send it there or we could -- but that's a long process and I know that.

And so maybe that's a bit -- the other option we have is we could say data should be shared with all stakeholders, right, as they go through a process of implementing PHRs and review whatever, blah, blah, blah, and something to that effect, where then it's not -- the data, because then they do, right?

And it comes potentially in a quicker learning base, what's going on here, let's all get

this right, it's of value, which then potentially leads to an easier, automatic, rapid, fast, effective, publicly released data, right? They're two different terms, even though in essence --

MS. KLEIN: All stakeholders and publicly available are the two terms that you're --

DR. REINHARD: Are the two terms, right, right.

MS. KLEIN: I guess, yes, but public is --

DR. REINHARD: Stakeholder.

MS. KLEIN: The public is a very broad term. Stakeholder can be defined quite narrowly, depending on who's doing the defining. And so I would be concerned that if we say all stakeholders, that that's not going --

DR. VETTER: This is Danah Vetter with the NAFV.

And just for a point of clarity as to what I was kind of talking about and sort of to lead into that crawl-walk-run, currently, if you're in-plant and stationed at one single plant, you can only see that plant's data. If you're a supervisor, then you

can only see your circuit's data. If you're a district you can only see your district's data. And so we don't even have access to that. That's not in place right now. I mean, it is for the headquarter staff.

And so when my comment was made in the beginning, it's where it can be used with that single in-plant level in a proactive manner. And so I think that's the crawl part.

And then when you get to the walk part is when you can start comparing it district-wide to see if you're having discrepancies and so on and so forth. And those things are already in place with PHIS.

And then, when you get to the point where it becomes visual to the plants themselves, I think that's where you start into the run, because they don't even have the ability to see that right now. We can share it with them and communicate it to them orally, but they don't see our system and they don't see our data.

And so I think that's also part of that

crawl-walk-run type of process. And I think when you get to that point where industry can see it and look at it across the board, then that's probably where you're at that point where you can share it publicly across the board. But you have to start kind of --

MS. KLEIN: But there's no timeline. I mean, I don't know that a recommendation from the Committee, that the data should be publicly available, says from the get-go or whether it just leaves it to that, you know, the goal is transparency.

DR. VETTER: At the end, when you get to that point.

DR. TILDEN: I may be hopelessly optimistic, but when I listen to Betsy and you and Rob talking, I mean, you say 60 days, everything, Betsy says two years, some. At some point, if you guys got in a room and said, what can we agree to that's actually feasible? You know, because what we did is we kind of talked around it and we put blah, blah, blah down on the thing and two years later

what's changed? Nothing. I mean that's extreme. I apologize.

But if you got the people who are actually the invested parties in the room and say, what we could all work together, where do we share common interests, I think we could really advance public health by figuring out, even if it's not everything, where are the things that we could start, where we could try this out and then see how hard it is.

And that might be a recommendation as we take the implementation plans, you've already got an implementation plan, and just see, do you have the input of the consumers, industry, and others and say, can we vet that thing and say let's actually commit to do this, because I think you could.

MS. GAPUD: I think what Sarah was talking about this time, of course, at the end, is the transparency, that the public should know. And again, I think the industry, there would be more pressure on the industry to act on something if they know that the public is also aware of what is happening in their establishments.

MS. DONLEY: Sunshine disinfects.

MS. KLEIN: So I guess we're still at that question, if we include this language, is everybody comfortable enough that we can include this language or do we need to categorize it as some members --

MS. DONLEY: I guarantee you, when we get this to the full Committee, there's going to be a whole other round of discussion.

(Laughter.)

DR. MARCY: Well, my perspective is that, you know, even among the Agency, they don't even have it in full context. So to spit this out in a public forum without context, I think that's a train wreck. No, I would not be -- you know, until it's working, for it to be publicly available.

MS. KLEIN: Okay. So I think we should -- let's give ourselves a time limit, including me. The computer says 3:57. So three more minutes on this topic and then we're going just stick some people believe. And I'm going to let Tony talk, too.

But I guess I still maintain that public

forum doesn't distinguish between average Joe and me, and I need there to be a recognition that I'm not going to be a train wreck with the data, in the same way that average Joe on the street is going to be a train wreck with the data.

MR. CORBO: Tony Corbo, Food & Water Watch, again.

What's been the discussion with -- I mean, you made it in -- he had a couple of general presentations that he's made. I mean, PHIS is supposed to stop me from filing FOIAs. It has not worked yet and it probably never will.

But what's been in this sort of discussion that Sarah has raised here in terms of the ECAS (ph.), in terms of posting data?

MR. ALVARES: So I think there's a number of discussions particularly around and focused on PII, personally identifiable information, and some of the information that FOIA would typically redact, either corporate confidential or others.

But beyond that I'm not sure that there's been a lot of discussion about anonymizing the data.

I think there's a real sense that if you're going to put out the very most granular-level data and you were going to anonymize the plant numbers, the FOIA process is the key to un-anonymize.

So I think there's some discussion there about what it would mean to really anonymize the individual records of the data? I don't know. I mean, we do need to -- the data posting issue, I think, is sort of bigger than the PHR issue and it gets to a lot of other data topics.

But I think one of the things, we have to figure out is what data is available and what data has the right context and what data I think is priority. Maybe PHR-related data is a priority because of some of the bigger issues. But maybe it's not for others. I don't know.

DR. TILDEN: So does it have any direct relation?

MR. ALVARES: Yeah.

DR. TILDEN: I don't think you're going to get the whole thing. So what I would do is to say, take part of it as a good step forward and say, the

Committee recommends that pull together a subgroup to look at, specifically, how you can find an information-sharing process that is acceptable to the consumer rights, industry associations and then work it out within the next -- you know, within the short term, in some way that some data element, you guys reach agreement on it and it's vetted and it's appropriate and then get that done within six months and then you can build on that and say where do we go from here? Because my fear is that we'll just put out platitudes and we'll go and do the same and nothing happens.

MS. KLEIN: Okay, I'm going to try and capture that thought while we continue on with discussion of other matters and then we can just revisit and make sure that I captured it in a way that's still -- that feels better to everyone.

So what else do we need to -- this was a little bit off of the beaten path but, I think, an important discussion, very important. So are there other things on Question 3 that we think need to be addressed?

Okay. So let's talk about enforcement, because that has come up several times, but I'm not sure that we've captured it adequately. Just remember what you say so that I can do this real quick.

MS. HARVEY: Danah, can you write that for me?

DR. REINHARD: What was the enforcement topic about?

MS. HARVEY: I think you were out there. Saying that it boils down to -- it all goes back to enforcement, as John had brought up, what can legally be enforced, and Nancy was talking about it as well, and of course I brought it up even earlier. And so we definitely need to have more room for enforcement action. And John is going to write -- we feel it's important.

DR. TILDEN: He is, is he?

DR. MARCY: There's that midnight pill.

MS. HARVEY: He's probably got it written down.

DR. TILDEN: I thought the issue was there

are ways you can do investigations to identify root causes that aren't related directly with enforcement. But you can't lose sight of the fact of enforcing what you need to is your legal compliance in the short term, while you're building the scientific basis for improving your program over the long term.

MS. HARVEY: Yeah, that was just what it came down to.

DR. TILDEN: And I know this is something we haven't talked about, but maybe we can do it in the second cut, when we do it tomorrow, is the whole training thing. I think we haven't really talked about it. And part of the reason why some of this isn't transparent is we've got different people scoring things different ways and writing and documenting. And I think it never hurts.

And this maybe under Question 1, is just go back to as the lessons are learned and as your data analysis, figure out how to convert it in ways so that the decision makers and the frontline and industry and government are getting that information

that helps inform their actions and it helps them improve the way they're controlling risks, whether they're a regulator or whether they're industry.

So feeding back what you're learning into training programs is going to be essential.

CDR TARRANT: You have about 10 more minutes.

MS. KLEIN: All right. So I've worked on this language. I missed the enforcement language. So did you guys figure it out?

So Chris, does that make sense, just prior to the completion of the PHR deliberations? So what I'm talking about is, before you guys finish this plan, you know, that you would convene the stakeholders to discuss the data sharing. It wouldn't be that you complete the plan and then six months later you get everybody together to talk about it.

MS. HARVEY: The main stakeholders?

MR. ALVARES: Well, okay, so just for clarification. When we talk about completing the plan and getting stakeholders, we're talking about

the data posting plan. That's different than the PHR regulations, right?

DR. MARCY: You're already doing that, right?

MR. ALVARES: Well, we have been doing the old one, which was suspended with the ECAS.

DR. MARCY: Correct.

MR. ALVARES: Now we want to start off new with the PHR approach.

DR. MARCY: Right. But you're going to do that either way.

MR. ALVARES: And that's if we can get some cooperation. That isn't necessarily --

DR. MARCY: Right.

MR. ALVARES: I mean, to wait on that for the public health, prior to the public data posting part, I think I'm not sure I necessarily see the need to --

DR. MARCY: But you're not deliberating. You're getting ready to implement.

DR. REINHARD: So prior to, I think, we can say it and we can get it. So prior to implementing

the data posting plan, because that has to come before it even happens, anyhow. The Agency should convene stakeholders.

MS. HARVEY: John, how did you say it?

DR. MARCY: I don't know.

MS. HARVEY: I like how you said it, that was good.

DR. MARCY: Oh, sharing PHR data. You can say, to identify methods for sharing PHR data. And I would like to add that it serves the goal of rapid and effective risk mitigation.

MR. ALVARES: Excellent.

DR. TILDEN: So that's the whole point, is we're trying to prevent risks or control risks.

MS. HARVEY: And didn't you say the Agency should bring together --

DR. MARCY: And process transparency or something.

DR. TILDEN: I think that's what they're going to do there.

MS. HARVEY: Oh, okay.

DR. TILDEN: Yeah, convene stakeholders.

So that include consumer groups --

MS. HARVEY: Yeah, uh-huh, uh-huh.

DR. TILDEN: -- plus industry plus Extension.

MS. HARVEY: Okay.

MS. KLEIN: Do we need to say this is including business or do we all know what stakeholders means?

DR. TILDEN: As long you're okay.

MS. HARVEY: Yeah, because it's outlined there.

MS. KLEIN: It is the will of the Committee that stakeholders includes --

DR. TILDEN: You can say it and then it'll be in the public record anyway.

MS. KLEIN: It's the will of the Committee that stakeholders include consumer groups, industry, and other interested parties.

DR. TILDEN: Agreed.

MS. KLEIN: So we still -- sorry, go ahead.

MR. SERRATOSA: I'm Jordi Serratosa and I'm talking at a personal level, not from the European

Protection Authority.

My understanding is that the fear from the industry is that if once you agree with all of that, is that if you put the data on a publicly available way, even if you have been doing the methodology and you agreed how to explain, there will be a time frame where things will not run as they wish. And this is the conflicted view.

So from our experience, we have sometimes run pilot programs where you have limited access of limited partners on a confidential agreement for a limited time. Even if you agree to the methods, you agree on sharing the data, discussing how this data is expressed, until this data comes in a regular way in a transparent manner.

So I think are there are different steps for the interest of everyone, and I think FSIS -- this I my opinion -- should be very much interested and not only industry. But the consumers are there because the sooner they get the criticism, they better they are prepared to react in another way.

MS. KLEIN: Yeah, I think that's a valuable

point and something that should certainly be discussed at the meeting of identifying these methods, should be whether there's phase-in, whether there's confidential sharing with partners, whether there are pilot programs. I think all of that would be useful to have during that discussion of data-sharing methods.

DR. TILDEN: So we didn't really get the enforcement thing. It's just acknowledging that there is the need for both information gathering to improve the scientific basis of the program, while not tying the hands of the people who have to implement existing regulations to protect public health.

MS. KLEIN: For information sharing.

DR. TILDEN: Information gathering --

MS. KLEIN: Gathering.

DR. TILDEN: -- to improve the scientific basis of the program without tying the hands of regulators who have to implement existing -- enforce existing regulations to protect public health. So two different objectives for what we're doing.

Is that closer? Can you guys make it better? Or take it out.

MS. DONLEY: I thought what you're basically saying is enforce better.

MS. HARVEY: Yeah, and more enforcement, more --

MS. DONLEY: More robust enforcement of current regulations.

MS. HARVEY: Yeah, current regulations.

DR. TILDEN: I think you can put that as a second bullet and say --

MS. HARVEY: Yeah, current and future regulations.

DR. REINHARD: Some on the Committee.

MS. DONLEY: Some on the Committee?

DR. REINHARD: Yeah, I think that would be best.

CDR TARRANT: There's a request for us to be downstairs in five minutes.

DR. TILDEN: Can I put in one more plea, Sarah, while you finish up that one?

MS. KLEIN: Yeah.

DR. TILDEN: That whole training thing. While you're doing that, I do think we've got to figure out how to feed back what you're learning through your data analysis. I think you can put that into training for industry and regulators.

DR. REINHARD: I think that's important.

MR. ALVARES: And inspectors and policymakers.

DR. TILDEN: Correct.

DR. MARCY: I think policymakers are kind of alone.

DR. TILDEN: They're incorrigible.

DR. MARCY: Yes.

MS. HARVEY: You can put all of the regulations.

MS. KLEIN: Yeah. Yes, um-hum. Yeah, because we can always wordsmith it again.

DR. TILDEN: And then under Question 1, I think that's where you can put the training.

MS. KLEIN: Yeah, okay. So tell me what you want Question 1 to say, of the data --

DR. TILDEN: Just say, the information

learned by ongoing data analysis should be used to develop and update training for industry, regulators, and I don't know who else. Extension, you don't really train Extension, but it's used with officials. I mean with university folks. I don't know how you phrase it. Don't exclude you guys from the loop.

DR. MARCY: Well, FSIS actually has a multi-conference call on this.

DR. TILDEN: And shared. So it's shared with Extension and used with -- you can say the information gathered on data analysis should be shared with Extension and used to update. That's a start. We can clean it up.

MS. KLEIN: I'm not sure what they want me to do with this, so I'll save it to the desktop.

(Whereupon, the subcommittee 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
SUBCOMMITTEE 2
DATA ANALYSIS
Washington, D.C.
January 16, 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.

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TANIA KENDALL, Reporter
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