UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON MEAT AND POULTRY INSPECTION

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PRE-HARVEST FOOD SAFETY BREAKOUT SESSION

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THURSDAY
SEPTEMBER 22, 2011

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The Advisory Committee met in the Ballroom Room in the Savoy Suites, 2505 Wisconsin Avenue, N.W., Washington, D.C., at 1:00 p.m., Robert Reinhard, Subcommittee Chair, presiding.

PRESENT:
ROBERT G. REINHARD, Sara Lee Corporation
PATRICIA K. BUCK, Center for Foodborne Illness Research and Prevention
NANCY J. DONLEY, STOP Foodborne Illness
VENERANDA GAPUD, Fieldale Farms
JOSHUA HAYES, Center for Veterinary Medicine, USDA
CRAIG HENRY, Deloitte & Touche LLP (by teleconference)
HEIDI KASSENBORG, Minnesota Department of Agriculture
SARAH A. KLEIN, Center for Science in the Public Interest
CRAIG E. SCHULTZ, Pennsylvania Department of Agriculture
STANLEY A. STROMBERG, Oklahoma Department of Agriculture, Food, and Forestry

LEONARD W. WINCHESTER, Public Health -
Seattle & King County

ALSO PRESENT:
BETSY BOOREN, American Meat Institute
DANIEL ENGELJOHN, USDA
LAURA McKEE, USDA

DANAH VETTER, National Association of
Federal Veterinarians

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

1:29 p.m.

DR. LINVILLE: Have you had a chance to deliberate on who the chair is going to be yet?

MS. GAPUD: I would like to elect Craig Henry.

DR. LINVILLE: It's you all's process. I just was curious.

MR. REINHARD: Who wants to be the chair? We're taking volunteers.

DR. HENRY: I would agree. Bob, you pick up and run with it. One thing is for sure, I can hear you well, as close as you are to the phone.

MR. REINHARD: Yes, I'm sitting on it actually.

DR. HENRY: Good, good.

MR. REINHARD: Okay. I will chair.

DR. LINVILLE: Okay, great. So before you get started, if you don't mind, let me just sort of re-frame that one question. I

want to make sure that everybody understands. I mean, there was the request that I elaborate a little bit on the residue piece.

MS. DONLEY: Yes. Where I was really coming from with that was just to know the process because a question was would that same sort of process, if you will, be helpful for --

DR. LINVILLE: Yes. Now, I have to apologize a little bit. I'm the salmonella guy. I'm not the residue guy. So to that end, I do have Dr. Laura McKee in the back who is much more of a residue expert than me. So if we get into issues along those lines, she can sort of help me out on that. But let me try and re-frame the question, at least from the intent that I had when I formulated the question. As we said, right now salmonella is not an adulterant in raw products, not to say that it won't be in the future but at this point in time it's not. We have processes in place when we take a sample in the field that

we gather some of the information on the grower, on the producer, that we would be able to track. So there's that one piece of information.

When we have the samples processed from a lab perspective, you know, we obviously know whether it's positive or negative. We also get the serotype. We get the PFGE pattern. We get the drug resistance information. So we have that information that's also there.

So the question is is there some way, shape, or form that we can use this information that is being collected, can we process that information in some manner and use it in a way similar to what we're doing in residues which is where we're tracking individuals who are repeatedly providing source animals that have residues in them to the establishment? Is there something similar that we could feasibly do in salmonella? And if so, what would that be, realizing, again,

that right now it is not an adulterant? I mean, would we focus on the top 20 serotypes? Would we focus on particular -- I mean, I don't know. That's the question.

Things that could be done, for example, just to throw some things out for thinking, we talked a little bit about prerequisite programs a little bit ago. I mean, there could be certifications on the side of the producers bringing the product in that they have things in place that mitigate salmonella of some sort, and so establishments that are receiving source animals from those types of growers might give them some incentive for doing that. And then FSIS could work at some means of incentivizing that.

We have the option of targeting where we do our sampling. We could, for example, target establishments that don't partake in such an exercise. So there's some things there.

Obviously, we, as an agency, always

have the option of developing regulations that we need in order to ensure something is happening if they're not being taken care of on their own, I mean, you know, if there's not sort of a voluntary means of taking care of that. We would hope that something could be generated here where we wouldn't have to go down that road.

Does that help sort of maybe re-frame the question a little bit?

MS. DONLEY: So is this a, this is a random sampling program that FSIS does?

DR. LINVILLE: Currently, and we're actually -- let's see, today is Wednesday, so on Friday we're actually going to be posting the revised algorithm that we use for sampling if there's not a huge difference between that and what we've had on there before. It's just including the Campylobacter portion of it, for the most part.

It's not really a random sampling in that sense. It is more of a risk-based

sampling in that we do look towards establishments that are showing less of a process control. We always would go after a category three establishment from a testing perspective first and then a category two and then a category one. And then within those particular categories, we have product-specific stratifications, so broilers are on the top.

So, you know, we have a ranking that we go down as far as picking which establishments are tested. We start 75 verification sets per month or up to 75 per month. So we do have a ranking that we would go down in picking those establishments.

Currently, because Campylobacter is now brand new, that's all been sort of changed around. We have to get two full sets under the new Campylobacter standard before we can really start using that information realistically. So we're treating all broiler and turkey establishments as new

establishments, which is the highest ranking. If it's a new establishment, they always would be picked first. So everybody is kind of on the, it's restarting everything, if you will, for those establishments.

So from that perspective, yes, it is a little bit random, although we could put in place, okay, if a particular establishment has a particular serotype that that would raise them up in that ranking. That is an option, yes. We're not doing that currently.

MR. REINHARD: Let's go ahead as a subcommittee and get to the questions, and I'll let Dr. Vetter go as we try to work through how we're going to do this. So four questions that we've been asked by FSIS that I think we want to try to answer every one of them. One of the questions is about the pros and cons of using a program similar to repeat residue violators at FSIS. It's actually question number three, and I actually think it's the easiest question to answer. So we

can do it first, and then we can move to the other questions because I think that's important. If you'd like, Nancy, I can walk through the residue program and how it works in detail. It will take two minutes, three minutes.

So FSIS has two programs that they do. They have the national residue monitoring program which is a random verification that they take samples in the barn prior to going into slaughter, and I'm not going to go into that at all because it's different.

But on the regulatory side, FSIS identifies animals that are potentially likely to be positive for residue violations based off of postmortem inspection. They rail them out. The veterinarian in the facility comes and takes a pre-screen, a fast test, for residues.

If it tests positive in the pre-screen then samples are taken of the carcass and sent to the Midwest Laboratory in St.

Louis. They'll take a sample, I think the kidney, the liver, and muscle, but not the muscle from the specific place that identified they should collect a sample.

The Midwest Laboratory will run them for a variety of different residues, and they will report those results back in a couple of different ways. The first thing that happens, I'll take it through the establishment first, is they notify the establishment if there's been a violative residue found and what it was found in and what it is. So the establishment, the district office, and the vet in the establishment get that information.

The establishment is required to have a program to deal with that and decide how they're going to handle it at the establishment, okay? So, generally speaking, the establishment -- well, before I get there, the establishment does provide to FSIS all the information on the origin of the animal that

they have, if they have that information. So if there are ear tags or tattoos or any other way to identify the origin of the animal, that's provided to FSIS.

FSIS takes that information and they put it into a system called RVIS, Residue Violation Information System. They'll put the establishment where the sample was taken, the animal, the residue, and the producer information. That information is shared with FDA.

Now, on the FDA side, FDA has the authority to do all the things Phil mentioned. It's currently not really what they do. Right now, FDA writes a letter, basically, to the producer and says residue has been found that's violative.

FSIS monitors the producers in RVIS and they don't wait for FDA to say it's a repeat. But if they get a repeat producer in RVIS that nobody's squealing it wasn't me type scenario, then they'll take that repeat

producer and put them on the repeat violator list. FSIS used to wait for FDA to tell them, yes, we did confirm it was that producer, yes, it is blah, blah, blah, it is a repeat violator, put it on the list from FDA. They don't do that anymore. That part changed.

Now, with a repeat violator or the first violation, FSIS inspectors ask the establishment, at least they do the ones that I know about, when you receive animals from that producer again to notify them and they collect samples and follow up and verify that they're no longer sending in animals that are violating the residue policy. If you have repeat violators, the plant then would also have a program to decide what they do with that producer.

This system is built and the residue program is built under a couple of things, and this is where I think we can get through it pretty quick. Obviously, the reason the producers use different things is

for the health of the animal, but they're choosing to use them. They know when they get them. They know withdrawal times. They know everything about it. They don't really choose on salmonella, so it's a little bit different scenario.

So the program that is set up and the verification that goes on around residues is built on, actually, the ability to affirm and control it. And on the salmonella side, it's much different. You could put up a sign to not allow salmonella on the farm, but it may not work type scenario.

So the third question is do we see pros and cons. I guess that's basically the residue program. I know there are other experts in the room, so if I missed something or was a little bit off I apologize because it doesn't happen a lot but it does happen.

Now, the repeat residue violators that are out there, if you look at the list, they're on there many times. I don't know

what mechanism, if any, happens that really leads FDA, because of funding, because of all those other issues, to go do something and look for the injunctions and look for those things. It can happen, but I don't know that it really does from a practical standpoint of regulatory oversight.

Did anybody on the subcommittee have a comment about the residue monitoring program and how it works? Does that sound pretty close to right?

DR. KASSENBORG: I can give one addition. Some states do the investigations for FDA under contract. So a certain subset of those violators are tasked to the state to follow up on that.

DR. SHULTZ: Those are generally the first-time violators, and the lower risk, the less egregious violators. FDA generally does their own investigations on those that have repeat status or chronic status.

Also, on the national monitoring

program, actually the animals are selected off the line after they've been inspected and tagged, so we're not selecting them in antemortem. But we do use antemortem criteria, in addition to postmortem criteria, or we should be based on what the program says, to identify animals to be inspected. So we use postmortem and antemortem criteria to identify those.

DR. LINVILLE: Right. And realizing that, I mean, it's not a perfect overlap. Again, we're just looking for the basis themes of can we take the information that we have and can we encourage industry to take certain steps, you know, encourage growers to put things in place, encourage establishments to have things in place that encourages those growers, and that allows the FSIS to target their resources towards those that don't take those things into account. Those are the type themes that we're looking for, realizing that there's not a complete

overlap here.

MR. REINHARD: So then, Dr. Vetter, do you want to talk about the program, residue? All right. Well, let me ask, just for those in the audience, does anybody in the audience have anything they want to add about how the residue monitoring program works? Please go to the mic, and you'll have to state your name and your affiliation.

MS. MCKEE: My name is Laura McKee. I'm the Director of the Policy Development Division from OPPD. I'm in Omaha, Nebraska. Also, we have on the phone Dr. Jim Holterman, the OPPD lead for residue who has written a lot of the policies in conjunction with RIMD, and I think he captured it really well as far as what we do. The only thing that I would add is we have FSIS notice 1211 that came out in I think January or February, and that gave directions to the inspectors that kind of we're trying to lead industry more toward use in addressing the residues in the HACCP

program. And so we did direct the inspectors to increase testing after more than one violation, so that's the only thing I would add.

MR. REINHARD: And because we weren't asked to review the residue program, I don't want us to do that. I think it's important that we move forward on salmonella. So with that, we can deal with question three that we said, which is, now that you have a little overview of it, take it, spin it, make it different, how could it be used for salmonella if the agency were to develop some sort of approach for positive poultry or livestock? And I think the question is if they repeat or have multiple sample results that are positive, is there something they can do? Now, Dr. Vetter, you've waited patiently.

DR. VETTER: That's okay because my comment actually applies to question three and I think question one, to some extent. And I guess I have about two or three parts to it.

You're probably not talking about just one thing, but when you're talking about applying sort of our residue principles to how we address salmonella, are you looking to try to do that from a grower perspective? And if so, are we going to maybe try and start gathering grower information with our testing that we're doing?

DR. LINVILLE: We should already be. I mean, when we go out and take a sample, we are collecting the information on the lot. And with that, we would have who the grower is.

DR. VETTER: We might be getting the lot, but, at least, I've been out of the plant three years now and in recall, we were not recording the grower. And we were actually tracking that ourselves in-plant. We were writing it on a piece of paper.

DR. LINVILLE: And that is why I stated much earlier that there are some things that would have to be put in place in order to

completely track this.

DR. VETTER: Yes. Because that actually was not being collected on the lab forms when we were taking the samples. Now, lot numbers yes, but not specific growers. I guess that would be one part of it.

DR. LINVILLE: And PHIS is going to enable us to do some things that we were not able to do in the past.

DR. VETTER: Okay. And then so, from the perspective of applying our residue philosophy to salmonella, we really would be trying to go back to a grower type thing and possibly a repeat violator of particular salmonella with relation to the grower.

DR. LINVILLE: A grower or supplier.

DR. VETTER: Or supplier. Okay. And I'm talking poultry right now I guess more than beef. And so then the other question I have, I know it came up at the last meeting was the National Poultry Improvement Program

data and how that might be used for cross reference. And I know that that's a main focus on breeder and hatchery type situations, and it has a different purpose. But it could possibly be cross-referenced. And if you have people who are having problems in that area and it turns out that they're also being repeat suppliers of positives, then that could elevate their ranking, so to speak, to a higher level. And I didn't know if there's a reason we can't use that or why it wasn't mentioned. That's an APHIS --

DR. LINVILLE: Well, I mean, yes, it was discussed last year that the National Poultry Improvement Plan or poultry improvement plan type programs could be utilized by the establishments in many types of different control programs. Whether the establishment participates in the National Poultry Improvement Program or a plan or has their own program, those are things that obviously we would hope would be driven by

this type of policy, that on the pre-harvest side some things would be happening to help control this and that establishments then receiving those animals or receiving those products could sort of reward those particular growers in some manner, yes.

MR. REINHARD: Nancy?

MS. DONLEY: Thank you. I just want to make an observation here, a historical observation. And I'm going to use 0157 as an example. It seems to me that producers, if you will, got religion after receiving downward pressure because you had a situation where now the slaughter and further processing facilities were dealing with something that was an adulterant and that's where it really pushed the producers to do something about it. So I'm seeing a bit of a catch-22 here because there has to be some reason or historically it's taken something like a classification to make things happen at the animal level. I'm just putting out there

something that I see that could impede what we're really trying to do here, and I don't have the answer for it necessarily.

DR. LINVILLE: Well, and remember what we are focusing on here is what can be done by the establishment. And the establishment can, theoretically, put pressure on their suppliers. And so that is something that they could have in place, and that is something that we, in FSIS, can take into account when we're looking at how we do our testing.

MS. DONLEY: And that's a very good point, but I will point out also that it's come to some of our attention that there have been those suppliers who will refuse to sell to, you know, processors if they're going to put those types of restrictions on. I'm just raising these as real life --

DR. LINVILLE: And that's likely a good point in the non-vertically integrated industry.

MS. DONLEY: Right.

DR. LINVILLE: But in the vertically-integrated --

MS. DONLEY: In the vertically, yes, much different.

DR. LINVILLE: Yes.

MS. DONLEY: Yes.

MS. GAPUD: I just want to say something about, well, of course, there are poultry companies who are really doing everything they can with their growers. Of course, there are always exceptions, some people who don't care. But those people who care so much, because we are all on the same page when it comes to food safety and quality, we don't want to serve anything that would make people sick, okay? But we have to also realize that it's not just an easy process overnight that you can easily fix things, okay? We are working with our growers continuously, but, of course, there are lots of challenges to the growers. A lot of them,

you know, they don't know the scientific part of it. Of course, we are working with them, explaining to them here and there, but you have to also remember that, again, it's not overnight and it costs some money. You know, like a lot of companies, they don't own the chicken houses. They are counting on these growers also to supply them with products.

So it's tough, you know. And we hear everyone talking about safety and quality, and we are all on the same page. But it's not an overnight fix. We have to look at everything here and there. What will the farmer do, you know, if he doesn't say I don't want to sell my product to you because you are so, you know, strict or your regulation or your requirements are so tight.

MR. REINHARD: So that's the first question. Maybe we should go there. Ms. Klein?

MS. KLEIN: Yes. I just wanted to reiterate what Nancy said, that I do think

that one issue that can't be ignored, and whether it can be dealt with today or another day, that without the kind of downward pressure of the adulterant status it is, I think, difficult to have the kind of pressure that is needed to go all the way back to the grower. You know, obviously, my organization has submitted a petition to FSIS to do that for four different salmonella strains, and so I think that that's a conversation that needs to happen at some point.

MR. REINHARD: Dr. Henry, I know you don't have a little card to hold up and tell us you want to talk, and you're probably not going to interrupt anybody. If you just say my name and then I'll know to come to you and let you speak, if you would like to at any point, since you're on the phone.

DR. HENRY: You're a good man, Robert. I've just been taking in all of the commentary. I think to cut to the chase and get substantive information on the table, I

1 certainly concur with the comments as far as
2 downward pressure. Any kind of pressure is
3 always good. Media pressure probably
4 dominates over everybody else.
5 Relative to answering your question
6 on pros and cons relative to repeat violators,
7 regardless of what they are, I think a couple
8 of things need to happen. You know, I started
9 tracking salmonella by house in broilers back
10 in 1983. And, Bob, you and I both know that
11 the industry tries to take close stock of the
12 serotypes we picked up through the salmonella
13 testing program.
14 I think we need to have a reality
15 check. Pro. What is the pro of putting
16 somebody on a violator list? Well, that's
17 relative to how the violator list is acted
18 upon. And does that mean that you're going to
19 reject that supplier? I think when you're
20 looking at hogs and cattle and veal calves
21 and, in the past, veal calves have certainly
22 dominated the antibiotic abuse list. But

today, you know, when you're looking at easily sampling the whole chicken carcass and looking at a farm that comes in with 100, 200, 300,000 birds, you've got to say what's the disposition on that? Is it on the whole farm? Is it on the house? How are we going to manage that?

And I think that certainly a recommendation from the committee would be for FSIS to look at what data they have by serotype because we're looking at antibiotic resistance, and this is a moving target. We're dealing with over 2,000 strains of salmonella, and we know what the dominant ones are that tend to show up on poultry farms. But I think we need to know what do we currently understand, what's the baseline as far as serotypes that are coming in, and, as was brought up by Dr. Vetter, we've got lots and then the results that would be coming out from them. And then what would be the disposition of the flock? So downward

pressure, regardless of where it's coming from, what are we telling those people? I think poultry is your worst case scenario because of the high volume. But when you're looking at individual animals, now you can take a different disposition, you know, because they're larger, you tend to have fewer of them, but we still need to ask that question.

The other issue that I think comes up is the timing of the testing and how much we're doing through norms or some other way of really determining what that antibiotic resistance is. I think we're all fearful of getting more pathogens on the adulteration list, but what are we going to do with these animals downstream? So I'll throw it back over to you, Bob.

MR. REINHARD: Okay, very good. Oh, Stan?

MR. STROMBERG: I have a question on the cons on this question three is what

would this accomplish? Because I suspect that, in the vast majority of the cases, the companies are already well aware of who the suppliers are of this product and they already have this information, particularly in the vertically-integrated operations and I suspect in most of the red meat operations. They know where those animals are coming from already.

DR. LINVILLE: I would suggest that similar to what is accomplished in other areas is that if it actually is true that the industry has this information and they're not reacting to it that it would be an impetus to get them to react to it. I mean, here's the thing: if the establishments are not really focusing at what's coming in their front door, if all they're looking at is what's going out in the form of a performance standard, like for ground that's not 12 years old and was set at that time at what we consider to be the most effective means of controlling salmonella and at such a level that 50 percent of

establishments had to change their process to meet that. For the most part, it likely is the case that they have good manufacturing practices if they're meeting that standard. But if they're not paying attention to what's coming in the front door then serotypes of human health concern really could be on the rise and they not know that. And if they are focusing on that and not reacting to it, then I would say that's a problem.

MR. STROMBERG: In my own mind, I suspect that most of the time they know where those animals came from. Now, I'm not going to say whether they reacted to it or not, but I think they're well aware, particularly in the vertically-integrated operators and certainly in your large market steer operations. They know what lot those animals came from, and if they've got a problem I think they already have that information available to them. My question is by having FSIS develop this list and post it, is that

really going to provide anybody with new information?

DR. LINVILLE: Just posting the list, likely not. But, I mean, there are hopefully some things that we could do based on that list, and that's kind of the question. What would make sense? What could we try to do, I mean, you know, as far as incentivizing this both downward and upward?

MR. REINHARD: Dr. Vetter, and then there's a question or a comment from the audience, so then I'm going to go there and then I'm going to try to get us focused back on the questions.

DR. VETTER: Well, my comments I think apply to both question number one and question number three. I think that, as far as what we're talking about with applying, and I'm just going to call it the residue philosophy to the salmonella positives, that there's two separate ways of looking at it as far as implications and use goes, and those

are external implications and use as far as public notification similar to what we do with category one, two, and three, and then there are internal implications and use which, from our standpoint, when this information becomes available to us, we can make better decisions about how the establishment is reacting to it because, as you currently said, because it's pre-harvest right now, we don't necessarily have access to that when we really should because we should be also have the before and that's historically not really been the way that it is. So I think that accumulating it and determining how we can use it internally will be a very good thing because we can kind of go from there as far as downward pressure goes and what's needed regarding the food safety system as a whole.

I'd also say that one of the things to consider when we're talking about question one and maybe even question three is that Salmonella Enteritidis is certainly a big

concern with poultry but really primarily with chicken. And as you mentioned in your presentation, there's different ones for turkey. So I think when we're talking about looking at that, you need to think about the differences between the species.

And then lastly I would say we should take a perspective from what we've done with ready-to-eat products and prioritize based on the type of products that are more likely to make people sick when you're talking about raw product. And I think particularly that's going to be the ground because people don't always thoroughly cook them. There seems to be a lot of cross-contamination in the preparation of those types of foods, so that might also be a consideration when you're thinking about how to apply this information. That's all.

MR. REINHARD: I think those were good recommendations. I'll turn now to the audience, that there may be a comment from the

audience or a question.

MR. EWING: My name is Petit Ewing. I work for Koch Foods. A couple of comments on this. Fortunately, in the poultry industry we don't have a big problem with residues. Listening to the outline of how you went through that program and wondering how you can apply that, I don't think if we had a problem with residues in poultry that this program could logistically apply to us. I don't think it would work. Now you're talking about going from something which, as the gentleman said, is based on someone taking an action. Someone did something wrong to create that residue, and your program is designed to isolate and find that smoking gun and take some kind of punitive action against them to change it.

When you're looking at salmonella, you could have salmonella pop up where nobody has done anything wrong and you have multiple ways it could have come in. It may have been the grower, it may not. The grower may not

have done anything wrong with it.

As far as getting down to the grower, as the gentleman was talking about us knowing which growers did this, you have to remember in our industry we are vertically integrated. However, we're also all in and all out, okay? Our small bird operations, we turn that farm every 50 days. Birds are 35 days old, okay? Between the time that you found that flock that had the positive, okay, we already replaced that flock completely. That house may have been completely cleaned out or not. And now he's getting birds from a totally different breeder flock, which those are assigned at random. Each farm may be sourced from anywhere from five to a dozen different breeder flocks in there. So, in effect, you're looking at a different farm every time you cycle those birds. And like I said, that's 50 days you cycle it in our industry. I don't think there's a lot that you could take from the residue program and

put towards salmonella.

The other thing now, there's a lot of conversation about going back to the individual growers. Now, granted, we are vertically integrated. We have some control over our growers as what we do, but when you get to the point that you're starting to take actions against individual growers within our company, there's another seat that needs to be at this table and it's GIPSA. We cannot take actions against individual growers. We cannot separate them and take actions against one or another without some very good justification. And I don't know if finding salmonella or a particular serotype on that farm could justify us taking action against that grower because it could be introduced from numerous locations. Again, you're not dealing with a residue problem where there's a smoking gun. Somebody did something wrong.

I think one thing you need to look at with this is are you going to try to

control metrics, numbers, whether they're positive or whether they're negative, or are you going to try to control practices, realizing that someone may be doing all the correct practices and still produce a positive, versus if you're just going to hold people responsible for a positive no matter what their practices are? I think that's one basic question you all need to look at or a combination of those where you're going to control practices if there's a positive. If you do, we need to figure out what that breakpoint is going to be, and I haven't gotten a good answer on that yet as to what it takes to take action.

You know, you can go all the way, if it's going to be an adulterant, any where or any time we find it, you know, that goes on. I don't think that's a practical answer, personally. So, otherwise, we're going to have to really do some soul searching and figure out at what point are we going to start

taking some action.

MR. CUSTER: Carl Custer. I'm representing myself. I retired from FSIS in 2007, so I do some consulting and I'm working on a pre-harvest symposium for IFP next year. So I'm here, Craig. Four points. One, getting into the residue violation list is going to cost money because you're not going to be able to sell your animals public, veal calves, very well or if at all.

Second point is whatever you have on the animals going there at lairage, some of it is going to come out in the finished product. I mean, the interventions in slaughter will reduce the incident, but ARS has mentioned this several times both for poultry and for cattle and for pigs that if you have pathogens coming in you're going to have pathogens coming out. They may be reduced.

For finding out which growers would have positive salmonella or positive sugar

toxin, positive Eschecheria coli, FSIS could test in lairage or they could require the establishment to show that they are buying animals that are free of these specific human pathogens. And then there would be a cost to the grower if they are positive. That would provide some economic incentive to implement some of the many types of interventions for pre-harvest, whether it's probiotics, isolation, or some of the other things that we've come up with at College Station ARS.

And then the final point is that pre-harvest, the pathogens coming from flocks, herds, go into the environment. They go to produce, they go to recreational waters, they go to the environment. So pre-harvest, reducing the number of pathogens, human pathogens, in animals is critical.

MR. REINHARD: Thank you, Dr. Custer. I'll go ahead and go to Dr. Hayes and Dr. Shultz, and then maybe we can come back and answer at least the first part of question

three a little bit and offer out some ideas. Dr. Hayes?

MR. HAYES: Thanks. In the interest of not getting into trouble, I'd like to ask a question, you know, before considering that question. Even if, and speaking to one of the respondents, I'm not aware, personally, and I would ask the question can a person do everything possible and still have salmonella? You know, because my understanding is it's chickens, it's salmonella, it's Campy, that's what you're going to have. So is it going to be feasible then to have a system where you could possibly indicate violative growers and you would have a list that would basically be everyone in the U.S. at one time or another and possibly could that be counterproductive?

DR. LINVILLE: I mean, I would submit that, yes, you can have such a system. Denmark has done it. Now, whether we, as a country, want to go down that road is a

separate question, but is it feasible? Yes.

MR. REINHARD: I want to follow up just on that comment because, actually, Denmark does require testing of flocks prior to shipment to slaughter. That does not mean the flocks, when they are processed, are negative, okay? And so for Dr. Linville to say that you can have them free of salmonella, it's a play on words. You can have negative flocks that two to three weeks out, in the barn, still have positives at slaughter in the facility.

DR. LINVILLE: Okay. So let me back up then. There are greater flocks in this country that are certified salmonella free. I mean, it can be done. There's a heavy price that's paid to do it, but it can be done.

MR. REINHARD: Dr. Shultz?

DR. SHULTZ: From the standpoint of individually and small group sourced cattle or other slaughter animals, I think there would

be a concern relative to salmonella in terms of those animals commingling both at livestock markets and other points of concentration and commingling at the slaughter plants, the fact that an animal may acquire a salmonella, a multi-drug resistant salmonella organism in the process of traveling to or at the slaughter plant. And in addition, there's also a cross contamination risk during the de-hiding process. So once you've identified a carcass at the final rail that you've tested and it's tested positive for say a multi-drug resistant salmonella, that doesn't mean that that originated at the premises that carcass came from compared to a violative residue which is in that animal's kidney or liver or muscle tissue at the time that it left the farm. So I think that's a significant concern.

I also would like to point out that, in our experience with dealing with various salmonellas and particularly multi-

drug resistant salmonella in the ground beef industry, they have a tendency to come and go. About the time that you're really getting interested in a particular salmonella, and I'll use multi-drug resistant Newport in 2002 and in the northeast we had a significant problem. We started to very intensively look at it, and environmental conditions changed and it disappeared and we had other salmonella that were challenging.

And some of your data from this morning with regard to what happens when you reduce Heidelberg and then all of a sudden Enteritidis sort of takes its place. And I think that's a dynamic with salmonella that we don't really deal with with 0157:H7. There's a huge environmental component there.

MR. REINHARD: Ms. Donley?

MS. DONLEY: Thank you. You know, I think there's a distinction here that has to be made, and that's all salmonella, you know, in the generic sense, and those of the real

concern which the agency has identified as the antibiotic resistant and SE. And so we certainly know in the case of antibiotic resistant that there are things that can be done to prevent animals from developing those, let's just say from developing those particular strains of salmonella and, you know, the sub-therapeutic uses of antibiotics. So that's something that's more identified than the whole huge salmonella issue.

And second of all, SE, we know that that can be controlled, too, is if you are looking at, frankly, the producer. I know that they do it certainly for eggs, that they're having flocks that are guaranteed, you know, SE free to produce eggs. And I can't say I know a whole lot about this, obviously, from the comment I'm just making now about the SE. But I think that there are ways that can and should be, that producers can and should be utilizing methods that will control for antibiotic resistant strains and the SE. The

huge salmonella issue I think is too big for us to tackle, but I think we can and producers can and should be doing something about the antibiotic resistant strains and SE.

MR. REINHARD: Thanks, Nancy. I think to narrow the focus to something we can do as a subcommittee, that's what we'd like to do. Dr. Henry?

DR. HENRY: Yes. I think all good points made. It is important that we separate out what Dr. Shultz and others commented on, and that is, and I think Nancy or Dr. Vetter brought up NPIP. You know, over the years, and I had flocks that I dealt with. I was in the primary breeding business. Yes, vertically-transmitted salmonella we've controlled, etcetera. I mean, that we've been able to get done over many decades. The horizontal transmission that occurs within the house, and I think Dr. Shultz' point is the cross contamination that can occur in the slaughter, you know, in the holding pens or in

the holding sheds for poultry becomes a real issue.

So, again, back to the question three, pros and cons. One, I think you need to ask for clarification from FSIS and at what point do we consider it as positive? The gentleman from Koch Foods brought a good point to the table. You know, are you looking at quantitative data or are we looking at qualitative data?

Right now, qualitatively, certainly as a result of the turkey issue with raw ground, we're looking at ten percent. Now, in the past three or four years, we've seen an almost 60-percent reduction in the percentage of positives salmonella in raw ground turkey. It still says that, bottom line, we're still marketing the product.

We then go back and certainly look at the potential hazards being associated with poultry coming in that are positive, just qualitatively positive for a pathogen, a

salmonella pathogen, you know, the antibiotic traits that we're concerned with on resistance. But I think that we need to definitely get our hands around from FSIS, somewhere, we need to ask or say whatever action we'd be taking with a violation list, what are we going to consider to be positive in the case of salmonella, at what point in the process? Antibiotics are coming after everything is processed at the end of the slaughter line, process line.

In this case, yes, we go in there. Is it at the house level? Is it on the truck? In the holding shed? Is it on the shackles coming into the plant? We need to qualify that, and that comes back to then what are we going to do with it? What's the advantage of that information? Back to you, Bob.

MR. REINHARD: All right. Thank you, Dr. Henry. Are there any more comments from the audience?

MS. BOOREN: Betsy Booren with American Meat Institute. A couple of comments. I think, Nancy, to your point about wrapping your arms around this large salmonella issue coming into pre-harvest, I think it's critical that one of the things that needs to be broken down and it's been alluded to here is by species. The risks associated with different specie types, whether it's beef or pork or poultry, it really does need to be addressed. It's not a one size fits all. And in your risk associated with these organisms need to be addressed in that fashion.

To question number two, what innovative things can FSIS do, I think it would be important to have this committee address in some form or fashion the idea that we need more cooperation between agencies and get approval of new technologies. There's a lot of technologies that are out there. There are a lot of technologies that have been

researched and yet cannot get approved. I think a lot of your questions and concerns about food safety issues could be addressed if we could have some of those tools approved. And from an inspection standpoint, the idea of getting more of those tools in the toolbox that can be used by industry, producers, and FSIS is critically needed and it's not there yet.

And so those are just a few comments. I do think we need to approach this by species. I think there's a lot of issues that the poultry industry have that are different than the beef and the pork, and it's not fair, it's not realistic to align strategies for each. Thank you.

MR. REINHARD: Thanks, Betsy. So I don't know if the subcommittee at this time wants to try to answer this question or if we want to come back to it. I think we have a good understanding of what it is, what the question is and what a potential answer would

be. But versus us just writing down something now, maybe it's best if we come back to this question because I think we're going to want to answer an alternative. If we were to say don't use the drug residue program, okay, what type of things should we do? I think we're going to want to come back to it.

So I want to go to question one to see if now -- because then when we get to question three it's going to answer itself. Question one was on verifying factors such as subtype and drug resistance and historically played a significant role in human salmonella outbreaks. And with that in mind, the question is what food safety hazards that can occur before entry into the establishment does the committee see as most important for an establishment to consider in their hazard analysis? So this is a little bit more specific to maybe what was talked about before. Are there different salmonellas that we think people should think about, I believe

that's what they're asking, as you should think about in your hazard analysis and then what preventive controls you'd put in place within your producing establishment.

Off the top of my head, I can't remember the order that we went through in the presentation when it was given earlier this morning, but, traditionally, the regulatory requirement that is being cited talks about before, during, and after production has been to identify hazards that you have to take action on to prevent, eliminate, reduce to an acceptable level. I can't remember the words right off the top of my head. But it's really been for the producing establishment to put things in their process to deal with those hazards. It hasn't traditionally been looked at backwards into somebody before you should put something in with the exception of establishment to an establishment transfer of products, where that may be taken into account. So that would be the example that

was given in the validation of the beef trim going to a beef grinder and the beef grinder has the beef trim operation have preventive controls in place because there's a regulatory connection. But it hasn't traditionally gone backwards to some other input into the system.

And so the question here is is that, because it's not establishment to establishment I think that FSIS is asking but are there things that industry, the establishment should ask, put in their prerequisite program, and look for as a hazard and a hazard likely to occur, not a letter of guarantee type scenario or something like that.

DR. LINVILLE: And question one really is very broad. It's not necessarily focused only on salmonella. It's meant to be very broad. You can focus it on salmonella, but question two really is honing in then on salmonella.

MR. REINHARD: Okay. So Ms. Klein?

MS. KLEIN: Before I had a comment, but now I have a question. Clarify again for me what you're saying about, and this goes back to what I asked Dr. Linville before, the authority here is before it enters the establishment? We're looking at before entry, but you're saying, and that's why I asked Dr. Linville before, I'm just a little confused about are we talking about things that the establishment, obviously they don't have control over what happens before.

MR. REINHARD: Right. So let me answer so if I'm wrong I could get in trouble and no agency employee will. The regulatory requirement is on the establishment to consider hazards that occur before entry. FSIS takes regulatory action on that establishment if they don't properly do that. FSIS doesn't take regulatory action on anything pre the establishment.

MS. KLEIN: Okay.

MR. REINHARD: And I believe your question was is FSIS then, they can take regulatory action on the producer, and I don't know that it was really answered. I think the answer is no.

MS. KLEIN: Right. But they can take regulatory action on the establishment, which can push back onto its producer.

MR. REINHARD: Correct. That is the model that is in place.

MS. KLEIN: All right. Just to double check.

DR. LINVILLE: Yes, absolutely correct.

MS. KLEIN: Okay. So then I do have a substantive comment on the particular food safety hazard. My organization recently petitioned the agency about four different antibiotic-resistant strains of salmonella to be declared as adulterants. The way that we determined those four strains was that we used a combination of data. We used outbreak data

both from CDC and from our own database. We used NARMS data, and we used recall data. So the four strains that we wound up with in our algorithm, as it were, were Salmonella Heidelberg, Salmonella Hadar, Salmonella Newport, and Salmonella Typhimurium. Until recently, we didn't have outbreaks linked to all of those. We now have at least one outbreak linked to every one.

And so I would suggest, as a starting point, I would say those four would be my suggestion, obviously. But also I would consider a similar algorithm that would help to identify other strains that could be included as hazards that are reasonably likely to occur because I think that it is, I think it would be foolish to look only at one source of data. And so I think that that would be a good starting point. I'll leave it at that for now and I'll come back.

MR. REINHARD: Dr. Vetter?

DR. VETTER: I know, John, you're

probably aware of this, but similar to what Bill gave in his examples of validation issues, I know that there are some specific pre-harvest things that have come up in particularly outbreak investigations and FSAs where establishments might have seen a spike in salmonella or they might have seen some problems in-plant, and what they typically do is they will try and trace that back to, okay, well, is our CCP not working properly or interventions not working properly to reduce versus truly going all the way back to cause and effect. And some of the things I think we've seen is trying to trace it back, trying to look at house associations, and maybe even to the point of trailers and those types of things that could cause cross contamination.

So one suggestion that I would have is that possibly FSIS might give a list of examples that companies need to be looking at, if they're not already, when it comes to things pre-harvest that could affect. And as

far as I know, we don't have any real, I know we've talked about it but as far as specific examples of what we found, and then they might not know that they had a hole and that might be a way for them to see, oh, this is something we need to be considering before.

DR. LINVILLE: I think you just hit on the heart of the question is what we're looking for is what further information could we provide in the form of a compliance guideline or an update. We have a compliance guideline out there that has information in it. How could we augment that?

DR. VETTER: And I think probably one of the first starting points will be the salmonella outbreak and then the findings of those and to give examples of pre-harvest examples from those and then possibly FSAs, which, again, with PHIS they'll be able to pull that information out much more easily than we can now and put them in some form of a document so that is almost a little, it won't

be an all-encompassing but a checklist.

DR. LINVILLE: Right. And we absolutely have that in mind, but the recalls that we've had so far are a fairly limited universe, if you will. And so our hope is that we can expand that universe through the expertise of this group. It's a very good comment.

MR. REINHARD: Thank you. Ms. Donley?

MS. DONLEY: Thank you. I would just caution that just using outbreak information is probably not the way to go. I think the CDC piece provides some very good useful, you know, illness statistics that aren't necessarily associated with outbreaks, and we need to be looking at really the public health aspect here. And just as a suggestion, and this, to Betsy's comment, would be for all species. And I do agree that it is not a one size fits all. However, what we do know, and it was just shown, for instance, on your slide

about the fact of for the spike in beef, for instance, of the salmonella resistant strains is really quite alarming.

What we do know is that the salmonella resistant one is, you know, no brainer, is way too flippant a term. But I think that there is something that can be immediately done with this that FSIS were to, as a for instance -- and now I'm going to say something and then throw out a question. FSIS certainly has the authority to conduct antemortem inspections, and they do that with flocks, herds, whatever comes through. Can they conduct a test prior to slaughter to detect the presence of these antibiotic-resistant strains? Practically speaking, it may not be that they can hold back to wait for results because I think you said these tests take a while, that they can hold it back and the animals will proceed to slaughter. But then if it's found positive, they should then be diverted to a cooking operation just as in

ground beef with what happens with E. coli 0157. And then I would submit that this would then create the impetus for the producers to be controlling the antibiotics in the animal, which will result in an ultimate public health benefit. I don't know if I said that quite clearly enough or if I need to --

MR. REINHARD: I understand what you're asking for.

MS. DONLEY: Okay, good. Thank you.

MR. REINHARD: Any comments from the audience?

MR. YANCY: Al Yancy, U.S. Poultry and Egg Association, and this is a real simple one, would that it were so simple as simple use of antibiotics creates resistance. There are so many other things that have to be factored into that discussion, and the simple use or the lack thereof has been proven over and over again to not be the only thing. In some cases, it is not even the major thing.

MR. REINHARD: Thank you, Al. Let me go out a little bit on a limb here and say why did this question even come to us because we went over it a year and a half ago about pre-harvest controls, and the reason it came to us is because there was a major outbreak. There was a large recall, and the agency is trying to address that. And I think, I know industry has gotten together and gone over this issue in detail to try to figure out what can be done and what couldn't be done. But the reality is it isn't that simple. And really if it was, we would do something about it.

I want to focus back on what was said a little over, I think it was a little over a year ago about pre-harvest controls by the National Advisory Committee. And I want to ask a question about this additional question and the statement that was made before, which was the committee recognizes that this approach, this was on looking at

pre-harvest controls, will require multiple public meetings, possibly a series, with all stakeholder groups in many areas of expertise representative and the meeting should focus on various market classes and species of livestock and poultry and focus on existing programs and policies.

So FSIS said in the presentation today that they're planning to do this in the fall of 2011, and I think what this specific question as were pre these meetings, I see it very hard for this subcommittee or the National Advisory Committee to say FSIS should require facilities to do something before they even have the public meetings to identify if anything can be done.

So I think what we could look at is saying this specific question could be incorporated into those public meetings and used as part of those public meetings to support a next step in a future phase. But the crux of this question is what preventive

controls could an establishment put pre-slaughter, what requirements, when, in actuality, what those controls would be haven't even been discussed publically.

DR. LINVILLE: And I would agree. I mean, the question is what controls could be put in place? It's really sort of secondary. Who puts them in place? Industry can put them in place voluntary, and then FSIS doesn't have to. If industry doesn't, then it's something that FSIS might look at as having to do.

MR. REINHARD: Ms. Klein?

MS. KLEIN: Well, I'm not sure that I agree with the premise that we can't make recommendations until these public meetings have occurred. I think that this committee is supposed to be comprised of relevant stakeholders from the same groups that will be represented at the public meetings and that we can best make recommendations that will probably be very similar to what comes out of

those public meetings but that it is the responsibility of this body to provide FSIS with some guidance, to play a leadership role in what we think should be happening, not just waiting to see what comes out of the series of meetings. And so I'm not comfortable with just saying that the answer to the question should be we can't answer the question until after we've had these public meetings.

MR. REINHARD: Stan?

MR. STROMBERG: Yes. I think that perhaps what we ought to think about is encourage the agency, once they gain this information from these public meetings, to then develop best practices and some compliance guidelines, again, that are species specific for these different types of animals that we're talking about and have this kind of information that's out there that's available that people can use because right now I don't think there is really anything out there that's going to tell people what they can do

in a concise manner to try to control the situation.

MR. REINHARD: Dr. Winchester?

MR. WINCHESTER: I just had a question really regarding the, this is pre-entry and you're talking about innovative things that companies could do. The lady from AMI brought up that there are new methods, there are things that are out there that can be tried that the agency is not letting it be done further in the processing. But is this a point where we should be saying, yes, let's get those innovative ideas and those new testing protocols and procedures, maybe show us what the results are because this is pre-entry, and can you take that data and use that or that information to rapidly approve or maybe move forward with new testing protocols?

DR. LINVILLE: I mean, I guess that really sort of depends on who the authority is that approves those things. But if there's something that FSIS sees that would be useful

that is approved by another agency, then we could obviously work towards getting that approved, yes.

MR. REINHARD: And I think in question two that asks about innovative techniques, and the reality is the federal agencies need to lead to get this moving forward because we have been stuck. Even if the agencies say they're going to allow things to go forward and they're going to interpret a regulation slightly different than maybe it has been in the past, we still end up getting stuck over and over and over in similar places. And so with question number two, it would be very good for FSIS to step up and lead to bring those agencies together, to bring those technologies to the front, and say how do we move these forward now?

DR. ENGELJOHN: This is Engeljohn with FSIS. So I would just suggest on that point if you could put those issues on the table that would be helpful to just identify

what are those impediments or things that you know could be feasible. If you know as a committee, then I think it would be helpful to just identify them and make that as a recommendation, from my perspective anyway.

DR. HENRY: Bob?

MR. REINHARD: Yes, Dr. Henry?

DR. HENRY: Thank you, sir. I'm going to reflect back again to the meeting we had, the last meeting, which you raised. In that meeting, we drew to everyone's attention, and, Carl Custer, I think you're still in the room, and, if I remember right, you were in the same meeting I was back in, I'm going to say it was '04 or '05. USDA, ARS, down at the southeast region, Dan Bailey was there and others, and we had a meeting down there. It was focused, in this case, on poultry, which tends to be the hot subject right at the moment, where all probiotics were addressed, vaccines were addressed. Multiple, if you will, alternatives for mitigation were brought

to bear. That needs to be brought back to the table. There were a number of impediments with vaccines being approved. I think CVM, APHIS comes into the mix. All of that needs to be brought back, you know, and considered. If they want to hold another meeting, that's fine, but I think we need to make very straightforward statements in our reply from this subcommittee as to, okay, let's assume the vaccine worked, let's assume that we put other controls in place. If a flock is found positive pre-harvest, because a lot of our questions here are all pre-harvest, if the flock is found positive, you know, what are you going to do with the flock? I still think we need to walk through the what-if scenarios.

Nancy brought up, you know, that if you have the downward pressure and the flock is positive and there's ways to test, acknowledge all that, are we now going to set up a slaughter facility that's only for positive flocks? Because if that positive

flock comes to the yard, and, realistically, it could take two weeks to confirm whether or not a flock does have the salmonella in question, but then it's brought to the yard. Now, are you going to cross contaminate or contaminate the rest of the product in that plant because Carl made a note earlier that the salmonella basically is going to follow through the plant one way or the other.

So I think that we have to have a reality check. If we say that vaccines, at best, usually are 80 or 85 percent effective, what are you going to do with 15 percent of the animals or the birds that are out in there in the field today? And if FSIS is going to enforce, enforce means what are you going to say? They can't come in, or there has to be a mitigation? How are we going to measure that? And I think we need to call these out and ask for hard answers to them because just to say there's technologies, there's ways to test. And I agree. Fine, we know there's a pathogen

out there, but what are we going to do, what can we do if the flock is found positive and we move that flock to some slaughter facility? Let's revisit the science and put it to the test. Back to you, Bob. Thanks.

MR. REINHARD: Thanks, Dr. Henry. Dr. Custer, go ahead.

MR. CUSTER: Actually, Dr. Custer is my wife. I'm just Mr. Custer. Anyway, two things. One, I think the bottom line is public health. How do we reduce the environmental burden of pathogens for crops, for chickens, for cows, for everything? The other part is there are some of these, a lot of innovations that cannot be applied during growing of poultry, as an example. And the question is -- it's not free. How do you get to growers to implement it? Where is the economic incentive? Do you develop a regulatory disincentive for them not to use these innovations? Well, I think that's sort of the bottom line. One, you're pushing

public health, but how do you fund implementing these innovations?

MR. REINHARD: I'm just going to comment because the other question on funding is is that is this the appropriate place to pour a whole bunch of funds, or is there another place that would be more appropriate? Dr. Masters?

DR. MASTERS: Dr. Linville, Dr. Engeljohn, you can pull out the transcript from the 2005 public meeting. Not one single one of the pre-harvest interventions mentioned at that meeting has been approved by the Food and Drug Administration or APHIS. The poultry industry still has a very strong interest in all of those being approved and has continued to work with both of those agencies to try to approval, and there's strong interest by the industry to use those compounds.

On the beef side, there's significant ones. I don't think there's a good place to get those documented, and we'll

work to try to get those to you. And I think having a central point to have those and discuss those, there's a strong interest. The National Cattlemen's Beef Association and AMI are working on research on all those compounds and have a strong interest to try to use those in pre-harvest and would be glad to do that. And pork, absolutely.

MR. REINHARD: Thank you, Dr. Masters. So we'll continue with the first or I guess the second. We trickled over to the second question without answering any of them. Ms. Donley? I'm going to call everybody doctor so I don't mess it up the wrong way.

MS. DONLEY: Senator. Before we move on to that, is there anything, Dr. Linville, that you can share with us about what Denmark does and can we learn any lessons there?

DR. LINVILLE: You seem to know more about Denmark than I do.

MR. REINHARD: I'm not an expert.

MR. YANCY: Very generally -- it's Al Yancy, U.S. Poultry and Egg Association. Denmark started in 1976, so that is the first thing. Their government paid, in other words reimbursed their industry for every loss that they took by slaughtering the flocks that were positive. So we're decades behind where they were. There's no funding from the government that's coming. The industry would foot the entire bill. And the other thing that's of interest is, prior to some of the plant idling that occurred in the Athens, Georgia area, more product was produced in Athens, Georgia than in the entire country of Denmark. So there's another thing.

When you look at the demographics of what we do in this country, the sheer volume, and the sheer volume of that country, it outstretches it by a factor of God knows what. But I'm sure someone knows, someone else knows other than God.

So the other final point that's

been made is a lot has been talked about the funding, the finances, what's it going to cost? I want to make this point as a representative of U.S. Poultry and Egg Association and our members. The funding is only important in this respect: does it actually do anything? I don't think the industry is concerned about we're spending this much money to address these issues. The question is are we having a benefit? Are we actually moving the bar on food safety at all? That's the context of this money that's being spent, and I think that's the important thing that has to be said.

I think if we can show through any of the actions that might come from this group or from any other group that certain things would actually be more beneficial than some of the things we're doing, I'm not sure that industry wouldn't be willing to spend that money. So I just wanted to say that, and I appreciate the opportunity.

DR. LINVILLE: I think we do need to acknowledge that Al and U.S. Poultry and Egg and others have a coalition that is working towards reducing SE, and we are getting ready to provide them with additional SE data. So I wanted to acknowledge in front that industry is working towards this absolutely.

MR. REINHARD: Mr. Ewing was it?

MR. EWING: Yes. Pettit Ewing, Koch Foods again. One thing you brought up is the question of whether this committee recommends even going forward with any regulatory action. One thing we've seen from this, Al is talking about it, Denmark has been doing this for 35 years with what they have. I don't know how their results have been. Dr. Engeljohn mentioned getting all the things approved on the list. Well, we brought that list up five years ago and nothing has moved. As far as I know, there hasn't been any new interventions introduced in the last five or

six years. The interventions that are out there, I've tried most of them at one time or another, you know, with little or no response.

As far as what we're looking for, when we start talking about looking for specific PFGE patterns or antibiotic resistance things, remember I had that flock in the field for 35 days. Our longest shelf life is 19 days, okay? So how long does it take us to get that information? And, again, like I say, it would be nice to say, well, we'll do historical data, but in our case, if you're trying to go back to pre-harvest on the farms, well, I've got a different farm every cycle. Every 50 days, I have a different farm with different parameters, and that's not even taking into account the weather with those.

So possibly one thing to do would be to pick something to go after and put some things together for some research. Let's get some more tools. The tools we have right now I don't think are adequate to do the kind of

regulation, especially if you're talking about down to specific PFGE patterns or resistance. So could one of the recommendations of the committee be say, okay, we need these tools and when we get these tools then we can proceed and make arrangements to hit in the direction of getting those tools in our hands?

If I had an intervention that would work as a CCP, I wouldn't mind putting it in. Right now, I don't. I mean, by regulation, a CCP must eliminate, prevent, or reduce to an acceptable level. When you start going out in the field, I don't have a single tool that I can prevent, eliminate, and I don't even know what an acceptable level is. So until we can get something like that, it sort of puts a roadblock in us. I mean, we can throw a lot of those interventions out there and require us to do them. We're doing most of them already. We're just not seeing a lot of results from it.

MR. REINHARD: Just procedurally, I

1 think we'll take -- I'm going to let Dr. Hayes
2 speak and anybody else that has a few
3 comments. At five minutes til, so in five
4 minutes, we'll take a 15-minute break. We'll
5 let everybody reorganize and then come back.
6 And we have until 4:15 to try to get through
7 the questions and answer them, so, like
8 always, there's not a lot of time for us to
9 work through these. And we start up first
10 thing tomorrow with our recommendations of the
11 subcommittee to the full subcommittee. So
12 potentially we could say, and you can talk
13 about it at break, we're going to come back in
14 here at 5 a.m. and keep working on it. I
15 mean, but the reality is is the time is always
16 short no matter what we do. So Dr. Hayes?
17 MR. HAYES: Yes. Thanks, again.
18 Just to address the question about we've been
19 here before and, you know, here we are now and
20 nothing has happened. Something I think
21 that's worth people understanding a little bit
22 is for products, for example, that come

through as drugs for Center for Veterinary Medicine, those things require a certain standard. You know, they have to go through a certain process. And so a lot of times what happens is you have really good research done, perhaps by FSIS scientists, where they put some papers together and show an effect and you see some interesting and some encouraging signs. However, to go from there all the way to approval usually almost always requires the involvement of a drug sponsor who's willing to put forth the effort to do the studies, to satisfy the regulatory hurdles in order to get an approval.

One of the respondents also mentioned, you know, what is the financial incentive for the industry to start using these things and whether it should be an incentive or a disincentive if they don't, you know, I'll leave that to FSIS or, you know, the committee to consider. But for CVM's perspective, we're definitely very interested.

1 Food safety is a priority of our
2 organization, and we're definitely interested
3 in new technologies and new products being
4 brought forward.
5 So I think that, you know, the
6 suggestion that perhaps we have better
7 coordination with the different agencies I
8 think would be great. But, you know, just
9 keep in mind that we're going to need somebody
10 to carry the football at some point to get
11 through the regulatory hurdles.
12 MR. REINHARD: So I'd like to
13 comment on it, and I'm not an expert so I
14 apologize. But on the animal drug side, it is
15 not an extremely, my understanding, profitable
16 business to be sinking all the innovation
17 into. And the regulatory process is so
18 burdensome that the risk and the cost to get
19 new interventions to market is extremely high
20 and that that may actually be something that
21 could be looked at and say where's the cost
22 benefit, why is it so hard to get through this

for food safety, to let some things come through, well, let things that all the controls are in place, so I'm not going to get into that, but come through it in a much more cost-effective model for the people that are willing to try to develop new interventions and those type things because I do sense there is a big expense to get through the regulatory process and it may be critical that some of those things are there. But I have heard that as a burden and a little place where the final, where things stop in the final from the academic, this looks great, something could be done with this, to the actual full-scale commercial production viable intervention going to the farm.

For Dr. Henry, I'm going to tell you what time we have. It's 2:54 p.m. We'll come back and we'll start again at ten minutes after three exactly. For Dr. Henry, we will start right at ten minutes after three. I'll turn the phone back on. I will mute it in the

meantime until that point in time. So if you do a stopwatch, you have 16 minutes or a little less.

DR. HENRY: Sounds good, buddy.

MR. REINHARD: All right. Thank you.

(Whereupon, the foregoing matter went off the record at 2:54 p.m. and went back on the record at 3:12 p.m.)

MR. REINHARD: So we'll go ahead and get started, and I can open it up and people can comment based off of what they discussed or thought at the break. Dr. Gapud? Oh, well, I told you I was just going to do that no matter what. I apologize to the doctors in the house.

MS. GAPUD: I just want to make a comment what we have just discussed so far, talking about what Nancy mentioned earlier. I think we should just concentrate big time on the priorities on the species and not just say, you know, salmonella, yes, you're gone.

You know, the moment you have salmonella positive, you're gone. We have to concentrate on the species. We should prioritize that.

And also have we thought about also doing some enumeration and stepping up the threshold for salmonella? Again, I have to assure you that, as far as I know, the industry is doing everything they can do. And also, even without FSIS saying you have to do this, you have to do that, looking at the history, the industry did the very, very best, worked so hard to lower the incidence of salmonella in the products that we are putting out now. That's why with this performance standards, that's why I think they use that also as basis of lowering even the requirement just by the fact that, of course, we in the poultry industry did our very, very best to lower it on our own, not just waiting for someone to tell us you have to do this. Of course, we all want quality and safe product to our customers because if it's not safe our

business will not go anywhere. So we're all on the same page.

MR. REINHARD: Thank you. Dr. Shultz?

DR. SHULTZ: Just a comment about trying to effectively deal with salmonella, multi-drug resistant salmonella as an adulterant and also some of the pre-harvest theories that we've had, as we go back into the early days of E. coli 0157:H7, that we thought were effective, changes in the way that we fed cattle and what we fed cattle prior to slaughter, and many of the other theories that came down that we thought would be effective that proved ineffective. So the point arises about do we have a defined set of best management practices, pre-harvest practices, that will deliver the desired result? And until we do, we're in the process of risk minimization. We're not in the process of pathogen elimination at this point. And I think pathogen elimination is, in terms

of an adulterant, is more achievable with 0157:H7 with infectious dose of one organism as opposed to a salmonella situation where there's definitely a dose relationship. So there's always variables that make it very difficult to regulate.

MR. REINHARD: Ms. Klein?

MS. KLEIN: In the interest of time, I wanted to propose that the subcommittee move to actually coming up with some recommendations that we can make before the committee tomorrow. And I have several to suggest, but I feel like we've spent a lot of time talking about what we can't do and so I'd like to propose a couple of things and then we can see. If they don't survive, then they don't survive. But the first would be a recommendation from, I guess it would eventually be from NACMPI that something like a recognition that improved testing methods are needed to shorten the time period between sampling and finding of antibiotic resistant

status. It seems like that's a sticking point for a lot of people is the 14-day turnaround time in that, so if the committee made a recommendation on --

MR. REINHARD: So, Ms. Klein, just procedurally, can we do this? I think it's a good time for us to go through and just make recommendations. So we can see them, I'd like to just list them all out, and then we'll go back through and talk about them and let anybody make recommendations of what they think. And so the first one is on improving -- and if you want to scribe, you can put the name after it to keep track of that, if that's necessary. So I think it's a good time to switch and start moving.

MS. KLEIN: Okay. Should I go ahead with my other recommendation?

MR. REINHARD: Go ahead.

MS. KLEIN: Okay. So the next one would be to consider pre-harvest sampling methods. You might have to help me wordsmith

this one since this is ours but pre-harvest sampling methods to determine the presence of select salmonella strains because, again, we're talking about narrowing that universe.

And then the third recommendation was a recommendation that would reflect a desire for streamlined cooperation between agencies that are responsible for approving and implementing new technologies for pre-harvest, so recognition that if we're having problems with drug approval that there needs to be cooperation between the agencies that are responsible for granting approval to use the technologies that FSIS might deem to be appropriate, etcetera.

MR. REINHARD: So very good. I'm going to ask a clarifying question just on the second one. Are you saying consider pre-harvest sampling methods or FSIS? Are you saying FSIS do pre-harvest sampling? I think that's what you're saying, right? So FSIS consider pre-harvest sampling and then get rid

of the word methods, right? They'd have to figure out how they're going to do it if they were to go do it. Okay. I think that's very good, and so we'll keep going.

DR. KASSENBORG: This is a procedural thing. Can you increase the font or move the scale over there? Because I don't think, it's hard to see here.

MR. REINHARD: Okay. Very good. And if you can't see there in the back and you want to move up around the table, I don't mind if that's what you want to do. Okay. So other recommendations? At this point in time, we'll take other recommendations. I'll make a recommendation that I think is necessary based off the last outbreak. It would be appropriate for FSIS to call on all producers to reassess their HACCP plans for salmonella control. It is what's been done over time with E. coli 0157:H7, with those type things, but it's appropriate when there's an event and I think the industry is doing it already

anyhow. But then FSIS has the ability, if they would choose, to do FSAs, to verify it, to make sure that people have in place best practices in the producing establishment, right? Because there's a lot to control the salmonella in the producing establishment and how you run it through your process and what things you do.

I do also believe in a preventive control program for salmonella as a prerequisite to your HACCP plan. So that is another thing that FSIS could ask for. Nancy?

MS. DONLEY: A point of clarification. We're talking about all species here, and obviously it would need to be tailored by species --

MR. REINHARD: Correct.

MS. DONLEY: Not just poultry industry.

MR. REINHARD: Right.

MS. DONLEY: Okay, thank you.

MR. REINHARD: Yes. I'm naturally

thinking poultry. I can't help it.

DR. KASSENBORG: Point of clarification. When you say producers, do you mean establishments?

MR. REINHARD: Establishments. Producing establishments.

DR. LINVILLE: Can I just ask real quick which question we're deliberating here?

MR. REINHARD: We aren't, per se, deliberating any of them. And so I'm assuming our answers are going to be for all the questions all the way around. Now, there's one question we haven't even talked about, and so I'm going to try to get to it if we can get through this. Heidi, do you have a comment? Okay. Stan?

MR. STROMBERG: My recommendation would be what I said earlier, that FSIS develop best practices and compliance guidelines for the reduction of salmonella in production facilities. And I'm talking about animal production, not meat production.

MR. REINHARD: So producers.

MR. STROMBERG: Producers, right.

MR. REINHARD: For producers. For this production facility, it's going to be FSIS develop best practice and compliance guidelines for pre-harvest producers. All right, good. Other suggestions? Dr. Shultz?

DR. SHULTZ: With the last recommendation, would you be mandating some kind of a HACCP, perhaps a CCP, that addresses pre-harvest as you have a mandated CCP that address 0157:H7, or how do the best practices fit into the HACCP rule?

MR. STROMBERG: Historically, FSIS has used compliance guidelines as guidelines. They're not regulatory requirements. They're just something to help producers maybe come up with a better way to eliminate this pathogen.

DR. SHULTZ: So in their HACCP plan, they may or may not address pre-harvest?

MR. STROMBERG: Yes. This wouldn't necessarily be a requirement for a HACCP plan.

It would be something that would help producers eliminate salmonella in their facilities.

MR. REINHARD: Ms. Klein?

MS. KLEIN: I would actually love to see the recommendation be that FSIS consider the best practices to be part of a critical control point, a required critical control point for HACCP plans. Again, that could be, I mean that may not be a consensus point but I'd like to at least have it as a debatable option.

MR. REINHARD: So we'll talk through it when we talk to them. Are there any more recommendations?

MS. GAPUD: I would like for FSIS to consider salmonella enumeration of select salmonella strains. Consider salmonella, enumeration of salmonella, not just say if it's salmonella you have positive salmonella, you're gone, okay, because we have to re-prioritize what strains we are talking about.

1 But considering enumeration of salmonella and
2 then setting up threshold, I think that can be
3 beneficial.
4 MR. REINHARD: Dr. Vetter?
5 DR. VETTER: I would just go back
6 to the recommendation that we look at
7 prioritization, that you do consider products
8 and high-risk products, that the types of
9 products be considered. Particularly, I
10 guess, that would apply to question one with
11 when you're looking at hazards associated with
12 salmonella. And I know it's before, and
13 that's not necessarily before but when you're
14 producing a higher risk product you may not be
15 as likely to say not likely to occur as you
16 would be to say likely to occur as far as it
17 being a food safety hazard.
18 And the other thing that I would
19 recommend for FSIS is that possibly look at
20 bringing, you talk about the public meetings
21 in the future but bring APHIS into this
22 discussion, particularly with their NPIP

information, because it is possible, while we might not be able to make it public, we might be able to cross reference some of the things that we're finding.

MR. REINHARD: Nancy?

MS. DONLEY: I'd like to just add another one, and that would be that FSIS should have some sort of a public posting system of producers that have had contaminated flocks or herds with the salmonella strains of concern.

MR. REINHARD: The 20?

MS. DONLEY: I'm sorry, what?

MR. REINHARD: The 20 salmonella or the 4?

MS. DONLEY: Well, I guess we were trying to, well, we didn't say exactly what we were limiting our discussion to, but it was certainly the ABR strains and SE.

MR. REINHARD: Okay, all right. That's fine. I'm sure we'll work through it. So I'll open it if anybody -- Dr. Shultz, did

you have another -- okay. If anybody else has something they want to throw out, I'll take it from the audience. Barb Masters?

MS. MASTERS: I just want to add to Ms. Klein's. I think we should also look at improved testing methodologies for rapid identification of serotypes. It's difficult for the industry to get rapid identification of individual serotypes of salmonella.

DR. BOOREN: Hi. I would also like to add to recommendation -- Betsy Booren, B-O-O-R-E-N. I would like to have recommendations as you're examining data for trends and such that you do not only look at it as a species but, for instance, in beef, look at veal versus dairy cattle. I think it's important with these areas of residues. I think we have classes of animals that are at higher risk, and if we're doing risk management those classes should be identified in the beginning, not at the end. Thank you. MR. CUSTER: Okay. I'll do lucky 13. Actually, I

want to build on Masters' number 11 and not only serotypes but virulence markers in salmonella and even Escherichia coli.

MR. REINHARD: So does anybody else have anything else they want to put up here to discuss? Yes, Dr. Henry?

DR. HENRY: Yes. Bob, adding to the list of participants, there was discussion for the public meeting ARS, as well as APHIS and CVM, should all be in those pre-harvest public meetings and look at mitigation factors and technology. There's meetings. There should be a very close review now of the efficacy of vaccines, especially in light of the Salmonella Enteritidis work that's been done in layers. The meetings certainly should consider the control of horizontal transmitted salmonellas and also, of course, vertically transmitted, which is the NPIP. The FSIS should consider foreign country experience and success with salmonella control with horizontal and vertical and especially

utilizing input from Canada, Australia, Denmark, and the UK. And then last recommendation for FSIS to create guidance on the disposition of animals found positive for antibiotic-resistant salmonella pathogens of human concern when those positives are found pre-harvest. And then the last recommendation is that FSIS define a pre-harvest testing program. Barb has already called out I think the methodologies on the tests that I think could characterize where, when, and how sampling and at what point do we consider flocks to be positive or negative prior to slaughter or an animal prior to slaughter.

MR. REINHARD: Hold on real quickly, Craig, because I want to go back through. So here's what we have written. There should be a close review of efficiencies of vaccines in light of Salmonella Enteritidis work in layers.

DR. HENRY: Right. Focus on let's review and evaluate the efficacy of vaccines.

Right.

MR. REINHARD: Consider horizontal and vertical transmission.

DR. HENRY: Right. Considering both horizontal and vertical transmission of salmonella control and we need that experience not only domestically but also looking at foreign countries such as and specifically Australia, Denmark, the UK, and Canada.

MR. REINHARD: Okay. And you recommend FSIS create guidance?

DR. HENRY: Guidance --

MR. REINHARD: Hold on, hold on, hold on, Craig. Just because we've got some typing going on. Recommend FSIS create guidance and disposition of animals found positive for ABR salmonella.

DR. HENRY: Yes, provide guidance on what the disposition of pre-harvest sampled animals should be when found positive for salmonella.

MR. REINHARD: Okay. For

disposition.

DR. HENRY: Yes. I mean, what is the recommendation to the grower and/or the company and/or the establishment on disposition of those flocks, which would take into account cross contamination throughout the process. And then the last one is how and when samples should be done for salmonella pre-harvest or, if you will, pre-slaughter.

MR. REINHARD: Got it.

DR. HENRY: That goes in tandem with what Barb Masters recommended.

MR. REINHARD: All right. Can we go up above to number eight?

MS. KLEIN: FSIS create guidance and disposition is not correct. It should be FSIS should create guidance for the disposition of animals.

DR. HENRY: Correct.

MR. REINHARD: Thank you. Go back down. Did he get it? No. Go back down. FSIS --

MS. KLEIN: For the disposition of animals.

MR. REINHARD: Of animals. Okay. And you said something else, but I think it's already on here and he just wanted to add to it. So if you go up to seven or eight, oh, and nine. So bring APHIS into discussion, and, Craig, you had said ARS?

DR. HENRY: Yes, ARS.

MR. REINHARD: So on number nine, can you say bring APHIS, ARS, and CVM? CVM. Okay. Heidi?

DR. KASSENBORG: I would add, I don't know if it's 8 or 13, but adding in lessons learned that FDA might have with implementation of their egg layer rules, SE rules. You might be able to add that onto something.

MR. REINHARD: Okay. Nancy?

MS. DONLEY: I like what you had said earlier, Bob, about FSIS taking the leadership position with, you know, between

sister agencies in getting this agenda pushed forward. And like a sub-point to that would be to work with FDA and we heard discussions about these interventions and things that are being held up for approval.

MR. REINHARD: So how about if we really put some teeth in it and say we recommend FSIS take a leadership position in evaluating interventions that are currently moving through the regulatory process and on a quarterly basis report out their movement and what they've done with their sister agencies to move them forward?

MS. DONLEY: Sounds good to me.

MR. REINHARD: So I think we have a lot, and we have a lot of good ones and a lot that actually are practical and can be done and can be a focus. I don't know how directional it is. Dr. Ewing?

DR. EWING: One thing I would raise, we've had these interventions around for about five or six years for both in-plant

and pre-harvest out there. To improve communication and dissemination of information, I think FSIS should take a real close look when they're doing investigations and publish a report on the effectiveness of interventions that have been put in place during their investigations. In other words, what interventions work and what didn't out in the real world. Most of our stuff is just based on pure research stuff, but I think when they look at an intervention they should look at how effective it is and report it back to us so we know which ones to use.

MR. REINHARD: Okay. Yes, sir?

DR. SHULTZ: I know we've pointed this out at last year's meeting, but all of this is sort of contingent upon an effective animal disease traceability program and it all hinges on that and the interaction between the various federal agencies that are responsible for it. It's a cooperative interagency initiative, so it's challenging.

MR. REINHARD: So I didn't let you comment. Let's go back through. We only have a few minutes for each one. Let's go back through what was said. If we get a sense that the entire subcommittee agrees with leaving it, we'll leave it. If we don't, we'll say the subcommittee didn't agree. We'll still leave it, I think, to report out, and then we'll move forward.

So if we could go back up to number one. So this is for improved testing methods are needed to shorten the time period between sampling and finding of ABR status 14-day turnaround time. Now, if it's okay, I would like to add what Dr. Masters had said onto this one. So if you go down to Dr. Masters because it's similar, improved testing methodology. You can make it one --

MS. KLEIN: You can make that the sentence. FSIS should improve testing methodology for rapid identification of --

MR. REINHARD: Yes. So if you put

it at the beginning. So improved testing methodology for rapid ID of serotypes, virulence markers, ABR.

MS. KLEIN: No, just delete all of that and put and antibiotic resistant and then ditch the 14 day.

MR. REINHARD: So for the subcommittee then, and at this point I'll let the audience comment, but the subcommittee itself, any discussion that we want to have about this statement and if we're okay with leaving this as a recommendation for FSIS?

MS. KLEIN: Just a question. All of our recommendations are only for FSIS, right?

MR. REINHARD: Correct.

MS. KLEIN: Okay. Okay. I wouldn't want to mean that industry couldn't take it upon themselves to do any of these things if they so choose.

MR. REINHARD: I think that certainly it could be read that way, and I am

sure they'll review it in detail and try to move forward with anything that can be done. So the first one, anybody have any comments or things they want to say about it? Does anybody object to it being a recommendation of the whole subcommittee? So we'll leave it, and so that one is agreed to. I don't care if you bold it or mark it somehow or do whatever. That will be a subcommittee recommendation.

Okay. Number two is to consider pre-harvest sampling to determine the presence of select salmonella strains. Any discussion about number two? Dr. Vetter?

DR. VETTER: I think it's a good recommendation. I don't know that FSIS would have the authority to do it.

MR. REINHARD: Correct. FSIS could perform tests at antemortem prior to them going through the slaughter process.

DR. VETTER: And it could be that there wouldn't be I guess the potential to necessarily divert the product because the

results would not be back in time for that finished product. So I just think you just need to kind of make that, what the expectation of that question would be and what the reality of it would be.

MR. REINHARD: I'm going to take it the way it's written and then I'll let you change it. It says to determine the presence of select salmonella strains, so what FSIS would do is determine a prevalence rate, the presence. That's what this says. And then do something. I assume that once the data and the science was there then something potentially could be done, but that's what it says. And so if we want to expand what we've really requested, we can at this point. Nancy?

MS. DONLEY: Well, with the assumption that we get faster at, to point one, that we get improved testing methodologies, that once that's done that then there would be distribution decisions that

would be made when they're doing this, point number two, antemortem sampling, understanding that we're not there but that the ultimate goal, can we put it somehow that the ultimate goal then would be that number two would then result in product disposition decisions? Are you following me?

MR. REINHARD: Yes, I do. And so I'm going to let you write it, and I'm going to try to help you through it. So we would put and potentially use information in the future to determine product distribution and use.

MS. DONLEY: Well, I guess with the ultimate goal of --

MS. KLEIN: From preventing the product from entering commerce.

MS. DONLEY: Yes.

MS. KLEIN: You could take out potentially use the information in the future and just say with the goal of.

DR. HENRY: I think that Nancy's

comment ties back into the recommendation I threw out there for FSIS to provide guidance on the disposition of those animals, so now you can make that up depending on how it fits on the paper.

MR. REINHARD: So if you take Dr. Henry's comment of, yes, the last sentence.

MR. HAYES: But isn't that a separate issue from actually doing it? Guidance is one thing, doing something with the information is another.

MS. DONLEY: We want this done.

MR. HAYES: Right. Guidance is separate from actually --

MR. REINHARD: Let's write a copy of the last two sentences. Move them up and then stick them in after the first sentence but before the last sentence.

DR. HENRY: Bob?

MR. REINHARD: Yes, sir?

DR. HENRY: A quick question and it's my fault for not being there this

morning, but has FSIS taken the position that antibiotic resistant salmonella of human health significance is a hazard reasonably likely to occur?

MR. REINHARD: No. So hold on. Consider antemortem pre-harvest sampling to determine presence of select salmonella strains. I'd like to say, comma, create guidance for the disposition of animals found positive for ABR salmonella.

MS. KLEIN: I don't know that we want it only to be guidance. Is there a way that we could put more open language? Create a framework for, paren, guidance, rules, etcetera, closed paren, just so that it gives the agency room to determine whether it's best done in its guidance or rulemaking?

MR. REINHARD: Create framework for, I got it, and then get rid of the second "for," or the first one probably would be proper. The disposition of animals found positive for ABR salmonella of concern.

MS. KLEIN: It might be wise to have a preamble that talks about narrowing the universe of salmonella so that within our recommendations it's clear that we're referring to a delineated universe so that we don't have to state it every time. However we put it, whether it's virulence or ABR, but it's a recommendation further down but maybe that recommendation should just be a preamble that the committee recognizes that the universe of salmonella is broad and that the agency should narrow it down and that these recommendations refer to that narrowed down list of salmonella, whatever it may be. Does that make sense? To be determined by the agency and stakeholders, something like that.

MR. REINHARD: So what does the subcommittee think? Do we need to say this?

MR. HAYES: I think that's good information. It could be a separate point. FSIS determine, blah, blah.

MS. KLEIN: Yes. That that's the

first thing they have to do is determine the universe and then, once that universe is determined, these other recommendations follow.

DR. KASSENBORG: You mean narrow the universe?

MS. KLEIN: Yes. Galaxy, whatever is smaller than universe.

MR. REINHARD: I think, from a practical standpoint, this is right scientifically, but it's very difficult for a producing establishment to change right now. And that's the point of the first one, which is get faster tests, get more information, use it then to narrow the universe. I don't know. I'm going to leave it up to the subcommittee to comment about -- and it can be number one. I don't think the order matters.

MS. DONLEY: I think what's going on here is that the whole idea is that, again, we're not talking about all salmonella species. We're just trying to focus in on

1 those species of the highest public health
2 concern.
3 MS. GAPUD: And I concur with
4 Nancy.
5 MR. REINHARD: Right, right. Is
6 the subcommittee comfortable with the
7 statement that's there now: FSIS should narrow
8 the universe of salmonella to a selection of
9 salmonella strains of highest public health
10 concern? Ms. Klein?
11 MS. KLEIN: No. I was just going
12 to say I'm not comfortable with the
13 wordsmithing because I think it's too
14 colloquial for this. I was just saying narrow
15 universe, but I don't think we should actually
16 use that.
17 MS. DONLEY: Can I make a
18 suggestion? I had it and I lost it. We're
19 recommending our recommendations to FSIS.
20 Before you start typing and I make you crazy,
21 our recommendations to FSIS are based on the
22 salmonella strains of highest public health

concern. So we're not telling them to narrow it, we're just telling them that all this list here is recognizing that it's strains that pose the highest public health risk. Does that make sense?

MR. REINHARD: It's the committee's recommendation --

MS. DONLEY: Are for, are for salmonella strains. And then you can keep the SE, ABR, and/or others determined by agency that pose the highest public health concern.

MR. REINHARD: Well, it will always be the agency and stakeholders, right?

MS. DONLEY: Right. So the committee's recommendations below are maybe targeted to -- yes. So, yes, to salmonella strains, so we can get rid of selection of.

MR. HAYES: I don't disagree with any of the wordsmithing. However, I think it changes what you're actually asking for. Yes, this is the preamble for what follows, but if you're asking for FSIS to determine that then

that would be a separate action item because, yes, you're saying, these are recommendations targeted to this, but you're not asking them to actually do anything to identify what they are.

MS. DONLEY: Also, maybe number one --

MR. REINHARD: The parenthetical can come out, and we can make it number one, right?

MS. KLEIN: Yes. The third one should be the agency and stakeholders should identify those salmonella strains of highest public health concern.

MS. DONLEY: Yes. So that's the preamble.

MS. KLEIN: So maybe something like the agency, in collaboration with stakeholders, should identify the salmonella strains of highest public health concern and prioritize their control in pre-harvest consideration. Oh, yes, pre and post harvest.

And the second one, the second sentence would read something like these may include Salmonella Enteritidis, antibiotic-resistant strains of salmonella, and others. Yes. What do people think about that? So now we're asking the agency to do an algorithm basically where the agency delineates what strains they're most concerned about.

MR. REINHARD: So any comments from the subcommittee? Any comments from the audience? To add these may include specific species, SE -- so who proposed that? So if you go down --

MS. BOOREN: Yes. Within classes, if they're broken out dairy cattle versus veal cattle. I think you have different classes of animals within species that may be at a higher risk.

MR. REINHARD: So just cut Betsy's out, and we're going to take it up above. Just delete it. You're not going to need it. Go straight up to the top, and that sentence,

when we say and others, before we say and others add animal species, correct?

DR. VETTER: But you might just put a second sentence after that that says, after that sentence you put another that basically says that the specific strains -- you might want to wait until I get done talking so I don't drive you crazy just like Nancy. But the agency should consider species, class, and product type when prioritizing risk of certain salmonella strains. Yes, animal species.

MR. REINHARD: So what this says is that beef may be different than poultry and ground product may be different than breast.

DR. VETTER: Right. And prioritizing the risk of various strains.

MS. KLEIN: So what you guys are saying, I just want a point of clarification, that the salmonella strain of highest public health concern for ground turkey might be different than -- but wouldn't they all be the same list of these are the salmonella strains

of highest public health concern and it's just certain classes and subspecies of animals would be more at risk of contracting them but the list would still be the list? It's not like there would be five separate lists, a list of cattle, a list for veal, you know what I mean? There would be one list of salmonella strains of highest public health concern. It would have, for the sake of argument, six strains on it but not all animals would have the same likelihood, right? Is that wrong?

DR. VETTER: No, I don't think that's wrong, but I think when you're talking about particularly plants considering and conducting their health hazards that they are going to have to look at it that way. And the agency providing them data in that manner will help them address it better in their particular situation because there are plants that, they might slaughter five different classes of beef, and so they need to take in, knowing what applies to what classes will be

very useful, I believe, to the industry in addressing those particular risks and what they need to be testing for and looking at.

But, yes, you are correct. Overall, they would all be part of the same risk but not necessarily applied the same way in the different establishments.

MS. KLEIN: But it's not like the establishment wouldn't be responsible for controlling for all six? They just wouldn't likely encounter three of them, but they would still bear the responsibility for all six? Do you know what I'm saying? Does that make sense?

DR. HENRY: Hey, Bob, I've got to sign off and catch an airplane. I'll see you guys tomorrow. If you, by chance, have an opportunity, email me whatever that draft is tonight. That would be great. I can take an eyeball on it before tomorrow morning. And I assume we're still starting at 9 a.m. in the morning?

MR. REINHARD: Yes. So let me go over that now. So, procedurally, the other subcommittee is still on their first question. I think they had four. So I believe what's going to happen is they're going to let us go until 5:00 and not bring the two groups together, and then we'll bring the two groups together in the morning and just start the two groups together in the morning. So we'll get clarification here in a minute on that, but I'm thinking that's what's going to happen.

And then on the public comment part, because we've been allowing public comment all the time, unless there's objection, we'll not, per se, stop specifically to say public comment. You feel free to comment at any time, as we've done through the whole thing. It's like we have a subcommittee that's advised by the entire public. Yes, ma'am?

MS. DONLEY: I'm grappling a little bit with --

MR. REINHARD: Okay, Craig. I will send this to you if we can.

DR. HENRY: Okay. That's great. And then I'll see you at 9:00 tomorrow morning there, whatever room we're meeting in there.

MR. REINHARD: Yes. But if that changes for some reason or something happens, I'll let you know.

DR. HENRY: Yes. I appreciate it all. Bye-bye.

MS. DONLEY: I'm just grappling a little bit with that last sentence, and just so that I'm understanding it correctly, the agency should consider animal species, class, and product types when prioritizing risks of various strains. It's not really prioritizing the risks of various strains, is it? It's prioritizing how they're going to enact measures or enact, because we're saying these are high risk so they could consider the animal species, class, and product types when prioritizing how to maybe implement changes or

1 something like that to develop intervention
2 strategies or something like that.
3 MR. REINHARD: I think what's being
4 said here, and I'm going to be real, I think,
5 E. coli 0157:H7, if it isn't a hazard in
6 turkey, this sentence would take care of it.
7 That's what's being said. And I think, Ms.
8 Klein, you were more of the, well, I don't
9 like that because if it is a hazard and E.
10 coli 0157 is a great hazard of great public
11 health concern, turkey should address it, too
12 is what she's saying. I think. I'm just
13 trying to get down to the . . .
14 DR. LINVILLE: Can I make a real
15 quick comment? I mean, your point is well
16 taken. I think if you follow through with the
17 recommendation of prioritizing by species then
18 that could be used to help inform industry in
19 their hazard analysis as to whether it's an
20 issue or not. They would have to still
21 determine whether it was in their
22 establishment. And also it could help us in

developing algorithms for testing. Among other things, we would test differently in a ground turkey plant than we would in a chicken plant, you know, based on SE versus Heidelberg, for example.

MS. DONLEY: So you're saying the agency should prioritize by animal species, class, and product types?

MR. HAYES: I don't think so.

MR. REINHARD: Well, it could be consider and prioritize. It was consider before, right. I think it's consider hazards. Okay. The agency should consider animal species. Okay. So Stan thinks the way it reads now is good, and I'm going to, I think it's close so --

MS. DONLEY: That's fine.

MR. REINHARD: So for the whole subcommittee, is there objection to this entire sentence, all of them, number one, as it's written? Are we going to make this as a recommendation from the whole subcommittee?

Okay. Any public comment about the first? Okay.

MS. KLEIN: Do we want to, and it could be either in this one or another one, give the agency guidance as to how they should identify, or do we think that the word "in collaboration with," and what I mean by that is do we want to say something like the agency should consider outbreak data, NARMS sampling data, and recall data when making their determination? This is just an open question for everybody.

MR. REINHARD: Anybody have a comment or thought?

MR. HAYES: It would seem to nest within soliciting stakeholder input, but if you want to be clear that it's specifically addressed then you probably want to say it.

MS. DONLEY: You might be able to just add that these may include SE, ABR, and/or others and could utilize outbreak, recalls, and sampling information.

MR. REINHARD: It should just be and/or others by utilizing --

MS. DONLEY: Oh, yes, yes.

MR. REINHARD: Instead of and could it could just be by utilizing outbreaks.

DR. BOOREN: Bob, the other thing that could be considered here is, as they're doing baselines, that would be an opportunity to gather across whole classes and other information because there are some points here from a scientific standpoint that we don't have all the answers for them and doing and adding data during a baseline is an excellent way of getting good statistical data, and that might help with that, as well.

MR. REINHARD: So outbreak, recall, sampling information, and baseline. Yes. Okay. While he's typing this, I'm going to tell you procedurally a change. We will have public comment for the whole committee, so the whole committee is coming up here at 4:30. We will get more time to work in the morning, and

so they're going to tell us at 4:30 what that means. And so at 4:20, in nine minutes, we will break because the other subcommittee is breaking. That will give us ten minutes. If anybody wants to talk to any of the different stakeholders, that gives you a chance before the whole subcommittee comes in. Ms. Klein?

MS. KLEIN: I'm not sure about the baseline addition. I don't want to delay things by requiring the agency or by having somebody say, well, NACMPI said we should do a baseline. And so I --

MR. REINHARD: I really like the baseline --

MS. KLEIN: I'm not comfortable with the baseline language.

MR. REINHARD: It says may include, and so it's not an affirmative you have to, just like we wouldn't want them, if there's never been a recall, to think somebody could say, well, there's never been a recall for it, it can't be done.

MS. DONLEY: Can we insert the word "and available baselines?"

PARTICIPANT: Hey, Bob, this is Scott.

MR. REINHARD: Yes, Scott?

PARTICIPANT: You know, I think baselines are starting, and maybe there could just be some more additional questions added to those baselines when they're doing it? I think that's the point. I mean, they just completed their market hub baseline and, you know, they're trying to find out do you do X here and X here and X here? So when they complete their baseline, they kind of have a best practice, lessons learned kind of a thing possibly.

MR. REINHARD: Okay. So number one is good as written, number two is good as written. Number three is, and we've been through this one so we're pretty close on this one, too, consider antemortem pre-harvest sampling to determine the presence of select

salmonella strains, create a framework, guidance rules, disposition of animals found positive for ABR salmonella of concern, pre-harvest.

MS. KLEIN: It should be for the disposition of animals found positive for the strains.

MR. REINHARD: So Dr. Vetter wants to go back, consider antemortem pre-harvest sampling, and then she thinks a parenthetical of when and where, where, when, and how is what -- and then that last bit can maybe come out, right, is what we're saying? And that last sentence, do we need it? I don't think so either, so that can come out. And so for number three, is the subcommittee okay with the recommendation?

MS. KLEIN: After select salmonella strains and create framework, we need to either have two sentences there or we need to have a semicolon or an "and," something.

MR. REINHARD: Stan?

MR. STROMBERG: I am having a little bit of a problem with the very end of that about preventing positive product from entering commerce. I think that probably needs to be worked a little bit because if you do that that means you're not even going to allow them to cook it, and I don't think that's the intent of what the committee is trying to say here.

DR. LINVILLE: If it's cooked, it wouldn't be positive anymore, right?

MR. STROMBERG: I'm sorry?

DR. LINVILLE: If it's cooked, it wouldn't be positive anymore, right?

MR. STROMBERG: I just think it ought to be clarified because the way I read that, if it's positive it's positive.

MR. REINHARD: Unsafe. Is unsafe product okay?

MR. STROMBERG: Yes.

MS. KLEIN: We like adulterated.

MR. YANCY: Bob, may I say

1 something?

2 MR. REINHARD: Yes, you may, Al.

3 MR. YANCY: Al Yancy, U.S. Poultry

4 and Egg Association. I really have been

5 holding back, and I'm very concerned about the

6 approach that's being proposed because we're

7 really looking at creating regulations out of

8 thin air and basically adopting a zero

9 tolerance, a non-detector, and adulterant

10 status for not just one serotype but not the

11 entire species or genus, excuse me, but

12 certainly several serotypes. And there needs

13 to be science to support that. There needs to

14 be a conversation and a discussion about the

15 infective dose, about consumers' involvement

16 in proper handling of these products. We

17 cannot divorce ourselves from responsibility

18 of other parties except just the industry, and

19 I think we may be moving very close in

20 adopting these recommendations, certainly

21 number three but one comes close but three is

22 dead-on in moving us towards adulterant status

for several serotypes. And I would hope there would be proper science to support that and a thorough understanding of what this means for product and the riding of product and the condemnation of product and what that's going to do.

MR. REINHARD: Okay. Other comments from the subcommittee or the public? So here's what we're going to do. We're going to break. We've got ten minutes. We're going to come back together with the whole committee and take comments, and we'll start back on this tomorrow morning and keep moving forward. But we did pretty good and we made some progress.

This will give everybody a chance to think about everything else that's on the list. I don't know that it's possible for us to email it, correct? I think we asked for that last time, and we couldn't. But we could maybe print it and give it to subcommittees, do you know? Okay. So we'll find out what

1 options there are, if we can print this whole
2 list and give it to subcommittee members. So
3 we'll find out if we can do that in this ten-
4 minute break and, if we can, we'll pass it
5 out. All right. Ten-minute break. Thanks,
6 everybody.
7 (Whereupon, the above-referred to
8 matter was concluded at 4:18 p.m.)
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