UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

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HACCP VALIDATION GUIDANCE

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U.S. Department of Agriculture
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Washington, D.C. 20250

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I-N-D-E-X

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

(9:05 a.m.)

MR. DiNAPOLI: My name is Greg DiNapoli with the Office of Public Affairs and Consumer Education for FSIS, and I'll be your moderator for today.

I want to welcome you all to the first of three public meetings regarding HACCP Validation Guidance. I want to also welcome our audience participating through teleconference. The Agency will be notifying the public on the two additional public meetings via our website. So stay tuned for locations and times for those meetings. We're looking at the West Coast as well as the Midwest for those meetings.

Before I get started here, I'd like to give you the gist of today's meeting, go over some logistical information. The restrooms are located at the ends of each wing in the building. We are between Wings 5 and 6. The ladies' and men's rooms alternate so that when you enter the wing, the men's room then the ladies' room will be at the end of the

hall and vice versa. I know it's complicated, but Wing 4 is newly renovated and has both restrooms at the same end. Wing 5 is closed, and Wing 7 is also available. Our staff at the registration area out front will assist you with the information so you don't have to worry about remembering all those details.

As you see on the agenda, there is a 15-minute break scheduled after the presentations, and then we'll go right into the public comment without breaking for lunch. So just keep that in mind when you're on break in case you want to pick up a snack or an extra beverage. Food is not permitted in the auditorium. However, bottled water, soda, or coffee may be consumed. We just ask that you not leave your drinks under the seats and on the floors at the end of the meeting today.

The cafeteria is located on this floor in Wing 3 out to the right. The sticker you were given by security will allow you to come and go between the cafeteria and the auditorium. So just please have it on you when you leave. Again, staff will be

available to assist you.

How we'll proceed today. After each presentation, there will be a 10-minute Q&A. We'll take questions from the audience in the room and then from our phone line participants.

Do you have any -- if we have any technical -- if you have any technical -- if we have any technical difficulties with our phone lines, we have an e-mail address that will enable those of you on the phone to send in a question. That address is fsisupdate@fsis.usda.gov.

We have a list of pre-registered commenters that include a few from our phone line participants. I'll start from the commenters from our phone lines first and continue with our attendees in the room. I will then call on those of you that signed up this morning at the registration table.

If there is time left before we adjourn the meeting today, and there is still someone that would like to make a comment, we will do our best to accommodate you. We are allotting four minutes per person during the comment period. And please

remember you can still submit comments to draftvalidationguidecomments@fsis.usda.gov or you may mail your comments to the Docket Clerk, USDA FSIS, George Washington Carver Center, Room 2-2127. That's 5601 Sunnyside Avenue in Beltsville, Maryland. The comment period, as you all know, ends on June 19th.

We appreciate you coming here today. Let me now introduce Al Almanza, FSIS Administrator, who will be providing opening remarks. Mr. Almanza has been Administrator of FSIS since July of 2007 in a limited term employment. Was appointed by Secretary Vilsack as FSIS Administrator on May 6th. In this position, he leads FSIS and its more than 9500 employees. Prior to his service as Administrator, he was District Manager in Dallas, Texas, overseeing more than 350 federally inspected establishments. His career began in 1978 in Texas as a food inspector in a small slaughter plant in Dalhart, Texas. Since that time, he has served in a variety of positions throughout the Agency, including Deputy District Manager, Labor Management Relations

Specialist, and Processing Inspector.

Mr. Almanza hopes today's meeting and the two additional meetings I mentioned earlier tentatively scheduled on the new draft HACCP Validation Guidance materials will clarify the purpose of these guidelines to the industry and assist FSIS in drafting of a revised document.

Mr. Almanza.

MR. ALMANZA: I got all choked up.

Okay. I've got a few things I want to say, but I promise I won't take over the four minutes you've allotted for comments there, Greg.

First of all, this HACCP Validation Guidance document, as I said before, before I signed off on issuing the guidance document, I held it for quite some time because I knew it was going to have a significant impact across the Agency. And so I thought the longer I held it, the better document we would get to work with. And so that tells me if I'd have signed off on this six months ago, just due to the attention that this got, it would have been considerably more. So I am excited about the

opportunity to have this public meeting and the additional two meetings because I think that we need to clarify what our position is, and that's one thing that I think got lost along the way.

I do believe that we're all in this for the right purpose, and I think that all of you in this room, once we have these public meetings and we finish the comment period, will understand or have a clearer understanding of what our intent was. The draft document is only one of several tools that we're providing the plants in order to assist them in verifying that their interventions are achieving the intended food safety objectives. We're also reaching out to plants through educational web seminars, training, and our small plant help desk.

So what validation is, is two distinct elements. First, the establishment must have scientific or technical documentation showing that the process as designed can control the identified hazard; and, second, the records proving that the HACCP system as executed actually functions as intended. That sounds very simple, but if it were

simple, we probably wouldn't be in the position that we're in with these meetings because there are different interpretations of what validation is. And so as I -- as we decided to schedule these meetings and extended the comment period for this document, which closes the latter part of this week, then we will have a final document or another draft document that we will ask for comments again.

So this is only the first comment period. We do believe that there will be some significant changes due to the comments that we've already gotten and also including the comments that we get here today. So we're looking forward to hearing what you have to say, and with that, I'll close. I really think that the briefer I am, the longer you all will have to make your comments. So I appreciate everybody in this room coming and look forward to hearing your comments.

Thank you.

MR. DiNAPOLI: Thank you, Al.

Our first speaker is Dr. Kenneth Petersen, the Assistant Administrator for the Office of Field

Operations. Dr. Petersen was named the Assistant Administrator for the Office of Field Operations in December of 2005. His office manages inspection and enforcement activities nation-wide, ensuring that domestically produced meat, poultry, and egg products are safe, secure, wholesome and properly labeled. Before being appointed Assistant Administrator, he was a Deputy Assistant Administrator for the office and also served as supervisor inspector-in-charge of the field.

In today's presentation Dr. Petersen discusses the issues associated with current in-plant validation methods. He hopes the discussion will allow FSIS to better aid the industry in creating HACCP plans that are well supported and consistently implemented to ensure greater protection of America's food supply.

Dr. Petersen.

DR. PETERSEN: Okay. Good morning. Good to see everybody. Thanks for showing up today. And those calling on the phone, we do appreciate your calling in even though you couldn't attend today.

I want to start really with some basic principles so we're all on the same page and then walk through a few examples on what we've been finding directly in the in-plant arena and then through some of our food safety assessments to give you an idea of how we think this issue has really evolved to the point where we're talking about it today.

So, next slide.

So starting kind of with the basics. Of course, the pathogen reduction final rule was finalized in 1996. Validation in that document talks about scientifically demonstrating that a HACCP system, as designed, is effective in addressing the food safety hazards that are specific to that process. That's a basic HACCP principle that was of course incorporated in that document.

So validation includes documentation that the critical control points effectively address the relevant hazards, again, the relevant hazards to that particular process. And these can include typically microbiological hazards, which I think is

much of the kind of discussion point we're dealing with here today, *E. coli* 0157:H7, *Listeria*, though obviously there's other hazards, physical and chemical hazards that plants need to consider.

In that final rule, there is obviously the HACCP regulations at large, but there is a regulation specific to validation, again 14 years ago. 9 C.F.R. 417.4 talks about validation. And I think for at least for me, this final bullet point is kind of the point. Is the HACCP plan functioning as intended? Here's what the plant thinks they want to do. Here's how they want to do it. And then are they accomplishing that goal? That's validation.

Then there's data assembled to validate a HACCP plan, and they're really of two types. And for most of the last few years, we've really focused on the first type, theoretical principles. Does the science behind the plan make sense? Is it consistent with what's known about the science for that particular hazard that's being addressed in that particular HACCP plan? And it can come from multiple sources, expert advice from processing

authorities, scientific data such as peer reviewed studies or other information demonstrating that the process control measures are adequately addressing the hazards of interest.

Then the second part once you have the right kind of thinking, the right science, the right principles around your plan, can you deliver it in your particular facility and for that particular process? And so in-plant observations to show that the science can be delivered in a particular process. Observations, measurements, test results, and I think this last phrase has gotten lost a little bit in the discussion to date -- or other information demonstrating that the control measures can be operated in an establishment to achieve the intended food safety objective. So a variety of data points to be captured, documented, and assessed and corrected to show that the science is working to address the hazard.

So clearly we believe it's important the validation data includes some practical data or information reflecting an establishment's actual

early experience in implementing the HACCP plan. Okay. And why is it important? Well, validation must demonstrate not only that the HACCP is theoretically sound, but that an establishment can make it work in its particular facility whenever it's operating that particular HACCP plan. So the firm needs to determine whether the theoretical program can be delivered in the establishment. And so there is variability from establishment to establishment. We can have the most sound scientific study that everybody recognizes, the study to end all studies, but then a plant has variations in its source material, it has variations in its equipment, it has variations in its process control, it has variation in its workers. And so to those guiding principles and that study, do they work in that particular facility given what is happening within the confines of that particular plant?

So we've looked at a variety of data that we have access to. Some of the things we've learned over time: PBIS, which is our inspection database;

food safety assessments, which are more rigorous multi-week studies in a plant where we look at the design and the execution of a plant's HACCP plans; recalls, clearly when things go wrong; food-borne illness outbreaks when things go really wrong. What do we learn when we go back into those facilities where something bad happened? And we found that in-plant validation may not be consistently implemented by industry or consistently enforced by the Agency. And that's really been a communications point where we've clearly recognized defined scientific principles, but there has been a lack of clarity from starting with us on the use of things like corporate data, where you have a good study, how does that apply to other locations within that plant? We have inconsistency on what we expect regarding things called Appendix A and Appendix B, which are basic principles. And so not surprisingly, inconsistent kind of communication of expectations has led to some inconsistency in what industry is doing and some inconsistency of what we're doing for enforcement. So now we think is the

right time to reclarify those expectations, going back to what was stated in '96, and reclarifying some expectations on how to meet them going forward.

So we do have some concerns with what we've seen, and we'll get to a few examples here in a minute: where firms were not addressing and implementing all the critical factors from a supporting study into their in-plant process controls. For example, we have a study. There may be multiple points within that study, but only some of them were being tracked by the plant. That's a recipe for a problem. An inconsistency in understanding the need to measure the parameters of a study, parameters such as time, temperature, pressure, to ensure they're being met. The old saying what gets measured is what gets done. It's not good enough to have a study. Again, can it be delivered in that particular facility? And if a critical factor in that study is for example reduction of a pathogen, measuring the outcome after applying the process may be appropriate, but it may not be necessary to actually measure the pathogen.

Some of these pathogens can be present at extremely low levels, and so particularly in the validation process, it may be difficult to find it.

So there are terms like surrogates and indicators, which are other organisms that are almost invariably present in the study. Say we have a study to reduce 0157:H7 in raw beef. Invariably that study is going to have some other measurements for total plate counts, aerobic plate counts, generic *E. coli*. And so those can be indicators of how that process is being delivered in that plant. So reductions in the pathogen of interest. You may see some parallel reductions in some of these other organisms that behave in a similar manner in that particular process. And so that would be the type of supporting documentation that depending on the plant, depending on the process would be of interest.

So a couple examples. This is a plant that was using a well-recognized scientific study from a university on the use of lactic acid as an antimicrobial. And the study talked about some

critical factors on that study showing reductions of that particular pathogen for this use of lactic acid. Critical factors such as concentration of the acid, makes sense. Temperature of the acid at the point of delivery. Temperature of the product and pressure of the acid being applied onto the product. Those are all critical factors in the study. So when the study reached a conclusion, the conclusion was based on certain parameters, i.e., factors of that study.

And so what did we find? Well, the establishment was not measuring the pressure at the point of application, and yet that was a critical factor of the study. So whatever the pressure was, if you don't know what it really is being delivered on your product, then you're not following the study as designed. You have a theoretical program, but you don't have the in-plant support that it's actually working in that facility. The establishment was applying, as the study called for, hot lactic acid, but the study called for it being applied to a warm carcass. They're applying it to a

cold carcass. That's different. That's a different study. And so the critical factor of applying the hot acid on a hot carcass was not being applied. So they did not have good information for, here's what we wanted to do, but we're doing something else, and no explanation of why that made sense. It may make sense to do what they were actually doing, but it was not based on the study that that particular plant was following.

Then relatively common examples, establishments using or having some understanding of processes from basically their customers to support a hazard, this case *E. coli* 0157:H7, to support their decision that the hazard was not likely to occur. And so this is a firm that purchases intact primal cuts and intends to make them into tenderized non-intact steaks, using a needle tenderization process. And so they communicated, well, this is what the plant says, well, our suppliers are expected to have an intervention for 0157:H7. That's kind of what they expected to be receiving. And, yet, their hazard analysis of the plant making

the non-intact steaks contain just the generic letters from their suppliers saying, yeah, we have a validated intervention, and that was the support for the decision making. When looking at it, the plant making the needle tenderized steaks really had no information on what they expected from those interventions. And not all interventions are the same; not all locations of interventions are the same or the product that they're purchasing. And so the establishment making the non-tenderized steaks does need to have some understanding of what do they want? What are they expecting? Why are they justifying their decision that the hazard is not likely to occur? Why are they justifying it, what are they basing it on? And here they didn't know whether their suppliers have a -- their intervention was a critical control point or whether it was part of their prerequisite program. Nor did they have or look for information on where in the process their suppliers were actually applying that intervention. For example, if the interventions were being applied on the slaughter floor, as the terminal treatment

for example, well, if that plant was buying carcasses, then that intervention may make sense. But they were buying primals, and some of their suppliers had a intervention on a carcass and yet they're electing to purchase primals, and they cannot articulate why the intervention at the terminal part of the slaughter process is still applicable to the product they're actually purchasing. So for this firm, may have made sense to have perhaps at least one or more interventions with an intervention close to the point where they're purchasing the product; i.e., a primal-type intervention would make more sense for the product that they're electing to purchase. That would better support their decision that *E. coli* is a hazard not reasonably likely to occur.

Then establishments using corporate data. Many of these studies can be quite good, quite robust. But in this case, corporate studies were regarding allergen control. And couple of control measures were filtering the frying oil using a 20 micron filter to filter out in this case the

allergen. And then another part of that control measure was a dry flush of the equipment to remove any residue that may contain that allergen before they go on to a different process. That's the corporate study, a good study. Shows that when you do these things, the allergen was not being carried forward to subsequent products. But based on that data, they assumed that their control measures would work in their particular operation. As we mentioned earlier, not all operations are the same. The equipment's different. The people are different. The source materials are different. And so they had no in-plant data supporting that this good study could be delivered in their facility. So a mismatch between a scientific study at the corporate level and actual information showing that it could be delivered on an ongoing basis in that particular firm.

Then increasingly we're seeing use of prerequisite programs to support that a hazard is not likely to occur. Nothing inherently wrong with that. Prerequisite programs basically provide a

foundation for a HACCP plan to operate. Sanitation performance standards, sanitation standard operating procedures, those are fundamental prerequisite programs. You have to have a sanitary environment before you can even think about producing safe and wholesome food. Here we're talking about programs that basically describe the prevention of the hazard. And so, a prerequisite program does need to become part of the HACCP system and validation activities. This has been something because of the evolution of prerequisite programs over the last few years that has been inconsistently communicated. The expectations to validating that your prerequisite program, which you're using to support your decisions on your hazard, does it work? So does the prerequisite program consistently prevent the occurrence of the hazard? Critical control points reduce or eliminate the hazard, prevention programs, prerequisite programs prevent it. And you can't prevent it if you're not validating that it's doing what you think it does. And to do that, you have to validate the achievement of that program and

then have ongoing meaningful verification that you're delivering it on an ongoing basis. So if you're using a variety of prerequisite programs, back to the *E. coli* example I had, that was basically a prerequisite program with inconsistent information from the suppliers. That's not validating that your prerequisite program is delivering what you think it is.

Then finally just an example from the enforcement arena, where a notice of intended enforcement was issued following a food safety assessment, this particular plant produced raw, pre-boned stuffed poultry products. They used the validated cooking instructions as part of their support for the microbiological hazard not likely to occur. So raw poultry, the hazard in this case being not surprisingly salmonella, scientific support was at 165 degrees, reaching 165 degrees, and the finished product would deal with that hazard. Makes sense. The FSA, though, reveals some disconnects with their in-plant validation process for their validated cooking instructions. And these

included things such as the protocol on how to actually cook the product was quite vague, not all the critical factors addressed within the validation program. For example, where is the product in the oven? Where's the temperature measured? Does it account for varying product weights? Again, this is a stuffed poultry product. Does the validation account for some variability in the product sizing? Does it account for holding time following cooking where the temperature rises to a certain extent? That was inconsistently described in this particular validated cooking instructions. The protocol stated that each of these cooking tests would be repeated three times. And yet they didn't do it. Cooking instructions required an oven temperature of 375 for 35 minutes. They believe that doing that, the product would reach the critical temperature of 165, but their data didn't actually support that. So inconsistencies of what their risk of the product, what they thought they were communicating to deal with it, and then the studies they had that were incomplete as far as actually showing that those

validated cooking instructions could actually be delivered.

So, in conclusion, inconsistently implemented by industry and inconsistently enforced by FSIS for some of the reasons I gave. Some of it has been evolutionary with certain programs. The fact is now is a good time to reset the communication on expectations for enforcement. And much of this we've learned from just learnings over time, things that have gone wrong when we go in and look at. Not always is it a validation issue, but many times it is a validation issue. And even though they might have been running a process for months or years, at some point when it's not adequately validated, your number is going to come up, and your number is going to come up with either an inadequate system or worse a recall or even an outbreak. And so that's why we're here, to hear your feedback. Beginning late this week, some formal review of the comments before we publish a guidance document, and then Mr. Derfler will talk about kind of the process going forward from there.

So I'd be happy to take any questions to clarify kind of what we talked about as far as how we got here, what we're seeing, and maybe what it means for you.

MS. DONLEY: Thank you. I'm Nancy Donley from STOP, Safe Tables is Our Priority. I'd just like to start to say I really want to thank Jerry Mande and the Agency for setting up this particular format for this meeting. I think the consumer groups had some more concerns with the way it had been handled in the past, and it's really nice to know that we were listened to, and I want to thank you very much for that.

I also want to just commend the Agency for bringing up this very, very important issue and recognizing that there was a gap in what was intended 15 years ago and actually what's happening in the real world -- we had had concerns about it frankly from the beginning -- is that it's just so critically important that systems operate the way they are intended to do, achieve the results that they are intended to achieve, and there is a

mechanism, feedback mechanism in place to ensure that's happening, and recognizing that there have been some -- your cases where there have been some instances where this hasn't been happening, and the Agency is now seeking to close that gap.

Ken, I do have just one question, and it's referring to the slide that just -- it's labeled Food Safety Concerns, and it's right before your Validation Example 1.

DR. PETERSEN: Okay.

MS. DONLEY: Great. Right at the bottom there it says, however, it may not be necessary to measure the pathogens. Surrogates and/or indicators found within the supporting documentation could be utilized. My question is, is that it seems to me that you're backing away from what you had put in the initial draft guidance document where you said on page 8 of that document that testing for levels of both indicator organisms and presence/absence of the identified hazard is essential to ensure that not only is the establishment HACCP, i.e., some or all interventions, achieving the specific log

reduction as described in that hazard analysis indicated by indicator organism counts, but also that the interventions are successful at controlling the pathogens of interest to below detectable levels for adulterants or to acceptable levels for other raw processes. Are you backing away from having the absence/presence of the organism of concern be done in conjunction with indicator organisms?

DR. PETERSEN: Not necessarily. But I don't want -- the pathogen testing in the validation arena, depending on the product, is not necessarily the be all and end all. I'll give you an example. Say a plant's producing carcasses and shipping beef carcasses. You can look long and hard and collect a whole lot of samples for 0157 on a carcass and not find it. It's very, very difficult to find on a whole carcass. So what we're suggesting is depending on the study they're using is the study will show some level of reductions in a variety of organisms. And so to collect a reasonable number of samples that shows that your process is actually working, for an organism like aerobic plate counts,

generic *E. coli*, Enterobacteriaceae, is going to be likely in that example a much more fruitful endeavor than it will be for trying to find *E. coli*. They could test for *E. coli*, not find it, and make a erroneous assumption that the process was actually causing the targeted reductions in that particular process. I think the pathogen testing is certainly a good idea. We think microtesting is certainly a good idea. But as you'll hear from Phil, it's not specifically required. So depending on the study they're using in the validation part of their system, other organisms may be a better way to validate that they're delivering what they think they're delivering. Then when they get to verification, you may have ongoing verification for control of the pathogen, depending on what the product is. Say now we're jumping to raw ground beef or even beef trim. They'll be validating less of detectable *E. coli*, verifying less of detectable *E. coli* as an ongoing proof that their system is working. But in the initial concentrated data collection window for validation, depending on the

product, we want them to look at the study, what does the study deliver, and what is the reasonable organism to use to reach the right conclusion that they're delivering what they think they should deliver. So validation and verification are two different things.

MS. DONLEY: Okay. I'd just like to say that, you know, and I'm not an expert on this, but I do know that indicator organisms can be helpful but not necessarily be really truly indicative of what's going on. So I think the Agency needs to be careful with that. That, you know, to back away from testing for the presence or absence of specific pathogens would be a real cause for concern for our organization.

MR. DiNAPOLI: Thank you.

MR. WALDROP: Hi. Chris Waldrop, Consumer Federation of America.

Ken, the examples that you gave, are those real life examples that you all have seen in the plants?

DR. PETERSEN: Yes.

MR. WALDROP: I mean you took it from --

DR. PETERSEN: Yes.

MR. WALDROP: And does the Agency -- a lot of that information I don't think was captured in the guidance in terms of what the Agency's actually been seeing. Does the Agency feel like it has a really good handle on kind of the universe of validation problems in the industry based on your review of the PBIS and FSAs and all those sorts of things?

DR. PETERSEN: Well, I guess I'm careful to say I've got a handle on the universe. But when you look at the processes they're coming from, you know, they're pretty small number of processes that are out there. There's a whole bunch of products, but as far as HACCP processes, we do think we have a pretty good understanding. But it kind of goes back to the science. What is their scientific support for what they want to do? So the studies may change over time, and then they have to adjust their validation over time. But we've seen just as a general theme the two big ones at least for me is

here's the feature of the study that are important. Why wouldn't you check for those? Why wouldn't you check for them on an ongoing basis? And then here's some type of outcome, some type of information that shows the study is working. Why wouldn't you collect that information? So those are, as far as the universe, I mean those are kind of overriding themes that are inconsistently done in plants of all sizes. So from that perspective, I think we have a pretty good sense of it.

MR. WALDROP: And then is there a way to maybe, as you are updating or revising this guidance, to maybe communicate that in a way in maybe a separate document or some sort of, you know, here are some examples that we've been seeing over and over again, here's the big problems. I don't think that was communicated quite as clearly in terms of what was really going on that you guys are seeing that provides the impetus for doing this guidance now. So that may be a way to kind of help clarify some of the problems that FSIS is really concerned about.

DR. PETERSEN: Okay. Because jumping forward six or eight months with our other public meeting on our new data system, today I have no centralized way to collect a lot of good information we get out of food safety assessments. We commit a lot of resource to that. Industry spends a lot of time with us when we do those assessments. We learn a lot of stuff. And so we do intend to capture kind of the key facts in those, centralize them in a database so I can develop policy from them, communicate them. So from that perspective, I think it will help significantly. And then a similar theme for label approval database. We're on the track for a much more robust database. This kind of gets to the validated cooking instruction example. What are we approving labels for? What's the principles of some of those labels? And anything that proves not to be supportable over time, we can communicate it out, we can analyze that information and get it out to people not only in a timely manner but in a way that makes sense I think to everybody. So, today, that's kind of been the fits and start.

We've learned much of this the hard way. We've gone in and looked and found a problem. But by populating our data systems, that will position us in a better place.

Yes, sir.

MR. WENTHER: This is Jay Wenther with the American Association of Meat Processors.

First, thanks, Dr. Petersen, for the presentation. One quick question. On page 6 of the draft guidelines, it states establishments will need to provide support in instances where they believe microbial testing data is not needed to demonstrate the effectiveness for the control of biological food safety hazards. So in that statement within the draft document, is it stating the Agency's position that the industry is going to have to come up with documentation that first either shows indicator organism reductions, and if they don't have that, to provide documentation that says that they don't need any microbial data, which -- well, I don't know if I can find a paper that says I don't need it.

DR. PETERSEN: And I think Phil's going to

touch on that a little more, a little more head-on. So I think I'm going to postpone that a little bit until you hear his. But some of our thinking on Appendix A and Appendix B may fit into some of what you're reading in that particular part.

But then the first thing you said is also a key; it's draft. And so things that are inconsistent, things that you have a view or others have a view that are inapposite, clearly we need to get all that straightened out so there's no mixed understanding for either firms or the Agency or, you know, other constituencies. But so the data need, in a sense, could depend on the source of the study, I think is what I'll say for Appendix A and B, but Phil's going to, I think, get that a little more point on.

MS. NESTOR: Felicia Nestor, Food and Water Watch.

Ken, you were talking about studies correlating -- if the surrogate is reduced, then you might see a reduction in the pathogens. And I'm just wondering, are there studies that link every

pathogen with appropriate indicator organisms that plants could use at this point? So in other words, you know, if someone is testing for *Listeria*, you can tell them exactly. Or there's a document that you know of that can tell them exactly what indicator organisms to use?

DR. PETERSEN: No. To say there's a one-to-one relationship in all of these things, that would be way too simplistic. But there are enteric organisms, generic *E. coli*, Enterobacteriaceae, *Salmonella*, *E. coli*, do behave similarly. Not the same. Similarly. And depending on the application, the intervention, they behave similarly. So you can get and reach some conclusions when you look at the study. Say a study shows, you know, three log reduction for generic *E. coli*, and then it shows a lower reduction or equivalent reduction for 0157:H7. It's a lot easier to find generic *E. coli*. It's a lot easier to find *Salmonella*, which is one reason we use *Salmonella* as a performance standard. You want to have studies that give you data that you can analyze. Because the other side of that is -- back

to the earlier question on *E. coli* 0157:H7. Someone could collect a lot of studies or collect a lot of samples, by lot maybe 20, 30, reach a conclusion that, gee, they're all negative. But because of the prevalence of that pathogen is so low, without other information, they could be misinformed. And then when somebody follows behind them and says, well, gee, the prevalence of that organism is so low you didn't collect enough studies, enough samples to find it. So we're in a Catch-22 whereas today in many situations little data is being collected at all to even know if it's working. And so we're not talking, we're not -- we want to start getting some information, information that means something. And, again, depending on the study, depending on the process in certain circumstances, some of these indicator organisms may be a good way to go.

MS. NESTOR: I understand the difficulty with using the pathogens, but it sounds like what you're asking the plants to do is to scientifically validate, and that suggests to me that you're looking for something that's scientifically

reliable. But I'm not hearing you say that there is any documentation that would prove that. So I'm just wondering what is, you know, what is the rigor that the Agency will accept, and is the Agency going to establish some kind of standard, you know, so that plants all over the country and inspectors and the EIAOs all over the country understand what level of rigor will be accepted when you really don't have any solid science?

DR. PETERSEN: And we do need to communicate some basic principles. But the science is the study, with all the little parameters and then the outcomes. And then if the plant follows those exact parameters, temperature, pressure, whatever, are they delivering that outcome? That last part is what's -- well, both of those parts are missing. But even if they follow the study today, they don't know if they're getting equivalent outcomes, and that's something in our view that needs to be changed.

MS. NESTOR: All right, but it doesn't sound like you know how they can do that. We'll go

on.

DR. PETERSEN: Well, we're happy to take comments on what is the basic kind of sampling principles for different pathogens or processes that certainly we're going to put forward some thoughts on that. But this is a kind of a two-way thing. So just some basic principles on sampling numbers that give you useful information but that are reasonable and practical for somebody to implement, we're certainly interested in that, and we have some examples we'll put on.

MS. NESTOR: Okay. I have one other question. You mentioned something about if a plant uses a validation study, when they then try to implement it in their own plant, they're not using the same disk, the same source materials, the same -- they're not using the same people. I mean I would expect then that no validation study could be assumed to be correct because you're never going to be using the same people. Your employees are never going to be the people that ran the validation study.

DR. PETERSEN: Well --

MS. NESTOR: Or did you mean something else about --

DR. PETERSEN: No. What they're showing is here's the basic features of the study. And we know we, the scientists who did the study, know or believe if you follow those principles, you'll reach an outcome. So the open question is, okay, that worked in this laboratory, that worked in this plant where the study was done; if I follow those same principles, can it be delivered to my plant? Usually the answer is yes. There's not -- the source material workers equipment is not just some wide open, you know, variability. It could be, but usually it's not. But they need to demonstrate that it's not, and that's the point of gathering the data.

MS. NESTOR: So they would have to gather the basic --

DR. PETERSEN: Yeah, data or other information, you know, whatever, yes.

MR. CUSTER: Carl Custer, FSIS, retired and

currently self-employed, doing a little bit of -- a joke -- doing a little consulting. And I've had some problems with a couple of clients with this validation. Some of you may know that Wal-Mart jumped the gun several weeks ago and required validation of their suppliers. And this is just validation of the effectiveness of an intervention. Doesn't have anything to do with verification. Okay. So they had five points. One is in-plant testing and validation measuring naturally occurring relevant microorganisms. I and several scientists have problems with that. Utilizing USDA-approved nonpathogenic surrogate microorganisms, and that's from your Slide 9. And there are some AOHC, USDA -- I don't know, has FSIS really approved those surrogates yet? Okay. I think it's on Dan. I think Dan was supposed to do that. Pilot plant, number three, pilot plant testing as long as pilot plant conditions represent actual plant conditions, and that's, you applied that, you've mentioned that in your earlier slides. Literature validation based on published studies where the conditions of the

published study can be effectively and sufficiently replicated in the plant setting. Again, you've applied that. And then the fifth one is any other method of scientific validation approved by Wal-Mart. That was the fifth one. The one that I have a problem with, I and several other scientists, and that is using naturally occurring relevant microorganisms. The problem is if they use aged meat or some way of bumping up the organisms, they're going to be coliforms, maybe lactics. They're not going to be relevant to killing *Salmonella* or enterohemorrhagic *E. coli*. And I just wanted to push that you really ought to make in your guidelines very clear if they're going to use validation of an intervention, they should be using these surrogates. Okay.

DR. PETERSEN: Thanks very much.

MR. DiNAPOLI: Operator, could you open the lines to see if there's any questions on the teleconference? We've got time for maybe one question from the callers. Operator.

OPERATOR: Yes. If you would like to ask a

question, please press Star 1.

I'm showing no questions.

MR. DiNAPOLI: Okay. Thank you very much.

Thank you, Dr. Petersen.

Our next speaker is Phil Derfler, Assistant Administrator for the Office of Policy and Program Development here at FSIS. He is the Agency's representative responsible for formulating policy, establishing and modifying regulations, and for the design and evaluation of significant new programs and systems.

Mr. Derfler has been with FSIS since 1997. Previously he worked as a staff attorney at FDA. Today's presentation, Mr. Derfler will discuss the purpose of the draft HACCP Validation Guidance and address any questions about its implications, of course.

As Al mentioned earlier, FSIS hopes this presentation information contained and the comments expressed through this meeting will aid and emphasize revising the document to be of best possible use for the industry.

Mr. Derfler.

MR. DERFLER: Thank you. Good morning and welcome.

First slide.

I'm going to be reiterating a lot of the things that Ken said, or at least some of the things that Ken said, and that's because validation and understanding what validation is is really important, and that's why we're having this meeting.

First, as Ken mentioned, there's a regulation in our HACCP regulations on validation. We're not imposing any new requirements in the guidance document. This is a regulation that's been on the books since 1996 when the final rule was published. The regulation, as Ken said, the regulation says that the point of the validation period is for the establishment to conduct activities to determine whether the HACCP plan was functioning as intended. That's a very important aspect of this.

Next slide.

Now, the definition of validation that

appears in the regulations is supported by the National Advisory Committee on Microbiological Criteria for Food. In 1997, they published an article in the *Journal of Food Protection* in which they defined validation. And as the slide says, it reiterates what you've heard, validation is the element of verification that focuses on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the relevant hazards.

Next slide.

So validation is absolutely essential to the success of HACCP and the effectiveness of a plant's HACCP's system. Without adequate and appropriate validation, it's really not possible for the establishment to know whether its HACCP system will work to produce safe food. And so even though this document has been really controversial, and we've been called up to various places to talk about it, we have not backed off at all about the significance and importance of validation because of

the role that it plays in ensuring the safety of the food supply.

Next.

So we've prepared the guidance document because, as Dr. Petersen talked about, we've been finding incidents through our EAOs doing food safety assessments and through some outbreaks and other instances where the plants had actually failed to have adequate validation. Thus, we decided that we needed to have an improved enforcement strategy as Ken, Dr. Petersen, mentioned. But before we started implementing that, we felt it was most important to make establishments aware of what our expectations for validation are so that no one is taken by surprise and that everyone is able to prepare and have adequate validation when they are visited by an EAIO in the future. So that's the reason why we issued the guidance document that we did. We hoped that it would help particularly small and very small plants understand exactly what the Agency's expectations for validation are.

As you've heard, validation has two

aspects, and this is reflected in the preamble to the HACCP regulations, and it's reiterated by the quotation I cited from the National Advisory Committee on Microbiological Criteria for Foods. There is the scientific component, and then there is the technical component. And what these, what each of these elements, what each of these components require and encompass is the focus of our guidance document.

Next slide.

So we put out the draft guidance document on March 19th. We provided a total of 90 days for comment on it. Because the guidance document is draft, it's important that everyone recognize that it only represents our preliminary thinking. It's not intended to be a rule. It's not intended to be a definitive statement. We put it out in draft because we consider this to be an extremely important document, as I've said, and we wanted to see whether our preliminary thinking would cause confusion or misunderstanding. We got that question answered.

So, in addition, we wanted to get as broad a set of comments as possible, and so we made the document available through the constituent update, though the -- to the all interested persons, plus we mailed a copy of the document to all the plants in our inventory, particularly small and very small plants because we were concerned that those plants are not members of trade associations and, therefore, would not have access to the document. The comments in this document are extremely important to us, and so we wanted to make sure that it was as widely available as possible.

Now, turning to the document itself, I mean it's been publicly available for approximately 70 days, so -- 75 days. So it didn't seem to me, it doesn't seem to me that I need to go over it in great detail. Just to quickly summarize. It reviews the sources of scientific information that can be used to meet the first aspect of the validation requirement. It then talks about the types of observational data and in-plant measurements that can be used to meet this

requirement. It goes on and talks about the kind of studies that can be done in order to provide validation. And, finally, there's an appendix in which we go through some examples to try and provide insight into the kind of data that could be provided to meet the validation requirement.

The opportunity to comment closes on June 19th, but actually that's Saturday. So the comment period actually closes on Monday, which is the 21st. Because we didn't publish the document in the Federal Register, we weren't able to use regulations.gov and so, therefore, in the comments that we've received by necessity have come in through either e-mail or through regular mail. As a result of that, we've had to post comments by hand on our website. I can tell you that the documents were posted as of this morning, and if you want to view them, you'd be able to view them at the web address that's in this slide.

Now, because we have to post them manually, we won't be posting all the comments that we got. We got about 2,000 so far. But among the 2,000,

there's like eight different form letters that we've received. So what we'll be doing is we will post a representative form letter and then provide the number of comments that have submitted that form letter. So as we go through this process, it will change, as I'll talk about in a second, but for right now as a matter of convenience, that's what we're doing.

We learned fairly quickly after posting the guidance document that there were some fundamental concerns about the document, some of which have been touched on already this morning. As soon as we identified these concerns, we prepared a fact sheet in which we tried to address each of the basic ones that we've been able to identify. And we included this fact sheet when we sent out the document to the small -- to the plants in our inventory. So to sort of --

Next slide, please.

To sort of go over these basic concerns. The first one was does an establishment have to validate each of its HACCP plans? And the answer

that we've said is no. Establishments have to validate one plan per HACCP category. There are speculation that requiring plants to validate each of their plans would be extraordinarily expensive because a lot of small and very small plants have a whole lot of HACCP plans. And so this is the answer that we gave. We think this will provide an adequate basis for validation in each of the plants.

Next concern that we got was can establishments continue to rely on Appendix A and Appendix B as part of the validation for their HACCP programs? And the answer is yes. Establishment can continue to rely on these and similar documents to meet the first aspect, the scientific aspect of the validation requirement.

You know, there is a lot of concern that we were going to make people do studies to revalidate Appendix A and Appendix B, and there's no reason for us to do that. Appendix A and Appendix B were published, were developed by the Agency. We think they've been fully validated, and we see no reason to do so. And so plants can rely on them going

forward. If anything, our goal here is to ultimately wind up with another compliance guide like Appendix A and B that will be as useful for plants with respect to validation as Appendix A and Appendix B are to processing plants.

Next concern was if an establishment relies on Appendix A, for example, what does it need to do to satisfy the second aspect of validation? And what the answer is an establishment needs to have verification records that establish that it consistently meets the parameters specified in the document upon which it relies for scientific support. Now, remember, under our regulations, plants get a provisional grant of inspection. Then they have a 90-day period in which to validate their HACCP plan. And, ultimately, at the end of that, we either make the grant of inspection final or not. So the 90-day period gives them an opportunity to do the things that their scientific basis says to do to maintain verification records that show that they're meeting the parameters that are specified in their scientific basis and, on the basis of that, validate

their HACCP plan.

Another final key concern was do plants have to do microbiological studies? And the answer to that is no. There's no requirement that plants do microbiological studies. Again, there's a great deal of concern expressed at requiring plants to do scientific, you know, studies would be extremely expensive. We're not necessarily requiring that. In case plants want to or feel that it's an appropriate course for them to take, we are providing guidance on how to go about doing so, but there's also the point of validation as we talked about is to ensure that your HACCP process is functioning as designed, that you're able to deliver the kill or whatever that you're intending to do. And so that's the important part of this.

So the comments that we've gotten have raised significant concerns and have made pretty clear to us what we did wrong in writing the draft document. So, you know, once the comment period closes, we're going to try and address the things that we've learned as a result of the comments. But

one of the things that we would really like is -- and to the extent that you all have not finished drafting your comments, we hope that you think about, you know, what are the things that you would suggest that we include in the guidance to make it as useful as possible for the people who are going to use it, particularly small and very small plants. So, for example, last Thursday we had a meeting with small producers from Pennsylvania, and we asked this question, and one of the things that we heard, one of the suggestions that we heard was that the document would benefit from real life case studies, incorporating them and showing how that would work, which was along the lines of what we heard from Mr. Waldrop earlier. So, you know, that's the kind of information that we would really hope to get in addition to what did we do wrong? So it would be useful if you thought about in commenting on the guidance the questions that I put here. Would it be useful for FSIS to provide guidance on identifying critical parameters of the HACCP system? Would it be useful to provide guidance on how to gather data

to show that the critical parameters are being met? And then I actually butchered the last one because I didn't read it adequately. So I'll sort of read to you the way it should be. Would it be useful for FSIS to provide guidance on how to gather data to show that a process or intervention achieves the intended results? If you would think about these questions and address them in your comments or even if you have the opportunity today, if you decide to comment, that would be useful to us.

So what are the next steps? Once the comment period is over, we'll do our best to analyze the comments that we receive, and then, based on that analysis, we're going to revise the document undoubtedly very extensively.

Next slide.

And because the document provides significant guidance, it's subject to the OMB significant guidance procedures. That means that when we have a redraft of the guidance, its availability will be announced in the Federal Register. There will be a comment period. There

will be an opportunity to submit your comments to regulations.gov. And during the comment period, it's likely -- well, we've actually said, we're going to have two public meetings to obtain comments on the revised document.

So, last slide.

So once we finish analyzing the second round of comments and the comments on the revised version that we get, we will issue a guidance document. And then in conjunction with that, at that time, we will likely announce an enforcement strategy for how we're going to go about making sure that now that plants have been armed with our best thinking on validation, they have validated their HACCP plans adequately, and then that will be part of how we proceed going forward.

So that's everything I have to say this morning. If there's questions, I'm happy to respond.

MS. DONLEY: Nancy Donley from STOP, Safe Table is Our Priority. I have just one quick question. Is the Agency, you know -- let me start

by saying, you know, I can write a HACCP plan.

MR. DERFLER: I'm sorry?

MS. DONLEY: I can write a HACCP plan.

MR. DERFLER: Uh-huh.

MS. DONLEY: I can write a system. It may not be effective. Is the Agency, when it just looks to see to validate that to see that companies are validating these plans, also are they assuming that the plans, number one, are good plans? Are you just going to be looking at it and saying, okay, this plan, the validation I see validates this plan even though it may be a bad plan?

MR. DERFLER: Well, at this point, we don't judge the quality of the plans. What's important is that the plant address the hazards that are reasonably likely to occur. I mean we're going to be looking at that issue as part of the steps that we take and part of public health information system, which we'll talk about in the future. But the important thing is, are they addressing the hazards that are reasonably likely to occur, and is the method that they're using to address that

likely -- do they have a basis to believe that it's going to be successful? And that's what validation is all about.

MS. DONLEY: So is the Agency, are you validating good plans, bad plans, indifferent plans? Are you also looking at the plans to see that they are in fact dealing with hazards that are --

MR. DERFLER: I think you're going to have to see the direction in which we're going. For right now, the purpose of this meeting is assuming that they have a HACCP plan that addresses the hazards reasonably likely to occur, have they validated that the steps that they're taking are going to be successful.

MS. DONLEY: Okay. I just, I guess what I'm saying is I think I'd like to see that FSIS, when they're looking at the validation, are also looking at the efficacy of the plan.

MR. DERFLER: Okay.

MS. DONLEY: And then just one other quick question is, Phil, you say that establishments only need to validate one plan for HACCP category, and

you cited that it can be very expensive. Is there any scientific basis for this decision?

MR. DERFLER: We believe that just as a policy matter, that as long as they basically address the validated, the representative plan for that HACCP category, that will provide assurance that the other plans are being met and adequately designed.

MS. DONLEY: Thank you.

MR. WENTHER: Jay Wenther with American Association of Meat Processors. We've heard a lot already this morning regarding supporting documentation. And I guess overall I get really concerned. We all are in support of having the correct supporting documentation that represents the process. But within the document it says to provide adequate validation, study needs to relate closely to the process with regard to species, product characteristics, and equipment. And for a study to go through peer review with any scientific journal, the details of the study have to be very, very detailed out for the researchers and the

universities, specifying all of these criteria. And my concern is how closely is closely? Even your own documents in Appendix A state very specific products, state a very specific pathogen, being *Salmonella,* although the industry right now is utilizing that for all pathogens, *E. coli* 157, *Listeria* monocytogenes, to address all of those and control all those. How close is closely? Because there's no paper that's going to mimic everything that every process does. And inadvertently causing industry to do microbial sampling because it's the only thing that'll be acceptable.

MR. DERFLER: Right, and I would say I'm not going to be able to answer that right now. I would encourage you to submit that comment as a comment on the document, and we'll deal with it as we develop the next version.

MS. CHEN: Thank you for the presentation. Yuhuan Chen from the Grocery Manufacturers Association. You cited the National Advisory Committee's guidance document as kind of the scientific thinking behind validation for the

policy. I was wondering -- I know in the National Advisory Committee's guidance document on HACCP principles and application guideline, it talks about CCP validation and validating other components of the HACCP plan. So is the guidance document from the Agency the focus on CCP verification -- I'm sorry, CCP validation at this point?

MR. DERFLER: I mean, you know, the Agency has talked about HACCP systems. And so ultimately we're going to focus on the HACCP system, although the HACCP consists of various CCPs. And so ultimately the question is, is the plan in the HACCP system effective? And as Ken talked about, we've seen prerequisite programs and increased use of prerequisite programs. So it's important to look at the entire system.

MS. CHEN: Thank you.

MR. DiNAPOLI: Operator, at this point, I'd like to open up the lines for folks on the teleconference.

OPERATOR: Sure. We do have a question. This comes from Patricia Buck. Your line is open.

MS. BUCK: Good morning. This is Patricia Buck from the Center for Foodborne Illness Research and Prevention. And first of all, I'd like to thank everyone, especially in FSIS, for, you know, putting this meeting together for this draft guidance. My question is probably more of a statement, and maybe it's going to be embedded into this document, but from the tone of the questions being asked, I am wondering is FSIS looking to start conducting its own research so that they can better determine if specific validations are rigorous enough to meet HACCP's goal? There is many, many types of procedures that are probably listed in Appendix A and B that have become somewhat standard. And from the tone of some of the comments that both Ken and Phil made, it seems that you're moving in the direction of trying to have a broader view of what validation processes not only are being used but which ones are most effective. But to do that, you would need your own research capabilities. So I guess my question is, are you going to be seeking in your budgetary request money to do this type of

research?

MR. DERFLER: This is Phil Derfler. We're not funded to do research. However, we work closely with CSRES in the RE area, the research area, to try and get the information we need. We help create their research agenda. And so we intend to continue to work with them and to improve our relationship with them. But we're not going to be doing research.

MS. BUCK: You're not? Because I think as a agency there has to be some way that you can do your own research because I think it will -- I mean you're the ones who are directly collecting the data and working with the facilities. And --

MR. DERFLER: Well --

MS. BUCK: -- I think even your industry partners or representatives, they are talking about some of the same concerns, that we need to have feedback from the Agency, which would really indicate how we go about doing these verifications. That's it.

MR. DERFLER: Okay, thank you. I mean I

would just say again, we work closely with the research area, use the things that we identify, and work with them to ensure that they address it. You know, we have our Office of Outreach that is designed to help small and very small plants to be able to marshal the information that we're aware of that's available to help them validate their HACCP plans. But we're actually -- research is not part of our charges.

MS. BUCK: Thank you.

OPERATOR: And as a reminder, if you would like to ask a question, press Star 1, and record your name slowly and clearly when prompted.

Katie Hanigan, I'll open your line next.

MS. HANIGAN: Yes. Good morning. I have a question about letters of guarantee and what validation is going to be required on them. And, specifically, I am wondering if you are a plant and you are receiving dry ingredients like a sausage seasoning spice and your ingredient supplier is providing you with a letter of guarantee that the sausage seasoning spice is pathogen-free, is the

Agency going to expect the plant to validate the letter of guarantee by conducting microbe testing on the ingredient when it arrives? And I'm specifically talking about ingredients that do not come in with a certificate of analysis. They strictly have a letter of guarantee with them.

MR. DERFLER: Thank you, Ms. Hanigan. Again, I mean I would urge you to submit that as a comment. We will address it as part of the document. But for me to try and answer it now really wouldn't do anybody any good. But if it's in the comment, we will address it as part of what we develop.

MS. HANIGAN: Okay. Thank you.

OPERATOR: We do have another question that came in. One moment, please.

Mike Sloan, I'll open your line.

MR. SLOAN: Okay. Thank you. Yeah, my question is on -- you mentioned a establishment would need to verify one plan per HACCP category. And how would that affect the very, very small plants who make a multitude of species of whether it

might be beef, pork, elk, bison, deer, other products that are maybe in the same category but different species? Would that require additional testing?

MR. DERFLER: Again, I think it's most preferable if you submit that question in writing. I think -- I mean we understand the species issue, but the important thing is the HACCP category. But I would urge you to submit that question in writing.

MR. DiNAPOLI: Can I ask who that caller was that just called in?

OPERATOR: That was Mike Sloan.

MR. DiNAPOLI: And who are you with?

OPERATOR: This is the Operator.

MR. DiNAPOLI: Oh.

OPERATOR: This line has been cleared, so --

MR. DiNAPOLI: Okay.

OPERATOR: We have no other questions in the queue.

MR. DiNAPOLI: Okay. We have one more question in the room, and then we'll break after

that.

MR. RICE: My name's John Rice. I'm recently retired from Sansa Farms. Previous caller had a question about research conducted by FSIS. Of course, FSIS does no research, but the Agricultural Research Service component of USDA does a considerable amount of research, which has been useful to the industry. And that brings up the question that I had, will FSIS accept the data that ARS has developed in their pathogen modeling program as scientific documentation on time and temperature as it relates to pathogen growth?

MR. DERFLER: We would accept it as part of -- I mean we would -- you've got to look at the document the way it ultimately comes out. My guess is, standing here, is that we would accept it as meeting the scientific part, but the plant still is going to need and provide the technical information to show how that works within the plant itself.

MR. RICE: Well, I understand that the plant would have to verify that they are meeting those time and temperature parameters. The second

question I have is, how do you intend to address the situation when a plant uses a regulation as a critical control point? For example, a lot of broiler plants will use a critical control point of time and temperature such that the carcasses have to reach 40 degrees within a certain period of time after slaughter, and we really have -- does this point really -- no validation of that regulation. So would the regulation be accepted per se, or would additional work have to be done?

MR. DERFLER: Yeah. If it's a regulation, we would accept it. There is a number of people who are doing, requesting waivers as part of the SIP Program, and that may result in petitions to the Agency to change those regulations. But for now, the answer is if it's a regulatory requirement, yes.

MR. DiNAPOLI: Thank you, Phil.

We're going to go ahead and take a 15-minute break. It's 10:30 right now. We'll be back here at 10:45. Again, the cafeteria is out to your right in Wing 3. And we'll see you in 15 minutes.

(Off the record.)

(On the record.)

MR. DiNAPOLI: As we go through this list, I'm going to say the name and the organization that you're with, and if there is a mistake, just let me know, but I will try to pronounce everyone's name correctly and the organization that you represent.

We're going to start with the commenters on the conference call. So, Operator, if you could connect us with our first commenter, Don Johnson from Fraboni Sausage.

OPERATOR: One moment.

Don, your line is open.

MR. JOHNSON: Yes. Good morning. My name is Don Johnson from Fraboni Sausage. I thank you guys for the opportunity to comment on this. I understand that the validation process and the concerns that you guys have covered a lot of this morning. A lot of us small processors do rely on Appendix A and Appendix B, as was mentioned earlier, for all species. And I guess I'm going to be resubmitting comments again today after, maybe

addressing some things of what can be done. So, again, thanks very much for the opportunity.

MR. DiNAPOLI: Thank you very much.

The next commenter is Jitendra Shah from Johnsonville Sausage on the line.

OPERATOR: Jitendra, your line is open. Jitendra Shah, your line is open. Please --

MR. DiNAPOLI: We can come back, if you'd like, Operator.

OPERATOR: Okay.

MR. DiNAPOLI: First commenter in the room is Chris Waldrop from Consumer Federation of America.

MR. WALDROP: Thank you for --

MR. DiNAPOLI: Okay, Chris, go ahead and start over.

MR. WALDROP: Again Chris Waldrop, Consumer Federation of America. That's better. I just want to thank FSIS for this meeting. I think it will be a good opportunity for you all to gather the comments necessary to make this a better document and then hopefully get something that can be useful

to the Agency as well as to the plants. CFA agrees that validation is a critical component of preventive process control, in order to assure that a plant's HACCP program is working as intended, to reduce the risk of contamination and ultimately protect the public. Sampling and testing of course is a very important part of this. CFA has always advocated for more testing that is being done by both the Agency and FSIS. So we certainly support using sampling and testing to assure that the plant's program is validated.

That said, I think FSIS could provide additional details to help plants understand the Agency's expectations. In terms of sampling and testing, the Agency could provide more clarity and provide their expectations in terms of confidence levels and powers for sampling programs so that everyone is aware of just the level of rigor that the Agency expects. I think it also would be important for FSIS to communicate the problems that they're seeing and to provide sort of a better understanding of what's going on out there that

they're seeing as problems with validation. That would provide plants and the Agency with a better understanding of where the biggest problems lie in terms of validation. For example, are there areas where there's limited validation studies available? Are there particular areas where plants are not properly validating their interventions or processes? I think this information would provide the context and really the -- provide the plants and the public with a better understanding of what the problems the agencies are seeing so that they can move forward and make sure that those validation programs are assuring that the plant's program is operating properly.

Thanks.

MR. DiNAPOLI: Thank you, Chris.

Next commenter is Scott Goltry from AMI.

MR. GOLTRY: My name is Scott Goltry, and I'm vice president for Food Safety and Inspection Services at the American Meat Institute. Formed in 1906, the AMI is the nation's oldest and largest trade association representing packers, processors

of beef, pork, lamb, veal, turkey, and processed meat products. Approximately 80 percent of AMI member companies are classified as small or very small. AMI members continue to adopt food safety practices to produce meat products which are safe, affordable, and available. The AMI appreciates and supports the ability to provide comment to FSIS on the preliminary draft guidance HACCP system's validation.

Since making the guidance available, the Agency has issued a clarification to validation and acknowledged safe harbors. The Agency has also stated that the guide is being created to help establishment understand the existing requirements that do not impose new testing or microbiological requirements on establishments. AMI applauds these statements and actions. AMI also supports the premise of not imposing new testing or microbiological requirements on establishments.

The interpretation of validation given in guidance focuses on the effectiveness of the establishment's HACCP system and the prescriptive

use of requiring microbiological testing. The guidance states, "Establishments would need to provide support in instances where they believe microbiological testing data is not needed to demonstrate the effectiveness of the HACCP system in controlling biological food safety hazards." This is a misdirection of the establishment's HACCP plan and truly does not embrace the theory of HACCP as defined in the final rule. Other means such as physical and chemical attribute monitoring, which is consistent with FSIS focus, is more timely and effective way to demonstrate that the in-plant validation is being accurately and effectively implemented.

The Agency has commented on the widespread lack of understanding of validation exists and asserted that food safety problems have occurred as a result. Such sweeping generalizations are a disservice to the industry and the Agency. In that regard, such statements could create issues with trading partners and hurt consumer confidence and FSIS food safety system. Likely sporadic instances

have demonstrated that some of the establishments such as establishments undergoing a for-cause food safety assessment may not fully understand the HACCP final rule definition of validation and verification. It must be pointed out that HACCP has a systematic approach to food safety consisting of seven principles. Validation, part of the verification principle of the HACCP method, should not be considered the only part and defense to eliminate food safety hazards. To do justice to the HACCP system, further education is needed on verification, validation, and reassessment. AMI offers to work with the Agency in the development of an education program that addresses the Agency's concern pertaining not only to the validation but also verification and reassessment. AMI members are currently engaged in the review of not only what validation is but also how validation would be completed to meet the current regulations. This document will also address the use of prerequisite programs. The AMI Interim Validation Guide will be available this summer. AMI concurs with FSIS

validation information presented by the Agency prior to the issuance of the draft guidance. This information will be detailed in written comment.

Regarding prerequisite programs that are specifically used to conclude that a food safety hazard is not reasonably likely to occur, the AMI supports further review of how validation of these specific prerequisite programs would be completed. Furthermore, when validation data collection is completed, the supporting documents should be sufficiently related to the process, and the process should be realistically not exactly the same as contained in the supporting document.

In summary, AMI supports a clarification of food safety issues and the ability to provide constructive comments on proposed changes that may have regulatory impact.

Secondly, addresses/understands the current Agency validation definition, and concepts follow accepted principles of HACCP and, therefore, should not be adjusted.

Third, supports the concept that

prerequisite programs are an integral part of HACCP's system. Validation of these programs needs further investigation.

Fourth, would support training of inspection program personnel as well as owners and operators of meat and poultry processing plants in the determination of how validation is completed.

And, lastly, implemented processes should be effectively but not exactly the same as the supporting document, and the validation document should be sufficiency related to the process.

Thank you for allowing me to comment.

MR. DiNAPOLI: Thank you, Scott.

I believe those two mics are now working.

Next commenter is Debbie O'Hara from Case Farms.

Nancy Donley from STOP.

MS. DONLEY: Thank you very much. Once again, I want to thank the Agency for having this meeting. I think it's very, very helpful to hear all sides of the conversation and discussion. I just want to reiterate that I really think that the

Agency has an opportunity here to make sure that HACCP systems as designed by companies are, in fact, based on achieving the goals that we all share, and that is making a safer product that will better protect the public from hazards in their food supply.

Second of all, I just want to reiterate what I had mentioned about the need for there to be scientific reasons behind the Agency's decisions on how, as a for instance, is their intention to just have companies only have to validate per HACCP classification regardless if a company is producing -- has a number of HACCP plans within a classification? As a caller brought up earlier, you're dealing with different species, you're dealing with different processes, and you're dealing with different hazards and interventions.

And then, lastly, I'm just going to refer something that the industry, the September 22nd industry letters to Mr. Almanza said, and I thought this was a very good point, and it hasn't been brought up here today, and I just want to bring it

up, is it's talking about the validation definition and that in reality there are three components of validation: the scientific or other support that the process or interventions is capable of controlling a hazard; and then this I found to be very interesting, and I couldn't agree with it more, is two, the evidence that the establishment is capable of delivering the operational parameters specified in the support being used; and then three, the evidence that the process has the intended effect in the plant environment. I think that's a critical component is that a plant is in fact capable of meeting those parameters as designed. And I'm going to give one example, and that is, is that -- let's just use steam vacuuming as an example. I like to say if two people are given individual carpets that are equally dirty and a vacuum cleaner, my results are going to be different than your results, than that results and that result. Some of these interventions are just dependent on human effectiveness in using the tools. And so I hope that the Agency thinks along these

lines, that when you have a very maybe a robotic procedure or something that is not subject to worker error, that that be considered in this whole process. And I really think that that point number two that the industry made in its letter will help deal with that.

Thank you.

MR. DiNAPOLI: Thank you, Nancy.

Next is Phil Kimball from North American Meat Processors Association (NAMP).

MR. KIMBALL: Good morning. I am the Executive Director of NAMP, the North American Meat Processors Association. NAMP represents small to midsize federally inspected meat and poultry establishments across North America that produce a variety of meat and poultry products. Our members are committed to achieving the highest standards in food safety. Our association has a long history of working with FSIS to achieve this mutually beneficial goal. However, the draft guidance document on validation has caused our members much concern. I want to make three points here today.

We will also submit written comments to the Agency that further explains our position on the issue.

First, the guidance document in its current form can be misread and misinterpreted. The recently issued fact sheet on validation answers some of our concerns but seems to directly contradict some of what is written in the guidance document. I think we talked about this this morning, and we appreciate the fact that a lot of this will be cleared up as we move forward. But because of this, we think the guidance document should be rewritten in its entirety with clear language of what is and is not expected for FSIS to consider an establishment's food safety system validation. The fact sheet is much clearer in its language and style. The guidance document, likewise, could be written in clearer and concise language.

Second, we do not believe the guidance document provides the practical guidance needed by small and very small meat processors. There are multiple references to indicator organisms,

statistical validity, and conducting microbiological sampling at various points in the process. If the intent of the document is to help small and very small processors, additional information and examples will be needed to assist those plants that do not have full-time microbiologists or statisticians on staff.

Third, we are also concerned that these guidance documents will be viewed as regulations by field personnel, and plants that have currently adequately validated food safety systems will be forced to perform additional and potentially unnecessary in-plant microbiological testing in order to satisfy their inspectors, even though the fact sheet indicates micro testing is not required. This can divert resources from other necessary food safety activities, especially in small and very small plants.

In closing, I'd like to say we understand and support the need for meat and poultry establishments to have validated food safety systems. However, the draft guidance document

should be changed to address any specific needs or issues that FSIS sees rather than blanketing the entire industry with recommendations to conduct additional validation activities, which consists mainly of additional in-plant microbiological testing.

The Agency should consider and share what food safety gains will be realized, particularly in light of the impact on the small and very small meat processing industry.

Thank you for the opportunity to comment here today. NAMP very much appreciates the Agency's efforts to host this meeting and also to make the next release of the guidance documents in draft version available for additional comments in the next set of meetings.

Thank you very much.

MR. DiNAPOLI: Thank you, Phil.

Next is David Plunkett from the Center for Science in Public Interest.

That's not David.

MS. KLINE: It's not. I'm not David, but

I'm going to be speaking on his behalf. He's not able to be here. I'm Sara Kline from Center for Science in the Public Interest.

We wanted to thank FSIS for holding this meeting because, of course, validation is a critical step in ensuring the efficacy and credibility of a company's HACCP system. Ultimately we all want to protect the public health. And part of a working system is one that has been tested and retested to ensure that the HACCP plans that are in place will be adequate to protect the public from potential pathogens. It's important to recognize, as the Agency has said that they do, that this initial document is not clear enough in its expectations and in the research behind those expectations. To this end, one of the things we would suggest is similar to what Chris Waldrop from CFA has stated. FSIS should gather additional information about what processes are currently out there, what's being used, and that can be a starting point for the further dialogue that needs to happen on this issue. We're looking forward to seeing how the Agency will

fold all of the comments they receive today and throughout the comment process into the draft guidance moving forward, and hope that there will be additional opportunities to weigh in perhaps in another public meeting on this critical issue.

Thank you.

MR. DiNAPOLI: Thank you, Sara.

Next is Bob Hibbert from the Eastern Meatpackers Association.

MR. HIBBERT: Good morning. I'm Bob Hibbert. I represent the Eastern Meatpackers Association. Our members are a pretty good cross-section of small to midsize, primarily family-owned, businesses that to whom this issue is pretty important. Thanks to FSIS for this meeting, and thanks more generally for its commitment to really an open discussion of this important issue.

Our members support HACCP. They support the importance of validation within HACCP, and they also take FSIS at its word that problems have arisen in this area. In a situation like that, the notion of guidance is inherently useful. In any regulatory

system, you're better off knowing what the rules of the road are. Whether you like what the rules are or not, you're better off knowing what is expected of you. And that's particularly important in this area, in the HACCP enforcement area, because the Agency increasingly relies upon food safety assessments. What we have here is a system where the Agency is adamant about not prior-approving HACCP but is increasingly asserting the right to post-disapprove what it considers to be an unacceptable program. So the issue, again, whether you like that system or not, that is the system. People are better off knowing as much as they can about how it works, and they could use some guidance.

What you would hope after about 15 years or so of HACCP is that we all be moving in the direction where that is becoming increasingly known territory, where we have enough experience, enough precedent, enough understanding about what has worked and hasn't worked to be increasingly useful for people navigating that space. Unfortunately,

despite the Agency's intentions, I think the current draft is a step backward in that regard because it doesn't -- I think it's unanimity about the problem of concreteness, and I think that's clear. So what you have here going out to the audience, and it's important to understand that the important audience isn't in this room. The important audience are the people in the plants and the enforcers out in the field. And I think we can disagree about this, but I think the fairest reading of the current document is the enforcers of the field are being told we need to be looking for a lot more test results. So the message to the establishments now is you'd better test the heck out of everything if you want to avoid problems with the enforcement. Okay. That's a problem. What do we do about it? I think -- I'm not entirely sure that the solution is simply for the Agency to crank away for some significant period of time on a new one-size-fits-all document. I think one problem, and I don't think that's been addressed today, is what do we do in the year or so it's going to take to get that done when validation

is still out there happening? And what we have is we have this draft document that says one thing, and then we have statements from the Agency that sort of quasi-repudiate that. That's a recipe for more confusion in the short term. But I think there's the -- there accedes a consensus here that what we need is -- and I don't, I think it may be more of a dynamic ongoing process that maybe captures other aspects of HACCP enforcement, but lets people know on a continuing basis as the Agency sifts through its experience, perhaps enhanced by all the enhanced data capacity you're going to have in a few months, to be letting people know, okay, we've got these half-dozen more safe harbors that are okay. We've got these half-dozen products and processes that create a problem. So people can tell on an ongoing basis in real terms what the problem is. We think that might be a more productive approach than the one the Agency seems committed to now.

Thank you for your consideration.

MR. DiNAPOLI: Thank you, Bob.

Savonne Caughey from Elanco Animal Health.

Please correct your name or anything I --

MS. CAUGHEY: It happens a lot.

MR. DiNAPOLI: Sorry.

MS. CAUGHEY: No problem. I'm Savonne Caughey with Elanco Animal Health. Elanco is an innovation-driven global animal health company that develops, manufactures, and markets products to ensure animal health and welfare and ultimately provide for a safe and affordable and abundant food supply.

Last year Elanco launched a new business platform focused on food safety and now markets food safety products and services to the meat and poultry industries through Elanco Food Solutions. Elanco Food Solutions is committed to being a leader in developing and marketing comprehensive line of science-based food safety technologies and services to help meat and poultry packers and processors to meet the growing demand for high-qualify, safe, and affordable food. I appreciate the opportunity to make comments today.

My first comment is with regard to

prerequisite programs. Prerequisite programs should not be confused with critical control points with regard to this regulatory requirement. Currently the definition prerequisite programs are not part of HACCP. In the draft guidance document, it appears that the Agency considers prerequisites to be part of HACCP. Prerequisite programs are put into place so that hazard does not occur, and critical control points are put in place in order to control a hazard that a plant has identified as likely to occur. Therefore, validation of that critical control point is required to demonstrate efficacy of the HACCP plan. If a hazard does occur due to an issue with the prerequisite program, then a reassessment should be performed and that prerequisite program may need to become a critical control point.

My second comment is in regard to validation of single microorganism interventions. Novel intervention strategies are being developed and implemented in plants in HACCP programs today. With the continuous improvement approach to the reduction of *E. coli* 0157:H7 levels in plants,

packers and further processors are adopting new strategies to help further reduce the incidence of this pathogen. Validation of these new technologies and strategies is a key component of the HACCP system. According to the draft guidance document, validation of intervention should use certain indicator organisms to demonstrate efficacy in actual plant operations. Some of the newest technologies in use in development through suppliers are specific to single microorganism such as *E. coli* 0157:H7. For these novel technologies, indicator organisms will not provide an accurate portrayal of product efficacy for HACCP validation documentation. In addition, it is not the plants nor in the best interest of public health to inoculate cattle, carcasses, or pieces with pathogenic bacteria in the plant itself. Therefore, a more broader approach to the validation and efficacy should be used, i.e., model studies, et cetera. Further, FSIS should not limit the development of new technologies to only broad-spectrum antimicrobials through the use of narrow guidance protocols for in-plant validation.

In closing, on behalf of Elanco, I'd like to thank FSIS for allowing us to comment today, and I look forward to working with the Agency as you move forward in revising the draft guidance documents.

Thanks.

MR. DiNAPOLI: Thank you, Savonne.

Next is Joe Cloud, T&E Meats.

MR. CLOUD: Yes. My name is Joe Cloud. I'm a co-owner of True and Essential Meats. We're a very small multi-species plant that's been operating continuously since 1940 in Harrisonburg, Virginia, in the heart of the Shenandoah Valley. I wanted to say thanks to Mr. Almanza and his staff for giving us a chance to comment today. I'd heard about the validation regulations and the draft regulations in April, and I submitted a comment letter at that time that was expressing some concerns about the costs to my plant. So I won't reiterate those concerns.

We're a Talmadge-Aiken plant with inspection by the Virginia Department of Agriculture and Consumer Services. I'm here today because I do

have a concern that FSIS does not necessarily understand the needs and the realities of very small plants. The Virginia plants fought a very hard budget battle this winter to retain TA inspection in the state for that reason. In Virginia, the small community base plants such as my own have been running at full capacity since April of this year due to the demands created by the local food movement. This is a major change from the historical past. I think the community-based plants such as T&E are a critical asset to family farmers in the maintaining healthy and resilient rural communities.

My basic comment is that I'm particularly concerned with avoiding the law of unintended consequences. When HACCP came into the small and very small plants in '99, 2000, I've seen estimates that somewhere around the neighborhood of 20 to 25 percent of those plants were out of business within several years. Ever since Ezra Taft Benson said "Get big or get out" in the '50s, America has had a systemic bias against small-scale agriculture, which

is reflected in public policy. And it's true that plants such as mine do not have the resources that large agri-business plants do. At the same time, we do not put major populations of consumers at risk. I'm here to ask that the Agency keep in mind the realities of small community-based plants as you proceed with your rule-making process. And that's my basic comment.

I would like to add that small plants are fully committed to food safety. We are tested on a regular basis. We've never had a positive for pathogens of concern. I don't want to be seen as being casual in my approach to food safety. I just do feel that we work in a somewhat different world than most plants that the FSIS works with, and I'd like the Agency to keep that in mind as they develop these regulations.

Thank you very much for the opportunity to comment.

MR. DiNAPOLI: Thank you, Joe.

Next is Felicia Nestor with Food and Water Watch.

MS. NESTOR: Good morning. I'm Felicia Nestor with Food and Water Watch. We're going to be submitting written comments, but I'm just going to make a few comments here. Food and Water Watch is very interested in supporting the growth of small business. We published a small slaughter report several years ago, and one of the focuses of that was how Agency regulations have made it extremely hard and have pushed small businesses out of business. We think consumers have an interest in locally produced food, and so we want the Agency to prevent this from happening with this validation rule. We saw what happened, all of us saw what happened when HACCP was implemented. The Agency was criticized multiple times from multiple different directions, including other government agencies, for the vague requirements and the inconsistent enforcement. And we're so concerned at reading this guidance document that the same thing is going to happen again. There are multiple real problems with this kind of approach that we know from speaking both to inspectors and small plant owners. First of

all, inspector morale just plummets when they don't know what's expected of them. The good plants, there are good plants that get pushed out of business because they don't know how to meet the Agency's expectations. And there may be some bad plants that stay in business because they happen to be in an area where the regs are not being enforced the way they should.

The other, the final real problem that we see with this is a lack of transparency for the public. The public cannot be involved in this unless they understand what's going on. And I would suggest that the Agency's guidance document would suggest to any reasonable person that this type of validation is possible for every process that's going on today. My understanding is -- well, when I was doing the slaughter report, I was told that there were so many processes out there for which there were no available validation studies. I don't know what the current state of affairs is, but I think the Agency needs to make that clear to the public so that the public doesn't assume that

industry is just not doing something because they don't want to.

We're going to be making a few recommendations, and some that I would support what Chris Waldrop recommended. We think the Agency has abundant information in the FSAs, but perhaps the Agency should conduct something like a notice 6507 survey of all the plants. I think it would be good for the public dialogue if people understood what specific processes are there on good validation studies and what specific scientific methodologies are not available currently for people to use, for instance, the correlation between the indicator organisms and the pathogens.

So we look forward to the Agency's next document and hope that the Agency's expectations are a lot clearer than they were in the one that's currently available.

MR. DiNAPOLI: Thank you, Felicia.

Next is Jay Wenther, American Association of Meat Processors.

MR. WENTHER: Thank you. My name is Jay

Wenther. I'm the Executive Director of the American Association of Meat Processors, an organization that's been around since 1939 and represents a wide diverse group of meat processors, small and very small independent processors across the United States.

I want to first start out by thanking the Agency for putting on this public meeting, and specifically thank Mr. Almanza for the initial extension of the comment period that was truly needed on such a complex issue; and also the overall getting the document into the hands of the plants, that many don't have computer access and maybe didn't realize how this document that was out there may affect them.

Through the years, HACCP plans and food safety systems have been designed and redesigned and/or reassessed in federally inspected establishments annually. The HACCP food safety systems have been addressed, have addressed at a more frequent basis when actually needed. In the cases of BSE, that was truly the case. Regardless

of what statements have been made, the truth and the fact of the matter is in the validation guidance document, microbial test results are mentioned very frequently and very often, whether it be the criteria, the outline, or the design of microbial testing that is in the document. While we may have misinterpreted or been told we've misinterpreted the document and the contents of the document for several weeks now, and that it's not required, the clear and fact matter is that it's in that document and states it very clearly. In fact, 11 out of the 23-page document is dedicated to microbial sampling. And we fear that it will be accepted and needed as microbial sampling to prove to the industry and prove to the inspection personnel that validation has truly been completed.

At this point, AAMP is unaware of how the Agency is making statements that establish -- to validate one plan per HACCP category, considering the wide group of diverse processors that I represent, my organization represents, questions what will truly be acceptable when inspection

personnel look at these and how it will be scrutinized and have -- most likely the Agency will require that the industry will be expected to provide more supporting documentation or decision making documents and how a particular plan was chosen over another document, in which we've talked about supporting documentation already this morning.

Although the Agency continually reinforces that the validation information is guidance and is not regulation, it seems as though the Agency is taking a naive approach of how this guidance may be interpreted at the establishment level and by the inspection personnel that regulate those establishments.

Over the years, the meat industry has learned that guidelines quickly become minimal Agency expectations, and in the absence of supporting documentation available to present to the FSIS, microbial sampling may be the only alternative that is expected as the minimal expectations.

In conclusion, the meat industry has observed a decrease in plants over the years through

the development of HACCP being put into place. AAMP is firmly committed to the implementation of HACCP supporting our members, helping our members out throughout the process of putting in HACCP plans and supporting HACCP plans with valid supporting documentation. This may force more other meat industry establishments to put more products outside the reach of inspection through retail exemption or outside of inspection in general in going custom exempt or simply going out of business as they struggle to meet the demands or meet the expectations of the Agency.

AAMP appreciates the opportunity to comment on the draft validation guidelines. We will be respectively submitting more comments in a written format that's much more detailed than the ones I've presented today. We also respectively request that the Agency extend the comment period already with the document coming out as a revised document. As we all know, this is a very complex issue that we've talked about today and seen over the last 70 days with this document's release. And the 30-day

comment period may not be enough for -- to review the second revised document. We look forward to seeing the revised document and look forward to working with the Agency in coming to an amenable solution for all parties, the Agency and the industry involved.

Thank you for the opportunity to comment today.

MR. DiNAPOLI: Thank you, Jay.

Next is Carl Custer.

MR. CUSTER: Carl Custer, representing myself. I'm FSIS retired. I worked 37 years for FSIS, and I think in that time I pushed the science end for clarification, and I appreciate Al's comment that we're looking for clearer understanding of the intent.

There's two issues whose clarification I'd like to point out. One is validation. I recommend amending the regulation and point out that there are two kinds of validation. There is validation of the efficacy of an intervention, and there is validation of the implementation of that intervention. I think

Ken Petersen pointed that out very clearly in his presentation. But the regulation is a little vague, and I think it should be amended to make it clear. Now perhaps the guideline will make that clear.

The other point is the issue of surrogates for validation of an intervention. I mention that because I had one plant who was going to try to age meat and show that their intervention in-plant would produce a 2D kill. And I gathered some comments from some colleagues of mine. Jim in Iowa said, after USDA FSIS paid us to find and validate surrogates, the District Office refused to let us use them in our university establishment. So I think Dr. Petersen needs to talk to the District Offices and clarify the issue of use of surrogates both in the Des Moines and the Atlanta offices at least. Jim goes on and says Dan has been promising a memo that will allow the use of surrogates for nearly two years, though we haven't seen it yet. So maybe Dan will get that in the guidance document so it will be clear as to the use of surrogates. Gary from Texas says, well, I am biased, but I would like

to use the surrogates. Jim and I gave them to ATCC, so they are easily available. And those numbers, for the record, are BAA-1427, 1428, 1429, 1430, and 1431. They have no pathogenic properties and will clearly demonstrate what kind of kill they would get with 0157:H7 or *Salmonella*. We recommend doing this. If it's done in the plant, we recommend doing this at the end of the day, followed by intensive cleaning and sanitizing.

And then last, John from Colorado, who was in Italy, caught up with me and says, I believe Dan really needs to deal with this. Picking on you today, Dan. We have faced several times. I agree with all you say. Everything is right on target. People in my group are validating a major company's interventions right now using a model pilot scale sprayer by inoculating the surrogates isolated by Acuff and Dixon. They were isolated for *Salmonella* and 0157. They are deposited with ATCC. So there seems to be some confusion between District Offices in Colorado and Iowa. And that's, again, clarification of FSIS' policy needs to be done on

the use of surrogates.

That's all. Thank you.

MR. DiNAPOLI: Thank you, Carl.

We'll go back to the caller on the line. So, Operator, if you could tie us in with Jitendra Shah, if that's possible.

OPERATOR: Yes. One moment.

Jitendra, your line is open.

MR. SHAH: Thanks, FSIS, for affording this opportunity and sharing some thoughts with you. Looks like my -- all the comment has been already covered up with all my predecessors. So I don't have any more comment at this moment. But I always encourage the folks to communicate on how you are going to communicate with the general processor, and I encourage that this kind of a meeting we should have more often so we can have the open dialogue.

That's all I have.

MR. DiNAPOLI: Okay, thank you very much.

And Debbie is -- is Debbie O'Hara still not here? Just want to give her another opportunity. Okay.

Before I invite Al back up to give closing remarks, I just want to give a few reminders of the two following public meetings that we're working on, one in the midwest and one in the west.

And the transcript of today's meeting will be available online. So check for that in the next two to three weeks. And the e-mail that I mentioned earlier for the draft validation guidance to be sent in. And then, of course, you can mail your comments in as well. So you can e-mail and/or mail your comments to the docket clerk in Beltsville.

OPERATOR: And excuse me. This is the Operator. We do have Debbie O'Hara on the line.

MR. DiNAPOLI: Okay, great.

OPERATOR: You like me to open that up?

MR. DiNAPOLI: Yes, please.

OPERATOR: Your line is open, Debbie.

MS. O'HARA: Thank you. Good morning. There seems to have been some confusion. First of all, I'd like to thank you for this opportunity and to state that I certainly have had most of my comments already stated by my colleagues. However,

one point I'd like to bring up that I don't think was clear is in your validation guideline, which I also enjoyed, you stated regular and consistent compliance to the regulations. I think it would be meaningful to inspection as well as small processors to have a definition for regular or consistent. We use statistics and define things in the performance guidelines. And I think this might be another key location to give an example.

And with that, I thank you.

MR. DiNAPOLI: Great. Thank you very much.

At this point, I'm going to ask Mr. Almanza to come up and give closing remarks.

Thank you very much.

MR. ALMANZA: Okay. Well, I just want to thank everybody, everybody that participated on the telephone and everybody that showed up here. As you heard, there are very many opinions, and certainly I hear you Jay, I hear you, Nancy, Felicia, and Scott, and the rest of you that commented. And so this is where we move forward. And so trying to come up with a document that is meaningful, something that

we all understand what the rules are before we put the rules in play, and so I think that is something that is critical to this process because one of the things that I've struggled with in my short time here is that there are -- though we intend something to be in one way, the application on both sides doesn't necessarily turn out to be that way. And so this is something that we are committed to having a very uniform articulated way of applying in the field. And so we need our FSIS personnel to understand what they are going to be looking for, and we need everybody in the industry, the consumers, all of our stakeholders to understand what it is that we are going to be doing.

So, again, I appreciate all of your comments, and we'll look forward to the next public meeting.

Thank you.

(Whereupon, at 11:36 a.m., the meeting was concluded.)

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

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

HACCP VALIDATION GUIDANCE

Washington, D.C.

June 14, 2010

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

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VICTOR LINDSAY, Reporter

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