UNITED STATES DEPARTMENT OF AGRICULTURE

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FOOD SAFETY AND INSPECTION SERVICE

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HACCP SYSTEMS VALIDATION PUBLIC MEETING

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June 25, 2013
8:30 a.m.

Patriots Plaza III Auditorium
Washington, DC

CHAIR: MR. ALFRED V. ALMANZA
Administrator, FSIS

MODERATOR: GREG DINAPOLI
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PRESIDING OFFICIALS:

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I-N-D-E-X

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

(8:30 a.m.)

MR. DINAPOLI: We'll get started in just a minute here, everyone take a seat, and good morning to those of you on the phone calling into the meeting. Can you all hear me? If I don't lean.

Good morning. I'm Greg DiNapoli with the FSIS Office of Public Affairs and Consumer Education. This morning's meeting on HACCP Systems Validation. We'll be talking about the updates to the compliance guide regarding HACCP Systems Validation. So without further ado, I'm going to ask our Administrator, Al Almanza, to come on up and give opening remarks.

MR. ALMANZA: Okay. Well, Greg was short and I'm going to be shorter. So I want to get on with this.

So, this has been a long, long process. In fact, I was trying to remember when we had our first public meeting, so it's been awhile. But I think that this is valuable to have everyone's input and then certainly, to hear everyone's comments and to be able to record them.

So, with that, I'm going to go ahead and kick it off and let Bill Shaw, our Director of Risk, Innovation & Management Staff take the podium and let him get down to his business and brief you all.

Bill?

DR. SHAW: So, good morning, everyone. Yes. And as Mr. Almanza said, this has been an interesting journey we've been on and I think it's been a really educational journey for all of us and talking through these issues around HACCP and HACCP validation. And so I'm going to -- okay. I'm not being able to sort of -- this is like frozen up. Where is the --

(Side conversation.)

OPERATOR: Folks on the phone, one moment.

DR. SHAW: All right. Sorry. We're having -- I think we've got it. I think we've got it. Here we go.

So I just wanted to review a little bit about the HACCP final rule. As you all know, that that was published on July 25th of 1996 and the validation regulatory language is contained in 9 CFR 417.4, which is the section entitled Validation,

Verification, and Reassessment, which has been part of our interesting journey through this is the difference between those three. And I think we've had good discussion over the last couple years as this process has moved.

And the -- and that final rule in the preamble also included the Agency's position on how the regulatory language should be implemented, which has guided our guidance document development. And because both of these pieces of information guide our implementation policies, both the language in the preamble and then also, the exact regulatory language.

And as we've discussed previously, FSIS re-determined from its -- from our HACCP verification activities that many establishments had not properly validated their systems. And that's not to say that that's everyone. It's -- it -- but there was a -- we determined that there was a sizable section of the industry that had not properly validated their HACCP system and it was sort of a run the gamut, the gray area -- like, it wasn't black or white.

There were establishments that were -- that

we found that were, you know, completely validated, those that had very little validation and then there were many establishments in between. So there was not one size fits all, you know, positions for validation.

And what we were seeing is inadequate validation had been linked to food safety problems, and some of those examples had been the chicken pot pie outbreaks in 2007, the Lebanon bologna outbreak of 2011, and various analyses of non-O157 policies in 2012 that we had dealt with in the beef industry and, particularly, the veal industry.

So, this is sort of a timeline of our compliance guide development. In March of 2010 was the initial draft that was posted and received a little over 2,000 comments. In June of 2010 though, we had our first public meeting to discuss these issues, and in September of 2011, we also took a second draft of the compliance guide to our advisory committee for meat and poultry inspection and gained some valuable feedback from that group.

And in response to that -- to the comments that we -- and guidance we received from NACMPI, we

issued a third draft in 2012 and that also had a request for comment. And in that third draft, we received 51 comments and those comments were received from, you know, small and very small meat and poultry processors, trade associations representing animal producers, small business owners, corporations, state departments of agriculture and consumer advocacy organizations. So it ran the gamut.

And so in response to those 51 comments, we have made some additional revisions, which I think have been, you know, really helpful in moving the process forward. I do want to thank all of those that commented. We received a lot of good information, a lot of -- that has helped this process move forward over the time period. And this last draft that has been released clarifies some previous issues that we received comments on and we will -- and we're having this meeting today on the 25th and our final public meeting.

So our next steps, we will follow today's public meeting and we will accept any minor additional comments through July 25, 2013. We will address those

comments as necessary. We do believe, as Mr. Almanza said, this has been a process that we've worked through, so we don't anticipate any significant or major comments at this point.

And so with that, that's sort of our background and I'm going to -- we're going to hold questions until the end and I'm going to hand it over to Dr. Meryl Silverman, who has been our lead writer and she is going to go through some of the changes that we've made through the comment period and sort of walk you through them.

DR. SILVERMAN: So as Bill said, I'm just going to go through the updates to the compliance guidelines since the last draft.

UNIDENTIFIED SPEAKER: Hold on one second.

All right.

DR. SILVERMAN: Okay. Great. So, as we have talked about, we've had many iterations of the guidance document to clarify some questions that have come up, but throughout this whole process, the two elements of validation have remained the same: design and execution.

So in terms of design, we're talking about the scientific or technical support for the HACCP system design. And then in terms of execution, we're talking about that initial practical in-plant demonstration data that's supporting that the HACCP system is functioning as intended. But as Bill said, throughout this whole process, we've been making clarifications in response to the public comments, but again, the main concepts have really stayed the same.

So in this last draft, the few areas of clarification that we've made have been around those two elements of validation, the types of scientific support establishments may use, applying and matching scientific support to the actual process, how to select a product within a HACCP product -- within a HACCP category to gather execution data for, the difference between initial validation and ongoing verification, and then the need for guidance in this area.

So, in terms of the two elements, again, the principles of design and execution have stayed the same, but what we've tried to do in this most recent

draft is summarize the elements into six succinct steps to give establishments, you know, a quick understanding of what they need to do in order to validate their systems. And we've also added this graphic to illustrate the two elements. And you'll see in our guidance documents, we're trying to add more graphics to help with the usability and readability of the information.

So, in terms of the first element, again, the key steps are summarized. So to meet the first element of validation, establishments should identify supporting documentation that closely matches their process, identify supporting documentation that provides adequate support for the hazard identified in the hazard analysis to support that it's controlled, and then identify the critical operational parameters from that supporting documentation.

In terms of the types of support, as I mentioned, we've added information in response to public comment about using pathogen modeling programs as a type of scientific support. We've also added additional examples of what would be considered

incomplete scientific support. So we talk about just referencing no objection letters or support from Directive 7120.1 about new technologies because we know not all the critical operational parameters are contained in those documents, so we'd expect additional support for the other critical parameters of the process.

We also talk about cases where supporting documentation should contain microbiological data for the same hazard identified in the hazard analysis. An example we give is interventions at slaughter. So, if there's an intervention for beef processing and it's to address *E. coli* O157:H7, we wouldn't expect scientific support for *Salmonella* in pork. We're looking for a match between the pathogen and the hazard analysis and the pathogen in the scientific support. And I'll talk about later, about cases where we can use one organism as an indicator for others.

In terms of identifying scientific support documents, we've added an additional section to explain how to identify scientific support that matches the process and what are the key

characteristics that should match between the two. And we've also added ways in which an establishment can identify supporting documentation that adequately addresses the level of hazard or reduction to be achieved in the process.

In terms of matching the scientific support to the actual process, we give new examples for biological, physical, and chemical hazards which would aid establishments and, again, ensuring that scientific support closely matches the process. We had a lot of comments asking for clarification in that area. And for biological hazards, we've discussed and clarified the limited cases where microbiological data for one pathogen could be used to support adequate reduction in another pathogen.

So the examples we give are related to non-O157. We don't expect controls for non-O157 to be different than those for *E. coli* O157:H7, so scientific support for one pathogen may be used for -- to support reduction or control.

And then *Salmonella* in ready-to-eat products is an area where we got a lot of comments about. We

know that *Salmonella* is more heat resistant than other pathogens, so for ready-to-eat products, we discuss how *Salmonella* -- reduction in *Salmonella* can be used to support that other pathogens, like *E. coli* O157:H7, are controlled. We don't expect establishments to have additional scientific support showing *E. coli* O157:H7 is controlled if their support was for *Salmonella*. And that's specifically for lethality treatment in ready-to-eat products.

And we've actually added a key question to really address this issue because we did have comments around using Appendix A. We know Appendix A was designed for *Salmonella*, so we got questions about whether that could be used to support that other pathogens, like *Listeria monocytogenes* and *E. coli* O157:H7, are controlled. And again, the answer is yes. For a heat treatment, those types of lethality processes, we know since *Salmonella* is the most heat resistant of those pathogens, that scientific support can be used.

We also got questions to clarify the use of data around indicator or surrogate organisms, so the

guidance document also clarifies when it's appropriate to use scientific support containing data for indicator or surrogate organisms. And specifically, we discuss how, if similar and consistent reduction or control can be established between the indicator and the pathogen identified in the hazard analysis, then that support can be used.

And we give an example that's actually from the jerky compliance guideline about some research from the University of Wisconsin in which the researchers showed consistent reduction between two surrogate organisms and *Salmonella*.

In terms of the second element, the initial in-plant demonstration data, again, we've tried to summarize the key steps that an establishment should go through when working through that second element. And these would be implementing the same critical operational parameters and the supporting documentation, identifying at least one product from each HACCP category to gather in-plant demonstration data for and then actually gathering that data, demonstrating the effectiveness of the implementation

of those critical operational parameters.

So, in terms of in-plant data, we did want to clarify what criteria establishments can use to select that one product from each HACCP category to gather in-plant demonstration data for. These criteria are not exhaustive. Establishments can come up with their own criteria, but we wanted to include some food science principles that could be use to select that product.

So, for example, here, I've shown how fat content could be one criteria used if an establishment's producing products of varying fat levels. We know that fat level has been documented to affect heat resistance, so we would recommend that establishments pick the one product from the HACCP category with the highest level of fat to collect that in-plant demonstration data for. And there's many other criteria that can be used.

In terms of the types of in-plant data that should be collected, we wanted to clarify what that data should be and this really hasn't changed from the last version, but we just tried to make it more clear

that in cases when an establishment implements the critical operational parameters and their actual process very consistently with the scientific support and where the scientific support contains data for microbiological data that matches the pathogen identified in the hazard analysis, the in-plant demonstration data that establishments should be focusing on is just related to those critical operational parameters.

Can the parameters and the scientific support be implemented consistently in the actual process? So, these types of quantifiable characteristics would include parameters like pressure, temperature, concentration, and we give a list of those parameters in the document.

But we know that there are going to be some limited cases where establishments are not able to implement the parameters consistently -- consistent with the support and their actual process or the microbiological data may not be for the same pathogen identified in the hazard analysis. And so in those limited cases, that's when we would expect

establishments to validate the intervention's effectiveness under actual in-plant conditions.

And also in response to public comment, we have clarified what we mean by implementing those critical parameters consistent with the scientific support, and what we mean is that changes among the critical operational parameters used in the support when we compared those to the actual process would not affect the efficacy of the intervention or treatment.

In terms of clarifying the differences between initial validation and ongoing verification in the revised guidance we've just reiterated, the distinct functions of the two moving from initial validation during those first 90 days of a new process or a changed process, moving on to ongoing verification which is done on an ongoing basis. And we've also clarified, in response to the comments, when changes that result from reassessment would require validation and when they would not.

So, if an establishment is producing ground beef and they're using 80/20 trim and the only change they've made is the supplier that they're receiving

the trim from, there's no other changes in the specifications, that could be a case where reassessment and that change in supplier would not result in requiring validation. Now, if the establishment went from using 80/20 trim to 60/40 or had other changes in the composition of the trim, then that could be a case where reassessment would result in the establishment determining that validation was needed again.

We've also revised the guidance to address the new reassessment requirements and, specifically, that official establishments are required to make a record of each reassessment. And then we've also made some changes to the appendix.

So, as Bill talked about, we wanted to really illustrate the need for this guidance document, and so we've included examples of food safety problems where as an Agency, we've found through our verification activities that they've been linked to an inadequate validation. And specifically, we've gone through three examples: one which was the 2011 Lebanon bologna outbreak where there were differences in the

scientific support in terms of the diameter of the products studied and the type of casing.

When it was scaled up into the actual process, those big changes were found to result in inadequate lethality in the product and were linked to those illnesses and analysis of non-O157 positives that we saw in 2012 linked to veal that were related to incomplete carcass coverage of the intervention. And then the chicken pot pie outbreaks in 2007, which, as a result of the investigation, it was found were related to incomplete validation of the cooking instructions.

So you can see there's a wide variety of food safety problems that have been linked to inadequate validation and we go through each of those.

We've also added an example of a decision-making document because there were some requests for clarification on how an establishment would walk through that process of when the critical operational parameters and the support don't match the actual process, how you would provide a scientific rationale for why those changes shouldn't result in a

change to the efficacy.

And so the example we give is for jerky, and the researchers in this example actually discuss specific cases when differences in processing temperatures should result in the same reduction in *Salmonella*. And we walked through how an establishment could explain the changes and the critical parameters from the support and why we wouldn't expect changes in the effectiveness of the process.

The third appendix is really the same from the last draft in terms of guidance to identify critical operational parameters. I just wanted to highlight that the information is the same. We just moved some text from the appendix into the body of the document because we felt it was really important to cover in the body of the document, but no other changes in that appendix were made, even though it may look different.

And then the last appendix are the worksheet examples, and we've added an additional example which shows how pathogen modeling could be used as

scientific support in conjunction with Appendix B. And we've also shown there what types of in-plant data would be collected.

And as Bill talked about, we've really felt that the guidance document has improved with each iteration as a result of the public comments, and I think this example is a great example of that. The idea for the validation worksheets came from previous comment period, along with the HACCP self assessment, which is at the end of the document, also came as a result of public comments. So, we really feel like the document has improved with each stage and, at this point, has really addressed all the different types of comments that we've received.

So, really, in summary, as I've started with, you know, the main concepts of validation, the design and execution haven't changed, but as a result of the public comments, we've -- I hope we've clarified the different issues related to each of the comments to really help improve understanding, and we feel like this iteration has really improved as a result of the comments at each stage.

So, with that, I'll have Bill come up here -- do you want to say something?

MR. DINAPOLI: Thank you, Dr. Silverman, and thank you, Dr. Shaw.

At this moment, we will take a few clarifying questions if anyone has any at this point. We will move into the public comment period. So please, we'll bring a microphone. Are there any questions in the room? Okay. We've got Scott right here.

MR. GOLTRY: Good morning. Scott Goltry, AMI. Although this is focused on the compliance guide, the validation compliance guide, how do you see this compliance guide interacting with training of EIAOs and the FSA fact sheet -- work tools, I mean?

DR. SHAW: I guess I would say as we move through this last comment period and work through any sort of last minute, last verifications, we will then decide and work through our -- how we're going to implement and our sort of training sort of ideas and how we're going to sort of implement that into our existing verification systems and that will be -- that

will come as we move forward.

So I'm not -- I mean, so we do now have our EIAOs, our Enforcement Investigations Analysis Officers do sort of, as part of their food safety assessments, work through looking at the total HACCP system, and as we move into the implementation phase, that cadre will receive additional training and such to sort of implement these principles into their daily work.

MR. CORBO: Tony Corbo from Food & Water Watch.

To sort of piggyback on what Scott just asked, in talking with processing inspectors, they will find that the HACCP plans change very frequently, sometimes from on a day-to-day basis. How will they communicate to the agency management that a HACCP plan has changed and how frequently will an EAIO [sic] go to that plan to verify that the changes to the HACCP plan were validated properly?

DR. SHAW: I would say that this has gone -- I take your question and we are here today to talk about the guidance document in itself and I think your

question does maneuver more into implementation. And I would -- and so I'll reserve a large part of that until we get into the implementation phase, but I would say changes at the level that we're speaking about with validation, I -- on a day-to-day basis, I would say that that probably does not happen in the fact that an -- many of our establishments in the processing world, they're using Appendix A and they're using Appendix B and those things are not changing from day to day.

And so I guess, if I would say that -- so that, I would sort of need further clarification and also, the reassessment requirements of our regulations do require establishments to document their reassessments. So, that is part of that regulation-making situation is when how we would keep track of changes in that way to a HACCP system.

MR. DINAPOLI: Any more questions? Okay. Great, thank you.

Operator, we'd like to see if there's any questions from folks on the phone.

OPERATOR: Okay. Very good. If you'd like

to ask a question, please press star 1 on your phone. Your line will be un-muted. At that time, just state your name and your question and if we do answer your question, you can hit star 1 again and be removed from the question queue. Are there any questions on the telephone?

Okay. I don't see any questions at this time.

MR. DINAPOLI: Okay, great. Thank you very much.

We'll move into the public comment period. If folks on the phone would like to make a public comment, we'll -- we will get to you once we finish with those in the room. So I believe --

UNIDENTIFIED SPEAKER: Which -- whichever. Whichever.

MR. DINAPOLI: So, if you could please identify yourself. It's up to you, Tony.

MR. CORBO: Oh, I will never resist.

MR. DINAPOLI: Well, we've got to make sure that mic is on because folks on the phone -- Tony, maybe come on up if you don't mind. Thank you.

MR. CORBO: Tony Corbo from Food & Water Watch.

First of all, I want to thank the FSIS staff for working on this project that -- I know this has been a long, you know, process and I've -- I noticed the adjustments that you've made to the compliance guide and so, you know, thank you very much for taking the comments and incorporating some of our ideas into the revised compliance guide.

But I have to say something. I mean, we're a month away from the 17th anniversary of the HACCP pathogen reduction rule and we're still debating the rules of the game. And I just find this remarkable that we're still trying to figure out what all of the elements of the rule were and how they are to be enforced.

I still have a question in terms of how very small plants will be able to access information in terms of, what is the right answer? What is the right answer on validating their HACCP plans? I know that the -- that when the Agency turned over this subject to the Advisory Committee a couple years ago, there

were some recommendations on how a consortium could be set up so that small plants could access information, but that doesn't seem to be incorporated anywhere.

As I raised just a little while ago on the implementation and the enforcement of validation, how are changes to HACCP plans going to be addressed? If they occur frequently, how does that get transmitted to the Agency in terms of making sure that the revised HACCP plan is validated? One of my favorite subjects, is the public health information system going to be capable of incorporating changes and dealing with the enforcement mechanism?

And so, finally, I want to thank the Agency for holding this public meeting. I've noticed that there have been more of these public meetings. It would have been nice to have held something like this on the poultry inspection rule. Thank you very much.

MR. DINAPOLI: Thank you, Tony. Do we have any other -- okay.

Operator, if there's any folks on the phone that would like to make a public comment, if we can open up that -- those lines?

OPERATOR: Okay. Again, please press star 1 on your phone if you'd like to make a comment. You'll be notified when your line is un-muted.

I see no questions or comments at this time.

MR. DINAPOLI: Okay. Thank you very much.

This concludes the meeting for the day. I'm going to invite Phil Derfler, our Deputy Administrator for FSIS for closing remarks.

MR. DERFLER: Well, first of all, thank you all for coming and thank you for the comments that we did receive. As you've heard, the comments are really important to us and we'll take the comments under consideration.

Remember that the comment period on the latest draft remains open until July 27th and any written comments that we get will be given full consideration, and we would urge everybody on the phone and in the room, if you have any comments or suggestions, please submit them because that's the way that the rule gets better or that's the way the compliance guide gets better, not a rule.

What -- the question -- you know, this has

been a long time in coming. It's been 3 years. So the question is, why has it taken us so long? And I think the reason is because validation is really, really important. We consider it to be really important. We want to get the compliance guide right because we want to make sure that small and very small plants, and large plants as well, get their validation right. So again, thank you for your comments.

Now, the -- I want to thank the people who contributed to this meeting because we couldn't have it without them. So I do want to thank Dr. Shaw and Dr. Silverman for their presentations. They were enlightening and helpful in setting the tone. I want to thank Joan Lindenberger who was really important in organizing the meeting today. Felicia Thompson and Bernadette Hudnell, Shanelle Basta and, of course, Greg DiNapoli, our moderator, and Carmen Rottenberg, who did a lot of work to get the meeting together as well.

So in that, thank you all for coming and the meeting's adjourned.

(Whereupon, 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:

UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

HACCP SYSTEMS VALIDATION PUBLIC MEETING

Washington, D.C.

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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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MIKE GILMAN, Reporter

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