UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

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# USING THE RISK ALGORITHM IN DETERMINING THE CATEGORIES OF INSPECTION IN 30 PROTOTYPE PROCESSING PLANTS

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I-N-D-E-X

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

(9:00 a.m.)

MR. TYNAN: Thank you to all of you for coming this morning. We're going to talk about using the risk algorithm to determine the categories of inspection.

In addition to the audience that we have here at George Mason, we also have phone-in participants. So we're going to be alternating back and forth a little bit in terms of taking questions and comments from the group here as well as those that are on the phone.

I should mention that all of the materials for those folks that are on the phone, all of the materials for today's session are on the FSIS website. You can just check on the search engine under risk-based inspection, and you can access all of the materials for today's meeting.

Just briefly, I'd like to take you through the agenda. Everyone should have copies of that. They were at the table outside. It's a very simple, straightforward kind of an agenda. We're going to

have a few welcoming remarks from Dr. Goldman and Dr. Raymond, and we're going to then get into in a little bit more detail into the issue of the inherent risk measure paper. Again, that's on the website, and we'll talk about the risk control measure as well. So that will set us up. These are papers that we discussed at previous meetings, perhaps not in as great of detail as we'll go into today.

And after those two initial sessions, we're going to talk a little bit about computing the risk-based inspection levels for processing establishments in our prototype assignments, how those two measures come together.

And last but not least, we're going to talk a little bit about the noncompliance records and their impact to their public health ranking. So we'll talk about that, and then we'll have a short closing, and we'll talk maybe about next steps and where we go from here.

So that's essentially the agenda. We're scheduled to close at 1:00. We've left ample time for discussion of the topics today, but one last thing

before I introduce Dr. Goldman. I wanted to mention that there are a number of topics that we're going to touch on as we go over the algorithm, and things such as production volume, industry data, perhaps even discuss the elicitation. Those are not the subjects of our meeting today. So we will be handling those. They will be touched on for purposes of understanding how they relate to the algorithm, but we have additional meetings set up for later in April and during the summertime, to talk about those in more depth. So we may handle one or two questions regarding those, but we're going to ask you to hold some of the more specific and in the weeds type questions for later on.

And with that, I'm going to introduce Dr. David Goldman, Acting Administrator for Food Safety and Inspection Service.

DR. GOLDMAN: Thank you, Robert. And I want to also thank all of you for coming today, those of you who are here in the room who have traveled in perhaps from out of town to D.C. or to Northern Virginia, and those who are joining us on the phone.

This is a very important meeting. This begins a series of meetings as Robert just pointed out in which we will discuss in great detail, hopefully enough detail, the various aspects of risk-based inspection so that as we move forward, we can all collectively be comfortable with its individual components.

This is my first public meeting on RBI in my role as Acting Administrator, and I think it's fitting that this is the first in that series of summits that I just referenced.

Although it's my first meeting in that role, I'm obviously not new to RBI. I have participated in the past in the smaller stakeholder meetings that we've been holding since the rollout in February. Of course, I was here last October as well and participated in that meeting.

I'm very pleased to see so many of our public health partners here, our industry and consumer representatives as well as our own employee organizations, and I want to mention in particular, we have Bob McKee from the Association of Technical and

Supervisory Professionals, Stanley Painter from the National Joint Council of Food Inspection Locals, and Pat Basu from the Asian Pacific American Network in Agriculture. And I think also on the phone we have Chris Bratcher who is representing the National Association of Federal Veterinarians.

FSIS and I remain committed to an ongoing and open process as we continue to implement this more robust risk-based system. This is a science-based initiative and it's critically important in our ability to maintain the safety of meat and poultry.

While we are creating the best system that we can, we'll continue to work on other public health initiatives that are very important to the Agency, that are somewhat separate from but yet in support of risk-based inspection. One example would be our data infrastructure project. Another would be the data consolidation project. You'll hear more about those both as we discuss RBI and as well as projects in their own right.

Risk-based inspection at FSIS rests on our ability to use real time data in an integrated public

health data infrastructure. This infrastructure will allow us to make better informed proactive decisions to protect public health, and we'll be able to save lives even before RBI is completely implemented.

Data is important to our Agency and to all of you, our public health partners, who are committed to building an infrastructure which is vital for any public health agency to have. It is important to protecting public health and improving food safety.

I look forward to our discussions today and to your ongoing commitment to this project.

At this point, I'd like to introduce to you someone that you all know well by now, our Under Secretary for Food Safety, Dr. Richard Raymond, who will continue to welcome you as well as to lay out a little bit more in detail about our vision for risk-based inspection. Dr. Raymond.

DR. RAYMOND: Thank you, Dr. Goldman. It's been a great experience working with you to create this dynamic risk-based inspection system that will help us insure the continued safety and security of the U.S. meat and poultry supply. You mentioned that

this was your first address as the head of the Agency, that you've been working on this for a few years. Well, you've been doing the rolling before. Now you are at the helm and you are guiding this thing. So I'm glad to have you with us.

And I want to echo your comments thanking all of our partners for coming today, some from as far away as the Republic of Berkley, California, and participating in this first of many upcoming public summits. Your comments and input are vital to this process and they are greatly appreciated by those of us within the Agency.

Everyone here in this room today knows I believe strongly in the importance of a more robust risk-based inspection system and the public health benefits that such a system will offer to all of us. It is also essential to realize that this idea of using a scientific background and understanding of risk to better protect the safety of the food supply, has been around a lot longer than the almost two years that I've been privileged to serve as the Under Secretary for the Office of Food Safety in the United

States Department of Agriculture. It's been around a lot longer.

In fact, this important idea has percolated through the highest levels of the Department and has been discussed and studied by respected academics for more than 30 years.

The really interesting thing that I discovered is that throughout the past 30 years, 3 necessary elements for an enhanced risk-based inspection system have always been agreed upon for pretty much that entire time. This includes improving a plant's control of risk. It includes varying intensive inspection based on risk-based factors, and it includes factors for failure to meet inspection requirements.

In fact, even the thinking of what would go into the creation of the algorithm to determine the risk that a given plant would pose has remained remarkably consistent over those 30 years. According to a report issued by the USDA, in 1978, focusing on a strengthened meat and poultry inspection program, there were five important elements that any plan

needed to have to categorize plants based on risk. Those elements in that document in the Federal Register included the nature of the meat and poultry product, the method of processing, the volume of the product produced, the compliance history of the plant and the ability to monitor plant performance through data collection and laboratory analysis of product samples.

Now 30 years is a lot of time for due diligence, and especially given the continuity of thought seen over that period of time. However, it's our opinion that, the Office of Food Safety, that this initiative is far too important to public health to rush. That's why we've decided to wait until this series of technical summits in April and May and June, as well as the most recent expert elicitation is completed, before we begin implementing the timeline that FSIS proposed in February.

One of our topics today was to discuss the timeline. So I'm letting you all know that the timeline has been moved backwards. We probably will roll this out in our prototype location sometime in

July. I'm not giving a firm date or commitment yet. It will depend how the summits go and the input we receive.

This is a big change. This means that FSIS will begin implementation of this probably in July rather than April. This means that we have listened and once again, we're trying to be responsive to the comments that we have received. This decision as made after listening to the constructive comments that have been coming in by a number of consumer groups, employee associations and industry representatives expressed after reviewing our proposed timeline and our formulas to determine establishment category of inspection.

We felt that the information that we were receiving deserved to be heard and discussed in public, with the rest of our stakeholders. So you all have a vote on how this will look. It's just another example of how important we all believe your input is to this process and of us acting on that input and reacting to that input.

I've heard some very good ideas. If I were

a dictator, I would have changed them and rolled this out in April, but I'm not a dictator and the good ideas I've heard, I want your comments on as we air them at public meetings, particularly on plant volume and plant data. We do need to make some changes there, but I want your input on what those changes will look like.

The timeline that we issued late February was never meant to be cast in stone. This is a science-based initiative and all good science has to be flexible enough to evolve as additional data and input is gathered throughout the process.

As our discussion continues over the next few months, I'm sure that additional improvements and refinements to this dynamic initiative will occur.

Today we want to talk about the algorithm. We're going to talk about the timeline. Specifically I want to hear your input on how we have used noncompliance reports. We spent a lot of time and effort to come up with a formula that I believe is responsive to what we have heard over the last year from industry, consumers and our own employees about

how to use noncompliance reports into this algorithm. That's our goal today.

Our goal today is not to talk about whether or not we're going to do risk-based inspection and it's not to talk about the politics. If we get into that area, we will waste those people's time who have come here to talk about the algorithm, the noncompliance reports and the timeline, and I ask you to keep your comments to those three areas. Anything else is not the subject of this particular meeting today.

Now I'll end on that note so we can get started with this important meeting. I want to thank everyone once again for coming and spending a beautiful day in November -- in November -- we're not there yet.

(Laughter.)

DR. RAYMOND: That's wishful thinking -- in April in Northern Virginia when you could be over looking at the cherry blossoms. They are beautiful. The peak was yesterday for those of you who came from outside of this area. You should get there yet this

afternoon. So I want to thank you for coming. I look forward to working with all of you today and in the future to improve the safety of the United States meat, poultry and egg product supply. Thank you.

MR. TYNAN: Good morning again. I don't think I introduced myself earlier, I apologize. I'm Robert Tynan. I'm the Deputy Assistant Administrator in the Office of Public Affairs, Education and Outreach in FSIS.

As Dr. Raymond said, we'll be done early, and you should get over to the Tidal Basin if you can. We're purposely closing at 1:00 so you'll have ample time to do that and, Craig, you agree with that. Is that correct?

DR. BRATCHER: Yes.

MR. TYNAN: Okay. I would like to introduce the folks that are sitting up here that are going to be speakers for today. To my immediate right, I have Matthew Michael who will talk a little bit about the inherent risk paper. Don Anderson, he'll be talking about the risk control measures paper. Bill Smith will be talking about how those two come together in

terms of determining our level of inspection, and at the very far right, I have Mr. Charlie Gioglio, who will talk a little bit about the NRs of public health significance. So that's our group of speakers for today.

Before we start, I wanted to ask you to try and make your comments and questions when we get to that portion as brief and concise as possible. We have a fairly large group. So I want to be fair to everybody so that we have an opportunity to get everyone's questions in.

We're not imposing a time limit on -- as we have in a couple of our other meetings where we've allowed for a minute or two minutes for a comment or a question. But I may ask you to wrap up a comment in the interest of time, and that's not because we don't value your comments, but rather we just need to stay, again to be fair to everybody and stay within the time limits that we've set for the meeting today.

I should remind everyone that you may also provide your comments, if you don't get a chance to get in everything that you wanted to say today, to our

e-mail address. It's riskbasedinspection@fsis.usda.gov. So that site is available. It has been used, and we're grateful for the comments we've received and hope to have more after the meeting today.

When we get to the comment period, we have microphones in each aisle. I would ask you to come to the microphone if you could, and state your name and your affiliation before you begin your question or comment. That will help us a little bit. I have a gentleman over here who is our transcriber, and if you give your name and affiliation, that's going to help him out to get us a transcript. I may gently remind you if you forget to do that.

We also again have callers, callers in. So when we get to that comment period, I'll alternate between comments and questions here as well as the people on the phone. In that regard, our technician here has told me that there is a possibility that there will be a little bit of a glitch with the audio portion for people presenting from the phone-in, that our gertner box isn't working quite the way it's supposed to for some reason. So we may have

difficulty with that. I hope that is not the case, but I just want to warn everybody in advance. And again, if there's some issues on things that we can't get to, then we will try and get those through our risk-based inspection address.

We did not build in, in the agenda, a specific time for a break. I'm sure everybody probably looked at that and closed their eyes when they saw that. But there is a lot of information that we want to get to. We're going to leave it to you to decide when you need to get a cup of coffee or grab a stretch break. The coffee is down one floor below us. I think there's a small bookstore that has coffee there. There's a coffee shop evidently right around the corner from that where you can get a little bit better coffee I think, and so if you need to take a stretch break or whatever.

The last thing I would mention to you, as you face the front of the room, if you haven't found them already, the restrooms are around the corner to the right. So my left, your right. And that's basically it. Any questions before we get started

with the day's proceedings?

(No response.)

MR. TYNAN: Okay. With that, I'm going to turn it over to Matthew Michael to talk a little bit about the inherent risk.

MR. MICHAEL: I'm Matthew Michael. I'm with the Program Evaluation and Improvement Staff at FSIS, and as Robert said this morning, I'll be talking about the measurement of inherent risk in the processed meat and poultry products.

MR. TYNAN: Let me get you on the presentation portion. There you go.

MR. MICHAEL: Thanks. For those of you who attended the meeting back in October, some of these first slides will probably look familiar to you. As most of you know, we use two measures of risk in RBI, the inherent risk measure and the risk control measure.

The inherent risk measure is a measure of the inherent risk posed to the public health by each type of processed meat and poultry product, assuming typical process control by the producing

establishment. The risk control measure is a measure of the amount of risk control achieved by each establishment and that's what Don will be talking about later. We use both of these measures together to create a risk-based score for each plant, and Bill will be talking about that later.

The measure of inherent risk provides a relative value for the risk posed to the public health by each category of processed meat and poultry product produced in an official establishment. It takes into account the species of animal processed and the type of processing. That's a hazard component. And then the production volume which is a proxy for exposure for that particular product that's produced at each establishment.

This next slide explains this better. We based our inherent risk formula on the general formula used for calculating risk, which is hazard times exposure equals risk. In our case, we have a species process value times volume equals inherent risk. We've combined species and process into a single variable to account for the different risks they pose

in combination. For example, all things being equal, raw poultry might pose more risk than raw pork whereas canned poultry and canned pork might pose equivalent risks. So by combining the two variables in this one, we can differentiate among different risks.

We've used production value as a proxy for exposure assuming a direct relationship volume produced and exposure to the inherent risk posed by the product.

Okay. The species/process values, those that we have now -- well, let me start. Each value represents a measure of the relative risk of illness posed by one or more categories of processed meat and poultry products. The values we have now and that you've seen on our web page were determined through a 2005 expert elicitation. We're having a new modified expert elicitation developed by a contractor now, and it'll be completed in June 2007.

In 2005, we did conduct the elicitation with 23 experts from academia, the Federal government and industry, and we asked them to score 24 species/process categories to reflect the relative

risk of illness per serving that each poses to consumers. The instrument we used in that expert elicitation was peer reviewed by experts outside of FSIS. These were experts in data collection and analysis, and we conducted that peer review under the OMB Guidelines for the Information Quality Act. A list of the experts can be found on the FSIS web page, and the site is up here. That's been up for a while.

In 2005, we placed a number of constraints on the experts. That is we asked them to assume a lot of things about the production of the products when they gave us the scores. For example, we asked them to assume that the product they were scoring was produced in a plant with typical processing and a plant that operated under SSOPs and had SSOPs and HACCP and operated under USDA inspection. We asked them to assume that the product isn't an eradiated product, that the consumers were healthy adults, et cetera. A lot of those assumptions were made in 2007, but in a lot of ways, the 2007 elicitation is modified in response to the comments we received back in October.

And again, these are the values from the 2005 -- these are the median scores from 2005, the 2005 expert elicitation, and you'll see here the 24 categories of products. For the purpose of the calculation, we'll be doubling these scores to put them on a scale of 100. It doesn't change their value relatively speaking. You'll also notice here we have -- we cover about every product, every type of processed meat and poultry product with the exception of thermally processed commercially sterile products. And when we conducted the elicitation in '05, we believe that those products were exponentially safer than the next most dangerous product, and therefore we would fit them in as the lowest score.

As a result of the October meeting, and some of the comments we received, we've now included thermally processed commercially sterile products in the 2007 elicitation. So we'll have values for those coming up.

As I said, the next elicitation will be completed in early June 2007, and we're using instruments -- we're working on those instruments now.

They were modified in response to the public comment as well as the peer review. The peer review was recently completed and we had a lot of very good significant comments that we've used to improve the instrument.

The major changes we made to the instrument is we are asking about severity. We'll have a separate instrument where we ask the experts to rank these products by severity of illness that could occur through their consumption, as well as the original instrument that asks them to rank the products by probability of risk per serving.

Another change we made in response to comments is that we'll have an upper bound of responses, on the responses from the experts. We think we figured out a way to do that to preserve the proportionality of responses. That comment came about from the October meeting, and I believe also from the Advisory Committee. A lot of people were concerned about the ranges of responses and some of the earlier responses. So we do have an upper bound. And then, of course, as I mentioned in the previous slide,

another change is we will be asking about thermally processed, thermally sterile product or typically canned product.

And then also in response to public comment, we're going to have a very specific make up of the expert group this time around, and we haven't recruited -- the contractor hasn't finished recruiting the experts yet, but what we want to get are experts in equal numbers from three groups, and those would be academics, public health professionals and experts from industry, and we're shooting for eight experts in each of those groups. The response rate in 2005, only about 66 percent of the experts we asked to participate did. So I can't say we'll get eight this time, but that's our goal, eight in each group.

Okay. We'll be using production volume for each type of product to develop the exposure component for each establishment. We've already collected volume data for every one of these categories from every inspected plant. The inspection personnel were giving us estimates of volume data into PBIS. They began entering data as a pilot in a single district

back in November of '06, and then it went national in December of '06, and they've completed it now and we've got a very good response on that. So we do have some volume data for every plant.

This slide shows -- this is a facsimile of what the inspection program personnel see in PBIS and we arranged it this way for a number of reasons. This is a grid we've seen before when we previously collected similar data. You'll see on our Y axis we have the pounds shipped in a typical day, and we have ranges of pounds and the X axis we have the number of days product shipped in the last 30 days. And then what I've put in each square then are the ranges if you multiply the axes together. You'll probably notice immediately that there's some overlap in these, and that's a shortcoming of this way of collecting data, but we felt it was necessary to collect the data at this time because, first of all, the experts had seen this type of grid before, they were comfortable with it. I'm sorry. Not the experts. The inspection program personnel were comfortable with this type of grid, and secondly, we didn't believe at this time

that inspection program personnel would be able to give us point estimates for product type per plant. I think in the future, we'll be trying to get more accurate volume data. But this data is pretty good.

This next slide shows the product of averages of the possible ranges of volume, and there's been a lot of comments on this, and the paper that's on the Internet, this is actually two graphs, but I combined them into one because I couldn't fit it into a single slide. Let me see if I can go back here.

You see on our Y axis, the volume is 25 and that is the average between 1 and 50 pounds, our first value on the top of the Y axis, and then you'll see on the X axis our first value is 2.5 days and that's the average of 1 to 5 days on our X axis. So we took the averages of our ranges and we multiplied them together to get the values you then see filled out in the box, the boxes. So 25 times 2.5 is 62.5. 25 times 7.5 is 187.5, and so on. These are products of averages and they are hypothetical possible ranges of production for each type of product. So we calculated these for each box in the grid, and then we arranged them and

divided them into quintiles or five groups. They're rough quintiles in that you'll see quintile number 4, in fact, has one extra value because otherwise we would have had the same value 375,000 in two groups, which we didn't want.

So we divided it into five groups and now the score of 1 through 5 is what would be used as the volume value in the equation. So were a plant to produce, to end up in the 62.5 box for example for raw ground, comminuted beef, they would get a 1 in the calculation.

Okay. Then I have a little -- some sample scores. This is just a general slide. This is from the paper on the Internet, and see the inherent risk score will be calculated on 100 point scale, with 2 being the lowest calculated score and 100 being the highest. The reason it's a 2 right now because our lowest value is one, and as I said, we're going to multiply them all times 2 to put them on a scale of 100. Once we get the new expert values including canning, I'm not sure if this will stay the same, but obviously it won't change very much because we intend

to keep this measure on a 100 point scale.

Okay. Here's an example calculation. The first one is fairly simple. We have two plants, Plant A and Plant B, and they both produce the same product. They're both raw ground beef. You see Plant A is relatively small or they're producing a relatively small volume of product. So they have a 1 in the volume, the V column. Plant B is the largest. It gets a 5. They both have the same inherent risk ranking because raw ground beef in our current table is a 20. You can ignore the next two columns. You'll see them in the next slide. They're for weighting numbers when we have plants that produce multiple types of product. So what we get here is Plant A gets a score of 20, Plant B gets a score of 100. They produce a single product but in disparately different amounts and so they receive a very different score that reflects a higher volume.

And here's some more complicated calculations. Each of these plants, Plant C, Plant D and Plant E, produce the same combination of processed products, raw ground beef, raw ground pork and raw

intact beef. If you look at Plant C and Plant D, they also produce the same combination of products in the same proportion, but Plant D produces twice as much. So if you look, the inherent risk scores are identical. In the volume scores, Plant D, their volume scores for each type of product are double or twice as much, and then we have computed the percent that the volume of that product makes up for their total production.

So if you look at Plant C for raw ground beef, the percent volume for raw ground beef is 20 percent, .2, and the way we get that is to look at the volume column, it's 1 divided by 5. Their percent for raw ground pork is 4. That's 2 divided by 5.

If you look down at Plant D, and you see that the percent volumes are exactly the same even though they make twice as much product. So when we weight their hazard score based on the proportion of different products with different risk rankings, they come up with the same score which is 14.4, and you see that in that final column. We re-multiply it then times their volume scores so that we can express that

Plant D in fact makes twice as much product but in the same, the same proportions, and appropriately they get double the score.

If you look down at Plant E, that's an example of a plant that's making the same combinations of processed products but in very different volumes and very different proportions. You see the scores are obviously very different. And that's it.

MR. TYNAN: Okay. We have time for comments and questions from the audience. Again, I would remind you that we are making a transcript of the meeting. So if you have questions, we'd like to ask you to come to the microphone and pose your questions. I'm going to start with the audience here, and then after we take a few questions, I'll ask the operator to help us with the phone calls, the folks that are calling in. And if you could introduce yourself and your affiliation.

MR. WALDROP: Chris Waldrop, Consumer Federation of America. Matthew, you mentioned that you are doing a 2007 expert elicitation.

MR. MICHAEL: Yes.

MR. WALDROP: You already have the 2005 that you've used for your examples here.

MR. MICHAEL: Yes.

MR. WALDROP: How are you going to -- are you going to compare the two expert elicitations once the second one is done? Does the second one replace the first one? How is the second one to be put into this?

MR. MICHAEL: I think the second one will replace the 2005 but we will compare them. I think we're expecting to see roughly the same distributions of values for a lot of the products. If we don't, we'll have to go back and figure out why but the second elicitation, it has some different constraints upon the experts which we think improve it. Of course, we're asking about severity and we'll have those values. So it will replace the 2005 elicitation, but we will compare them, yes.

MR. WALDROP: Okay. Because I would just, if you would compare them, because of those different constraints, I think that would make it difficult but if it's replacing it, that makes a little bit more

sense. Are you including susceptible populations in the new one?

MR. MICHAEL: We're still working on the draft including of the instrument with the contractor, and looking at the peer review comments and that is something we have in the draft instrument right now, vulnerable populations as well as healthy adults but it'll probably stay in there. I mean our concern is just that the more complex our instrument becomes, the more difficult it is for the experts to fill it out, but I expect that will stay in there.

MR. WALDROP: Thank you.

MR. PAINTER: They were up next.

MR. TYNAN: Thank you for helping me, Stan. Felicia.

MS. NESTOR: Felicia Nestor, Food and Water Watch. I just want to make sure I understand this business on volume. So a plant, the top value for volume that a plant can get is not 5. The plant could get -- if the plant made a good number of products, it could get even higher than a 10 for a volume amount, correct? I'm looking at the last page.

MR. TYNAN: Before Michael answers, we'll enter maybe a couple of questions to clarify but keep in mind that later on in the month we're going to do a meeting specifically on volume.

MS. NESTOR: Uh-huh. Yeah.

MR. TYNAN: Go for it, Matt.

MR. MICHAEL: The highest score you can get per type of product is 5.

MS. NESTOR: Right.

MR. MICHAEL: And then we weight them by proportion of product and we re-multiply. Actually, you know what? You see in that final column where there's the 4 and the 12.8 and 8, that is the re-multiplied score. So yes and no. I mean the 5 is the volume score they get for that particular type of product, but then the product of the multiplication is how we --

MS. NESTOR: Look at Plant D.

DR. RAYMOND: Let me try, Michael, if I may. And it would really help if we could get that slide back up, but I don't know if I'm smart enough to do that.

Felicia, the volume is 1 to 5. The inherent risk of the product is 1 to 20, and you take those two times each other and you get the score of somewhere between 1 and 100. And I think what you're looking at on that last page, for instance, is like 39.4 or something for the bottom.

MR. MICHAEL: That's right, yeah.

MS. NESTOR: Well, let's look at either Plant D or E, whichever one.

DR. RAYMOND: Let's take Plant E, and it's a score of 39.22.

MS. NESTOR: Yeah.

DR. RAYMOND: That's the combined score of the volume and inherent risk of the product. The inherent risk of the product can be no more than -- I mean the volume will be no more than 5. We're to take that number and then what Matthew has done here is taken a plant that makes three different products and so you have to weight the importance of each one of those three products.

MS. NESTOR: But you have a volume score here of 10 for Plant D and a volume score of 6 for

Plant E if you look at the volume column.

DR. RAYMOND: It's part of an algebraic equation. There's the total of the 6, but then you go take, and what you're doing is figuring out the percentage. Okay. So we'll take volume, that, that column, if everybody is with us on Plant E, your handout, you've got a volume of 3 for the raw ground, you've got a volume of 1 for the pork and you've got a volume of 2 for the intact beef which gives you a total of 6.

MS. NESTOR: Uh-huh.

DR. RAYMOND: But then you go to the next one over, the percent volume.

MS. NESTOR: Uh-huh.

DR. RAYMOND: The volume for raw ground beef is 50 percent, and that should say 50 percent instead of 0.5 but we all know where Matthew is going with this. It's one-half of the total volume of that plant is raw ground beef. So you take that number then times the 20 which is the risk of the product and you get a score of 10 for the raw ground beef.

MS. NESTOR: I understand that.

MR. MICHAEL: Those numbers that are higher than 5 are the products of the inherent risk are times the adjusted volume score. So it's not just the volume score by itself. So, no, they could only get a score of between 1 through 5, but once you multiply it times the inherent risk score, then the product is greater than 5, yeah. But the multiplier itself is 1 through 5.

MS. NESTOR: All right. I'm going to have to study that a little bit more.

I've got another question. It seems to me that you made some kind of arbitrary decision here that the volume categories top out at a plant that makes 50,000 pounds a day. And I think, you know, that's -- well, how nice for the large plants that make 500,000 pounds a day, but the risk of a plant that makes 2,000 pounds a day, 16 days a month, is not the same risk to consumers of a plant that makes a half a million pounds a day.

MR. MICHAEL: Well, we have to make a cutoff somewhere. This might be the one we eventually use and might not. You know, we can't differentiate

between every possible volume because we don't have point estimates.

MS. NESTOR: No, you can but having 5 quintiles up to 50,000 and then everything from 50,000 to --

MR. MICHAEL: Right.

MS. NESTOR: -- infinity is one --

MR. MICHAEL: Well, you also want to think about, we're going to use these values to allocate inspection resources, and they need to be figures that give us -- they need to be practical figures ultimately. You have two plants that are completely equivalent but one produces 10 million pounds of product and the other products 10 pounds of product. You're not going to give the larger plant 10 million times more inspection. So, yeah, there are cutoffs, and we do group these values together. That is true.

MR. TYNAN: Felicia, I don't want to cut you off but --

MS. NESTOR: I just want to say I completely object to that and think you need to look that over. I mean 50,000 and half a million is ridiculous.

MR. TYNAN: And you'll have another opportunity, as I say, later on in the month.

Ms. Buck? Ladies before gentlemen.

MS. BUCK: Okay. My name is Patricia Buck, and I am with the Center for Foodborne Illness, Research and Prevention, CFI, and I am coming to speak to you, of course, because of some of the concerns that my statistical members of my group have put together for me to try and explain. I please hope that you'll understand that I'm not a statistician. So going too deeply with me is not going to be productive.

MR. TYNAN: You have the same problem that I do.

MS. BUCK: Yeah. Okay. However, I do understand this because it's been drilled into my brain. You have volume which you are portraying in a uniform fashion, which if you would throw that up in a graph, it's going to look like a rectangular box because you've used uniform percentiles.

Now CFI does not have access to your data. So we can only make assumptions on what we have heard

about volume, and one of the assumptions we have made is that there's a very few number of plants that are performing huge amounts and then there are a quick drop off, and then most of the plants are doing small amounts of volume.

Based on this, and based on that assumption, it does not seem reasonable to take skewed data and attempt to put it into a rectangular box. There are other distribution methodology that can be used, and the question that my statistical people have are, who are this panel? Who is this panel of experts? And, will they be available to discuss with a consumer group like ourselves, the impact of volume? I understand you have another meeting coming up, but this is such an important issue. How quickly can that kind of discussion happen between FSIS' statistical group and someone who understands the statistics from the consumer side?

MR. MICHAEL: Well, I'll just remark. You talked about a panel of experts. The experts who will be participating in the elicitation this month will not be talking -- will not be giving a statement on

volume, only on the --

MS. BUCK: We're not looking to talk with your experts from your elicitation. We're looking to talk to your statistical analysis team.

MR. MICHAEL: Well, I believe there is a meeting on volume, isn't there?

MR. TYNAN: Right. On April 25th, we're going to do something specifically related to volume and get into the --

MS. BUCK: Because this whole thing is hinged, your volume and your product inherent risk is hinged on the fact that you have taken skewed data and put it into a uniform distribution, and that does not seem to be appropriate.

MR. TYNAN: Ms. Buck, do you have some specific methodology that you're proposing? Could you send those to us or --

MS. BUCK: Yes, my affiliations --

MR. TYNAN: Okay.

MS. BUCK: -- could do that, yes.

MR. TYNAN: Okay. That would be fine. Maybe in anticipation of April 25th --

MS. BUCK: Yes.

MR. TYNAN: -- if we could get those, we could start to look at them.

MS. BUCK: Would it be possible to have a discussion with your statistical team that is devising your algorithm?

MR. TYNAN: Okay. Let us take a look at them and we'll see how they fit.

MS. BUCK: Thank you.

MR. TYNAN: Thank you very much. We have three questioners on my left and then we're going to flip over to the folks on the phone. Mr. Painter, if you would identify yourself and your affiliation.

MR. PAINTER: Yes. Stan Painter with the National General Council. My question is regarding the poundage. Who's going to monitor that? Is that going to be incumbent upon the inspector to monitor poundage produced by the plant as it goes up and down? If so, how often would that be monitored? Or is it going to be incumbent upon the plant to report to someone, whoever that may be, regarding the amount of poundage that they're producing?

MR. MICHAEL: Do you want to answer that one, Don?

MR. ANDERSON: Yeah, this is Don Anderson, OPEER. Let me speak to the volume for a minute. Several months ago, I think it was around December, maybe November, the volume extension, this is what we call a PBIS volume extension, sort of like a survey but it's launched in a different way, the volume extension went national, if you will, to all IICs late last year, and we now have a 90 to 92 percent response rate. So IICs are actually providing the information about volume. Charlie may correct me, but my understanding is that when the instructions went out with the extension, inspection personnel were requested that at the earliest convenience to please go into the PBIS extension and complete the volume information which is the pounds per day and pounds per day and days per month for each of a number of questions that we believe based on data were pertinent for that establishment.

The instructions also told IICs that when they complete that information, that if there are any

inaccuracies kind of the questions that we've asked them, to please alert us about that and one way to do that is by changing, if necessary, the information in the profile extension itself as to what type of activities are occurring.

The instructions went on to ask IICs, if and when there are any significant, I don't remember the exact words we used, if and when there are any significant changes that would affect the volume of that establishment, please go back into PBIS and make the corrections. The PBIS extension is open to inspectors at all times. They can go back in and make the changes.

And the last thing I would say is that we've decided that at least annually we will go and kind of, if you will, rebroadcast or resend a request to the inspectors that even if they've made some changes to the profile in the past year, or if they haven't made changes, to please revisit the profile extension information and insure that the information in the extension about the establishment is still accurate to their best knowledge.

MR. PAINTER: Okay. So you're stating it's supposed to be the inspector's responsibility to insure that that's updated, correct?

MR. ANDERSON: Absolutely.

MR. PAINTER: Okay. Now how are they going to obtain that? Do they go to the plant manager and say how many, how many pounds are you producing and the plant manager says we're producing 99,000 pounds.

MR. ANDERSON: No, in fact, they're actually explicitly told not to ask the plant management for that kind of information. The IICs are required, are requested to provide the information to the best of their ability based on all the information and records and knowledge available to them.

MR. PAINTER: What records?

MR. SMITH: That would be the -- review records. They also -- anytime you have an adjustment in your hazard analysis, as you know, if that increases the production or adds a new product line, that would have to be considered in the hazard analysis and at that time would be a trigger to determine volume also.

MR. PAINTER: So it's going to be incumbent upon the inspector to calculate that whenever they ship. Some plants ship daily. Some plants ship weekly. So the inspector should calculate that on a weekly basis, monthly basis, a daily basis? According to what I'm hearing you say, it's all incumbent upon the inspector to determine how many pounds that the plant's producing?

MR. SMITH: Again, Stan, what Don just walked through on how the first calculation was done --

MR. PAINTER: And I understand that. That's not --

MR. SMITH: -- that established the base.

MR. PAINTER: I understand.

MR. SMITH: That establishes the base. That's their knowledge base. If, in fact, anything changes, either through adding production, a new product line, new pieces of equipment that increase production which they've known through their hazard analysis, that would be the stimulus and then he said once per year.

MR. PAINTER: Once per year.

MR. SMITH: It'll be -- we'll ask them to go back at least annually, if nothing else changes and make sure the original base was correct.

MR. PAINTER: But would I have to keep a running tally throughout the year?

MR. SMITH: No, they would determine that the same way they did for the base.

MR. TYNAN: Stan, you had a question and follow up to the follow up to the follow up. So if I can impose on you, if you could hold maybe your questions for just a minute to let some of the other questions in --

MR. PAINTER: Thank you, Robert.

MR. TYNAN: -- and then we'll cycle back if there's time. And Tony, we're going to allow Caroline to be the last one, and then we're going to the phones, and then we'll come back to you if there's still time.

Ms. Mucklow, I think you can take that off there if you need to.

MS. MUCKLOW: I think if I stand on my

tiptoes I can make it.

I love these Washington meetings, and on April 25th, I will be contemplating the magnificence of the Grand Canyon. So I will not burden you with my presence that day, nor even probably be on the phone because I don't suppose it works from there.

I would appreciate it if Matthew would restate so that I get a clear understanding, because I don't have it yet, why volume is included in the inherent risk rather than the risk control. It is my opinion that it is within every establishment's capability to set up the controls to manage the volume that they are running and I'd just like a clear clarification because I think we're going to have challenges on that, and I don't -- and I understand you have a meeting to address it. I'd just like to be really, really clear on that point. Thank you.

MR. MICHAEL: Okay. Well, again, we've based our inherent risk formula on the general calculation for risk which is hazard times exposure. We've determined, at least up until this point that our best proxy for exposure is volume. Assuming that

a plant produces "X" amount of product, we assume that it will all be eaten, and that is the exposure value. And that's the short answer. Volume is our proxy for exposure given that our inherent risk formula is based on the general calculation for risk is hazard times exposure.

MS. SMITH-DEWAAL: Caroline Smith-DeWaal, Center for Science in the Public Interest. I'm most interested in your new chart, median species process values, where you have reduced the number of categories from 24 to 19, and you've given them some median scores.

MR. MICHAEL: Yeah, we had median scores back in October as well. Though we reduced these to 19, it doesn't -- we haven't lost anything because where the categories were collapsed, they had the same score.

MS. SMITH-DEWAAL: Well, the chart that we were working from in the original expert elicitation had your products ranked 1 through 24, and one of the things I'm noticing is that your ranking pork, raw intact poultry, raw intact chicken together under one

-- under the value of 8 and raw intact turkey under the value of 9. Now in the original expert elicitation, turkey was 20 and -- raw intact turkey was 20 and raw intact chicken was 19, and we saw them as quite equivalent. So there appears to be a slight shift in the risk value and I would just like to understand it.

MR. MICHAEL: Well, if there's a shift -- if there is in fact one, it's a typo. This plant -- this table is a reduced version of the original table, and I'm not sure if it's the one that appeared -- this is the table that appeared in the previous paper based on this, but when we collapsed these categories, we used the same -- we only collapsed categories that have the same median scores. So we didn't lose any data. If one score became another incorrectly, then that's a typo and we'll fix it.

But the median, taking the median is something we discussed in the October meeting. There's a lot of literature on expert elicitation that advises using a median score when aggregating expert values, using the median as a measurement of central

tendency.

MS. SMITH-DEWAAL: And I don't necessarily object to that. I'm just -- as we had done the breakout from 1 to 24, we had seen turkey and chicken as quite equivalent and we've also compared it with the outbreak data. To have turkey now -- I just need to understand better your rationale for having turkey ranked significantly higher than chicken and it would be for both raw intact products, and that -- I need to understand better kind of how that differentiation was made because it didn't show up in the original ranking of 1 through 24 that we had seen.

MR. MICHAEL: Well, I'd need to go back and look at that chart, but I will remind everybody that we are doing another elicitation where the values will replace these.

MS. SMITH-DEWAAL: Yeah, we're having a meeting on Thursday dealing -- where this ranking will, will in part be discussed. I know it's not the major topic, but this, this comparison. So perhaps if you could talk to me at the end of the meeting on whether this is a typo or not, I'd really like to

know.

MR. TYNAN: We'll go back and look at that to be sure and we'll repost it if it is, in fact, an error.

What I'd like to do now is ask the technician if he can get us some of the phone-in calls, that would be great.

Operator, can you help us with the phone-ins please? Operator? Nothing is easy. We put the operator to sleep. Patrick, nothing happening?

Okay. While we're waiting for the operator to come on, Mr. Corbo, you had a question?

MR. CORBO: I'm just appalled at what I heard regarding how the volume is going to be calculated. You know, it's like Ronald Reagan saying, there you go again. You're getting garbage put into this system, and that's -- you know, I can understand, you know, developing algorithm but it depends on what you're putting into it. And I'm really, really appalled at what I'm hearing here this morning.

MR. TYNAN: Thank you, Tony. Our worst fears have been realized. There are technical

difficulties on the phone.

MS. NESTOR: I have a quick question.

MR. TYNAN: Okay.

MS. NESTOR: How many, how many plants, how many very small plants make 2,000 pounds of product 16 days a month?

MR. TYNAN: Could I ask you to introduce yourself?

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

MR. MICHAEL: I couldn't tell you off the top of my head. I don't know.

MS. NESTOR: Any idea whatsoever? Bill, you must have some idea from field operations? I mean is it one? Is it 200? Is it, you know, 20 percent of them? It's really hard for me to believe you have no idea? You can't even ballpark this.

MR. ANDERSON: If I may, one of the things that is important to understand is we set up the values for -- I think your question commenting on the -- I'm not sure I --

MS. NESTOR: Volume and quintiles.

MR. ANDERSON: Yeah, the volume and quintiles. The extension asks inspectors to complete that two-part question about days per month in the last month that a particular product was produced and shipped, and it asked about the volume per day in those ranges. Very small establishments, a lot of very small establishments produce multiple products. Indeed, most plants produce multiple products. So one of the things we need to be able to do is set up ranges that go low enough to capture small volumes of multiple product.

You seem to be thinking that, well, maybe there aren't many plants that produce that little product. Well, there may not be many plants that produce that little product of all the products that they produce in total, but there are quite a few establishments or IICs that are completing the information that says, yes, this establishment is producing a very small volume of this product and a very small volume of that product, and still a very small volume of another product.

MS. NESTOR: My assumption is exactly the

opposite.

MR. ANDERSON: I'm sorry.

MS. NESTOR: My assumption is that there is probably a good number of very small plants that make at least 2,000 pounds a day, and what you are saying by establishing this formula, is that a company that makes 2,000 pounds of product a day, deserves the same amount of inspection presence as the largest producer, the packers in the world that make, you know --

MR. TYNAN: Again, we're getting into the weeds of volume and not to deter you from having questions, but just in the interest of trying to move things along, can we make this the last question.

MR. MICHAEL: I'll mark -- earlier you had mentioned that the top, you felt the top off was 50,000 pounds. It's really not. If you look at the --

MS. NESTOR: 50,000 pounds a day.

MR. MICHAEL: 50,000 pounds a day, that's right, because if you multiply that times more than 20 days, you see that it's 1.5 million pounds.

MS. NESTOR: Per month. But I'm talking

about a day. I'm talking about, you know, say we're talking about a size of plant. This -- if I'm not mistaken, a mom and pop plant would get the same amount of inspection as a ConAgra under this formula.

MR. MICHAEL: No.

MS. NESTOR: No.

MR. MICHAEL: No. And I don't know the numbers off the top of my head of the distributions, but I know that from the distributions of scores we've done and the distributions of volumes we've done, we do have a range of RBI values per plant. It hasn't worked out that everybody's grouped at one end or the other.

MS. NESTOR: Okay. If you could give us sort of a ballpark about how many -- if there are any very small plants that are making 2,000 pounds a day, 2,001 pounds a day?

MR. MICHAEL: I couldn't. I don't know off the top of my head.

MS. NESTOR: Well, I'm not saying right now. I mean afterwards.

MR. MICHAEL: Sure.

MR. TYNAN: And we'll probably hold that one for the 25th.

And with that, I understand our operator is not working. We just have open lines. Is that correct, Patrick?

So I'm going to ask if there's any questions from our phone-in callers? The lines are open. So please anybody that wants to make a comment or ask a question.

(No response.)

MR. TYNAN: Okay. What we're going to do is see if we can work on the technical difficulties again and in the meantime, we're going to close out questions on this portion of the agenda, and I'm going to introduce Mr. Don Anderson, to talk a little bit about the management risk control.

MR. ANDERSON: Okay. Thank you, Robert. My name is Don Anderson, and I'm also in Program Evaluation, Enforcement and Review.

As Matthew said, we've got several measures of risk and several dimensions of risk that are important in risk-based inspection. One is inherent

risk which Matthew just talked about and the other which he mentioned is the risk control measure which goes to how well establishments control the risk that is inherent in their operations. So I'm going to talk more about that, and then Mr. Bill Smith will then talk about how the two measures, inherent risk and risk control come into a single measure that we might call the RBI measure to determine the levels of inspection.

There's also a part of my presentation which I'm about to do where I talk in some detail about one of the factors of risk control which are NRs and Mr. Charles Gioglio is going to talk later this morning also in greater detail about the so-called NR.

What you see on this slide are the different types of information that enter into the measure of establishment risk control. Look first at the center of the risk control measure that we call it or the RCM, is also by design a measure on a 100 point scale where establishments that have lower risk control measures, closer to zero, according to the data, have better risk controls.

So you see that there are seven different types of data that enter the establishment risk control measure. The data that you see in blue bubbles on the right here are the types of information that are available to the Agency, from Agency databases on all of the approximately 5400 or so active HACCP establishments that we currently inspect. So that so-called blue bubble data is available for all establishments.

The data that you see in the green bubbles, is data that is also available for a large number of the establishments that we inspect. The green -- the so-called green bubble data that I'm calling it again is available for some but not all establishments. So while all 5400 establishments have data of the type that you see in blue, we have data from at least 1, and sometimes 2 or 3 additional sources, that you see in green, we have that type of data for approximately three quarters of all of the establishments that we have under our inspection.

So again, the blue bubble data is available for all plants, and the green data is additional data

that is available for certain types of establishments.

Let's look for a minute on this slide at the number of establishments for which we have 4, 5, 6 or 7 different types of information. Again, these are the types of information or factors that we're going to use in our risk control measure. As I said, we do have 4 types of information for all plants, but there are approximately 1450 establishments for which the only type of information we have are the blue bubbled factors if you will.

But for most establishments as you can see, we have additional sources of information. And by virtue of what they produce, they may produce products that are subject to *Salmonella* verification. So they have *Salmonella* verification data.

Or they may produce RTE or I should say ready-to-eat products. And so for those establishments, we have much additional information.

We have data from out pathogen testing programs for RTE products and for plants that produce RTE products that are also exposed, subsequent exposure to the environment after the lethality, we

also have an RTE *Lm* control alternative.

So we have lots of additional kinds of information for plants that produce RTE products and we have still more data available for plants that do all of those things and if they also happen to produce products such as raw ground beef that are subject to still additional kinds of test data.

So as you see, we have actually most plants, I mean I should not say most plants, let's say the plurality of plants, almost 2500 plants, we have 6 different types of information from because of the nature of what they produce.

Let's look now at the weighting or the importance that the different types of data that enter the calculation have. Now this, this pie chart is for an establishment, and there are about 300 establishments like this. There are about 300 establishments under active Federal inspection that by virtue of what they produce, we actually have all 7 types of information from them. What this basically means, what it does mean, is they produce at least one product that's subject to *Salmonella* verification,

like raw intact chicken or raw ground beef. It also means that they produce -- in addition to that, they produce some ready-to-eat products, and in addition to that -- well, actually that would pretty much cover it. An establishment that would produce ready-to-eat products and would produce raw ground beef, they would have -- most of them would have an RTE *Lm* control alternative. They would have RTE pathogen test results. They would have *E. coli* O157:H7 lab results. If they're shipping again raw ground beef, we have a *Salmonella* performance standard for that. They would have a *Salmonella* verification category. And, of course, all of them have information on NRs, food safety recalls, consumer complaints and enforcement actions. So in an establishment that produces products and hence we have data for all seven of these factors, this shows here the relative importance or contribution of those different factors.

Now if you have an establishment that again by virtue of what they produce, doesn't have all seven types of information available from it, then as you might guess what happens since this is a pie chart and

it always adds up to 100 percent, if you have an establishment that produces products that aren't ready-to-eat or doesn't produce any ready-to-eat products, then they won't have an RTE *Lm* control alternative. They won't have RTE lab results. They may or may not have O157:H7 results. But basically what happens in a plant like that is the contribution, the raw contribution of each of the remaining factors goes up. So the pieces of the remaining pie, of course, get bigger, but the relative contributions remain relatively the same or approximately the same.

For example, public health in our data always contributes more to the risk control measure than the verified food safety consumer complaint data or the *Salmonella* verification data.

So let's talk about the first and arguably one of the most, and I can guarantee you the most complicated of the factors. So we'll tackle it first. The most important and complicated factor that we have are the public health NR data. And why do I say the most important?

Well, it's very important information

because we have inspectors in our establishments every day performing multiple inspection tasks, HACCP tasks, sanitation tasks, other kinds of inspection procedures. And when they perform those procedures, they report in the PBIS system usually the same day, always within a few days, they put into the PBIS system in Headquarters, for a synchronization process, the findings of their inspection procedures of that day, and when they perform an inspection procedure and they find that something is non-complaint, not in compliance with regulations, they note that in what is called a noncompliance record or a NR. And that is a term that most of you are familiar with.

For over a year now, since December of 2006, and this was a major change, and I think a very important improvement in PBIS, since December of, excuse me, December of 2005, so for over a year now, when inspectors write NRs, they write a NR narrative and they note a NR in the PBIS system, but they also cite with a dropdown, one or more regulatory -- specific regulatory requirements that they found not noncompliant in the performance of their work. And

there are, as of recently now, currently in PBIS, there are 564 regulatory requirements that are citable, and these 564 regulatory requirements have, have different importance for lack of a different word I guess or different levels of how strongly they indicate a loss of food safety system process control. So some regulatory requirements, when they're cited as noncompliant, are very strong, we believe, indicators of an establishment that is having problems with food safety process control.

Other types of regulatory requirements when they cite them, we think are also food safety indicative, but we don't think that they're as important as others. And we have a number of regulatory requirements that we really don't think go to food safety process control at all. We think they're purely economic regulatory noncompliances.

Mr. Gioglio is going to talk at greater length about this, but the important thing to recognize then is that the Agency does believe that NRs are not equal at all times in all establishments. We believe that some NRs are more important than

others, and so we need to weight NRs depending on how important we think they are or how indicative we think they are that an establishment has problems with process control.

So we use basically the weights from individual citations to compute a weighted NR and then a weighted NR rate. A traditional -- remember, a traditional NR rate, for those of you who are familiar with it, it's a bit of a nuance to some in the room, but most of you are familiar with this, a traditional NR rate takes the number of NRs in a specified period of time and divides it by the total number of inspection procedures that were performed in that period of time, and that's what we call a NR rate.

The Agency has been using those for sometime in its management controls and other types of other activities, other purposes.

Now what we're talking about is computing a six month, we're using a six-month window here, a six month public health NR rate which is divided -- which is computed by dividing the weighted NRs, NRs that are more indicative of public health problems, and divided

the weighted NRs by the number of inspection procedures performed, and we come up with what we call a public health NR rate.

If you look at a recent, a fairly recent six-month window of data, and computer public health NR rates, you get a distribution that looks something like this. In this presentation here, what we're showing is that approximately equal numbers of establishments, which I think is about 16 percent or something, 16 to 17 percent, of all establishments have NR rates within these bounds. So what I'm saying here is that we have, and I believe I have pretty close to the exact number here. If you look at a recent 6-month window, there are approximately 875 establishments that have a public health NR rate of less than 0.35 percent.

There are another roughly 875 establishments that have a public health NR range or rate that's between .35 percent and .89 percent. So what we're doing with this computation is we're basically calculating for each establishment a public health NR rate and then we're classifying it into one of these 6

ranges to identify whether we think the public health NR rate in that establishment should get 0 points which indicates that the establishment has very few public health NRs relative to the amount of work, if you will, that's going on in that establishment and we think that that establishment, according to this measure, has good establishment risk controls.

Or, if they have higher NR rates, they accumulate more points. So basically an establishment's public health NR rate, the more points they accumulate towards the risk control measure.

Remember, it's kind of like a golf score, a lower measure is a good score, and a higher measure is a less good score. So establishments are trying not to rack up points if you will for among other things public health NRs.

The next data factor, and again this is available for all types of establishments, I'm calling in-commerce findings, and these are recalls and food safety consumer complaints.

Let's talk first about recalls. In our measure of establishment of risk control, we include

two types of recalls. Both are public health recalls. They're not economic recalls. Class I recalls which are the most serious type of public health or food safety recall and Class II recalls. In the algorithm or formula that we're proposing, a Class I recall would get 3 points or an establishment that experiences a Class I recall would get 3 points, and an establishment that experiences a Class II recall would get two points.

We know that it's very rare but it's also possible that an establishment could have two recalls in a six-month window. So we do allow for that. So, for example, an establishment might have a Class I recall early in the period and then later on in the same six-month window, they might get a Class II recall. So we will account for that by giving them 3 points for the first recall and then 2 points for the second recall, but we would recap that so that it doesn't exceed or wouldn't exceed 6 points in a 6 month window, but I don't think there have been any establishments in the data that I've looked at for the last few years, any data indicating that

establishments have had two separate Class I recalls within a 6 month window. We do have establishments that issue a recall and then expand that recall, but we would treat that as one recall because we think that it's an indication -- some indication that one time that an establishment had a problem with a particular aspect of their risk control.

Verified food safety consumer complaints, is information that we get from our data warehouse which actually originally comes from our consumer complaint monitoring system, and we're proposing to allocate 1 point for each verified food safety consumer complaint that occurs in a 6 month window, not to exceed 3 points in a 6 month window.

And you might ask, well, why do we have a 6 point cap say for recalls and we have a 5 point maximum for NRs, we have a 3 point maximum for consumer complaints? These different maximum points, 5 for NRs, 6 for recalls, and a maximum of 3 points for example for verified consumer complaints, it's that point allocation that gives rise to the size of the pieces of that pie and I believe it was chart

number 3. Basically, this is how the weights of the different factors come about based on the number of points that we give for public health NRs versus recalls versus consumer complaints.

Another type of information that is available for all establishments are enforcement action information. Now if you look back, and I won't flip back to it, but if you look back at the bubble chart, near the beginning, you'll see that I call enforcement actions a status variable. Because we don't look at enforcement actions over a six-month window. We look at enforcement actions at a point in time. Of course, on any given day, the vast majority of all establishments that are under Federal inspection aren't under any type of enforcement action at all, but some establishments are in some kind of enforcement action, and these are the major enforcement statuses that we believe that we need to account for and reflect in the risk control measure.

And, I've got them sort of sorted in ascending order. So an establishment that's operating under inspection with an NOIE under deferral, that

establishment would be operating with 2 points in its risk control measure. And at the other extreme you see the most serious types of enforcement actions in establishments that have up to 6 points. So these are different, if you will, enforcement statuses.

The four types of data that I've discussed already which are NRs, enforcement actions, consumer complaints and recalls, those are the types of information that are available for all of the approximately 5400 establishments. We also have another type of information to us, and I think probably 1800, maybe close to 2,000 of our establishments, and that's the *Salmonella* verification category. These are establishments that produce one or more products that are subject to *Salmonella* verification testing.

The *Salmonella* verification categories that you see here, and I won't go into a lot of detail, but they would be familiar with many of you because this is a relatively new or recent development in the Agency. You've probably seen the Federal Register notice or notices on this, but basically we use a

system where we look at information on an establishment's recent *Salmonella* sets and based on that information, we put establishments into one of several *Salmonella* verification categories. And basically the better an establishment is showing us through *Salmonella* testing, the better they're showing us that they control *Salmonella*, the lower the *Salmonella* verification category.

So what we're proposing in this risk control algorithm, is that establishments that are in the lowest *Salmonella* verification category, which is category 1, would have 0 points. And remember this is good. Establishments want to have as few points as they can. It goes to good establishment risk control.

So establishments that have passed, not only passed, but actually exceeded the requirements substantially in their last two sets, are in *Salmonella* verification category 1 and they have 0 points. And at the other extreme, an establishment that failed its last *Salmonella* set, would have 3 points. Other establishments with kind of mixed results are in *Salmonella* verification 2 and they have

1 point.

This slide shows how we use information from our pathogen testing programs in establishments that produce ready-to-eat products and/or produce certain raw beef products. Establishments that produce ready-to-eat products, who perform *Lm* testing on those products and on food contact surfaces, would perform *Salmonella* testing and in products that are ready-to-eat and they contain beef products or beef ingredients, also perform in product samples *E. coli* O157:H7 tests. So those are what I will call the RTE pathogen test results.

Also in establishments that produce one or more products that are subject to the raw beef *E. coli* O157:H7 testing program, from those establishments, of course, we also have those test data. We believe that pathogen test results for RTE products and O157:H7, are extremely important and for those reasons, we actually are giving them a fair amount of weight, if you will, in our calculations. Establishments can accrue 3 points for each positive pathogen finding, not to exceed 9 points in a 12-month window. This is

the only data, the only type of data that's based on a window of time longer than 6 months. It's got a 12-month window.

The RTE *Lm* control alternative again is available or information that we have on establishments that produce ready-to-eat products that are also -- that are exposed to the environment after the lethality, kill step if you will. Establishments that have the best *Lm* controls, use sanitation and anti-microbial agents and post-lethality treatment in their products, in their RTE products, and those establishments because they have such a robust *Lm* control alternative, would have 0 points. At the other extreme, the establishment that doesn't use either an anti-microbial agent or a post-lethality treatment, they rely only on sanitation, they would have 3 points in their score.

We have this type of information probably on, I don't know, about -- it looks like we have either *E. coli* O157:H7 information for raw products and/or RTE products samples from about 62 percent of all the establishments. So almost 2/3 of our

establishments, I'm sorry, that's the lab tests. This is the *Lm* control alternative. So this is about, almost 2/3, maybe 2,000 establishments have this kind of information.

Now let's go through two example risk control measurement calculations. This will show how we actually use the information, the seven factors that we just talked about, to compute the establishment of risk control measure.

This is an example of in some sense the most, the most simple type of establishment that we have. This is an establishment that produces raw intact beef. It can also be an establishment that produces only raw intact pork. It could be some combination of raw intact pork or raw intact chicken. If they don't slaughter, and if they don't produce ready-to-eat product, and if they don't grind, then this establishment or establishments like this don't have a *Salmonella* verification category. They don't have pathogen lab results. They don't have an *Lm* control alternative. What they do have are the public health NR data, food consumer complaint data, food

safety recall data and enforcement information.

In this establishment then, the highest possible number of points that the establishment could get would be 20 because remember, the most you can get for public health NRs which is under that possible column, the most points you can possibly get for public health NRs is 5 points, consume complaints 3, food safety recalls 6 and enforcement 6. So there's a possibility of 20 points.

This establishment actually got an NR rate that gives it 3 points for public health NRs. They had two verified food safety consumer complaints for 2 points. The other data looked good. So this establishment got 5 points out of 20. 5 divided by 20 put on a 100-point scale is 25. So this establishment's risk control measure is 25.

The second and last example is a considerably more complicated establishment because they also produce -- in this particular establishment I said they produce fully cooked beef patties. So they have a *Lm* control alternative which gives them 1 point because they're pretty good at *Lm* control or a

robust *Lm* control alternative, and they also have RTE pathogen testing results. As you see from this particular establishment, all of their slab samples for RTE product came back negative. Their *Lm* control alternative is good. So basically for this type of an establishment, instead of their maximum possible being 20 points, it's 32 points, and this establishment has only accumulated 3 points towards that total of 32. So we have a lot of types of data for this plant and all of the data that we have indicates the establishment has good controls. So they have a very low risk control measure of 9.4, which is 3 divided by 32, again normalized on a 100 point scale.

MR. TYNAN: I was going to start with the phone people, but we already have folks queuing up. So if -- we'll start to my left.

MS. SMITH-DEWAAL: Thank you. Caroline Smith-DeWaal, CSPI. I have one question, and that is are you contemplating a system of rolling averages so that the six-month time period would change every month?

MR. ANDERSON: Yes, absolutely. This is Don Anderson. Absolutely. I should have pointed out our current plan is to compute updated risk control measures that are then available to the inspection force on a monthly basis, and that would be a moving six-month window.

MR. TYNAN: Thank you.

MR. PAINTER: Stan Painter with the National Joint Council. My question's regarding the NRs and the time period that was used for the NRs in calculating this, last 5 year, last 10 year, last year?

MR. ANDERSON: The results that you see on the chart, you're maybe referring to the public health NR ranges, for that particular data run, I used April 1st to September 30th. So it was that six-month window, but again, that information has been available essentially since December of 2005.

MR. PAINTER: Okay. And keeping in mind that the past couple of years that we've been extremely short. We've been double covering. We've been triple covering. So the likelihood of NRs, if no

one is there to cover or is only there for a short period of time, is going to go down. So I have a huge issue with the use of the NRs. And let me ask you this regarding the NRs as well.

When an inspector writes an NR currently, you could have multiple NRs under the one NR. Was that taken into consideration or was it just looked at as though it were one NR although there were 10 incidents tied to that one number?

MR. ANDERSON: It may depend on what you mean by that. One thing that is certainly true is that when, and this may not answer your question, if it doesn't, you can ask it again, and I'll try to clarify it. It is true and, in fact, when an inspector writes a noncompliance, they can make cite 1, 2, 3, 4 or more specific regulatory requirements that they found noncompliant. Is that -- was that not what you're asking?

MR. PAINTER: No, that's not what I'm asking. For instance, if I find an issue of a HACCP or operational sanitation issue, I could have 10 different incidents that would go under that 1

particular number. So if I'm at one location and I have 10 incidents under that 1 number, is plant "X" down the street, if they only have 1 incident under that 1 NR number at that particular plant, is that the same?

MR. SMITH: Presently, yes. If you're reporting under one inspection procedure, that cite and that value goes with that inspection procedure performed.

MR. PAINTER: Okay. Thank you.

MR. TYNAN: Okay. Dr. Raymond, I think you had a comment?

DR. RAYMOND: Yeah. Your comment about possibly plants at various times of the year getting less inspection because of a shortage. Rating the NRs I think will take that in effect. If you only have time to do one procedure per day because you are doubling up, then the NR score is weighted by the procedures you've done. So I think it does take that into account. If I have four hours in the plant, and I do three procedures, that's three times the chance of getting a NR as opposed to if I only had one hour

in the plant and I only do one procedure, but it's weighted divided by the number of procedures done.

MR. TYNAN: Tony, I'm going to ask you to yield. I see that -- Stanley, Stan, do you --

MR. PAINTER: I was just stepping up to hear Dr. Raymond.

MR. TYNAN: Okay. I thought you might have a follow up.

MR. PAINTER: No.

MR. TYNAN: Mr. Corbo.

MR. CORBO: Tony Corbo, Food and Water Watch. Last October at two successive public meetings I asked the question regarding the status of an IG audit report on your prep program. At both meetings Agency officials denied even knowing about it even though the report had been handed over to the Agency back in September.

Question number one, have you all received -- have you all reached management decision with the Office of Inspector General on that report? And number two, are any of the plants involved in the prototype rollout of RBI, part of the issue of dispute

with the Inspector General on *Salmonella* testing?

DR. RAYMOND: Dr. Raymond for the record. Tony, you know, I asked that we keep the comments to the formula, the algorithm, so we can discuss that. The Inspector General Report, as you know, because you were at my hearing on Thursday, has been read by me. We have full management agreement with the OIG and for those who aren't familiar with what Mr. Corbo is talking about, the OIG said we had some poultry plants that did not get a *Salmonella* set done during the period they evaluated. We have about 224 poultry slaughter plants, 185 get *Salmonella* sets at least annually, and those 185 constitute 99.7 percent of the chickens and turkeys that you eat. And we're off of that subject now, Tony.

MR. CORBO: Thank you very much.

MR. TYNAN: Thank you, Tony. Chris, if you could identify yourself.

MR. WALDROP: Chris Waldrop, Consumer Federation. I have two questions. One is a follow up on Caroline's window question. So if a plant gets -- has a Class I recall every 6 months, is the plant then

treated the same as the plant that gets their first recall, Class I recall in say several years based on the point system?

MR. ANDERSON: One thing I'd say is what's done in the point system and what's done in practice is two different things. That establishment would probably also be looking at enforcement actions that would raise their score. Of course, you mentioned what? *Salmonella*.

MR. WALDROP: Just a Class I recall.

MR. ANDERSON: A Class I recall. Yeah, they would have -- they would always have 3 points in their score I mean at all times but they would also have other things that would enter their risk control factor like enforcement action that would further raise their score. The establishment would most certainly be under a higher level of inspection.

MR. WALDROP: Okay. And then on this page with the contribution of risk factors, how did you guys develop those percentages? What is that based on?

MR. ANDERSON: Well, it's maybe a two-part

answer. One is that the percentages that you see there are the mathematical result of the number of points that an establishment can get for these types of information. If you're asking more of a policy kind of question which is why are recalls weighted more than consumer complaints and why are lab data weighted more than recalls, the answer for that is these are, these are different levels of importance that the Agency believes go to the question of risk control because lab data is such an important finding, that a product actually tested positive let's say for O157:H7. We think that that needs a lot of weight in the score.

Verified consumer complaints, again these are valid or verified consumer complaints. We trace these back to the best of our ability to the establishment but we don't think that consumer complaint information needs or, if you will, deserves as much weight in the calculation.

MR. WALDROP: Well, I think consumer complaints probably are less likely to happen than say -- maybe this is the wrong sort of analogy, but

you have *Salmonella* verification category at 9 percent and consumer complaints at 9 percent. I wouldn't think complaints would happen very often. So I'm just kind of confused as to why that would be the same as --

MR. ANDERSON: I think I see what you're saying. One thing that's important to understand is that all establishments have recall data and have consumer complaint data. When an establishment produces product 6 days a week, 25, 26 days a month, and they ship out huge volumes of product, and they don't have consumer complaints, or they don't experience recalls, we believe that the main reason for that is because that establishment is by and large exercising good risk control measures. So all establishments have recall data and consumer complaint data. The fact that they don't have recalls or consumer complaints is a good thing, and it goes to risk control.

MR. WALDROP: Well, recall is different than consumer complaint though because I mean the recalls, there's been some sort of finding in the marketplace,

and consumer complaints, I have to -- the -- is actually on me to call and say, my beef tasted weird or it made me sick the night before. That's -- I would say they're equally important in saying a plant is doing a great job.

MR. ANDERSON: I think you're comparing I think the 3 points we give, for example, for *Salmonella* verification versus consumer complaints. I think what you're saying that you think maybe the consumer complaints, if I hear you, should have less weight or perhaps the *Salmonella* verification for example should have more weight.

MR. WALDROP: Yeah. And I was just trying to get an understanding sort of how those percentages came out and from what I'm hearing, it's -- you sort of went through and figured out the weights and the numbers and then created your percentages. Is that correct?

MR. ANDERSON: That's correct. These are basically policy decisions based on what we think is the importance, the validity, the recency and those kinds of things of the different types of information.

MR. WALDROP: Okay.

MR. TYNAN: Chris, can I impose on you? If you have other questions, we'll kind of loop back. The people who are up at the microphone or are coming up, those are all the questions, and then we'll go to our phone-in callers. And, with that, Ms. Buck, I think you were next.

MS. BUCK: Yes. I'm Patricia Buck, CFI. And I actually would like to just reiterate what Chris was trying to get at. The consumer complaint files should not be at your 9 percent. I feel that that's way too high. And from what I hear, what you were just talking with Chris, you actually sort of as an Agency sat down and figured this out without really reviewing the data, the totality of the data, because this is part of your whole algorithm problem. You have to have a statistical analysis of each of these components to make sure that you're weighting them correctly so that you can come up with a correct algorithm.

I mean I'm not a statistician but I do understand that. And if you don't have adequate data

systems to help you devise what that all is weighted for, then you really don't have the systems in place that you need to have a risk-based inspection system. That's not why I came to the microphone. That's different.

My problem is with the weighting that you've given -- well, not only to NRs but in particular let's use the NRs. And this again is a little fuzzy for me but I will read from my notes.

You have given a system where you've put 0 down for no food safety problems. And then you have for minor food safety 1, according to your paper, not according to this chart, and then for 2, you have probably caused problems, and number 3, definitely caused problems. I don't know exactly 4 and 5 are more definitely causing problems I guess.

Anyhow, these categories are not really weighted well because you've included that 0.

MR. ANDERSON: I think that probably one thing that would help would be hold that particular question until Mr. Gioglio's presentation because the topic of his talk and we'll know a lot more after

that.

MS. BUCK: Oh, okay. Well, then all right. The last question that I would have to ask you about, going back to your chart, we have evidence that multi-drug resistant *Salmonella* is coming out, and I think you just said in the presentation that there are 2,000 -- 1800 to 2,000 plants that get *Salmonella* verification. We know that the United States does not have *Salmonella* under control. So what are we going to be doing to increase *Salmonella* verification or testing so that we can drive down those numbers? Is there anything planned in the risk-based inspection to increase *Salmonella* testing given the evidence that multi-drug resistant *Salmonella* is on the rise and it has longer range health problems for victims.

MR. TYNAN: Is that a question that you can address?

MR. ANDERSON: I would say that as the *Salmonella* verification system improves and becomes more sophisticated and looks at some of these types of things like serotyping which I know that we're looking towards, we would certainly update the algorithm to

reflect that.

MS. BUCK: Thank you.

MR. MICHAEL: I'd like to comment just on the first part of those comments, that we did do analysis on the data that led to each of these factors, and they do have all of this data. That's one of the reasons we picked these various factors, but statistical analysis of the data is not all that went into the decision to write these things. It's also determining how much we think these reflect how well a plan is controlling risk.

And then finally I'd remark, and Don said this in his presentation, these percentages here are hypothetical. They're for a plant that has all seven factors. If the plant didn't have seven factors, they would change, but they do -- but they wouldn't change in terms of the relative value to each other. They just show sort of a hierarchy of values.

MR. TYNAN: Okay. We're getting a little bit close on time. I'll let Bill have the last word.

MR. SMITH: Well, I just wanted to -- we seem to have some misconception about the consumer

complaint. That was verified food safety. So that means we've done a trace back. We can verify that we have evidence that that particular consumer complaint contributed to a food safety issue. Otherwise, those -- when you say verify, those were the ones we'd be using. So they are important.

DR. RAYMOND: I'm going to play Loren Lange and get the last word instead of Bill. I think I would be remiss, Pat, if I didn't respond a bit to your question about *Salmonella* and the fact that we do not have it under control. And that's why, of course, we did announce the *Salmonella* initiative and for those in the room that don't know it, I think you should know that when we started this initiative, 36 percent of the plants, poultry plants were category 1, and at the end of the year, 49 percent were in category 1. That is not victory, but we're moving in the right direction.

And, of course, if a plant fails a *Salmonella* set under this risk-based inspection system, that may be enough points to move them into a higher level of inspection. So I think we are

addressing your concerns.

MR. TYNAN: Thank you, Dr. Raymond.

MS. BEALS: Sharon Beals, Tyson. A question and a clarification. For the calculation for the NR risk, that will include all procedures and tasks including scheduled, unscheduled and non-food safety?

MR. ANDERSON: It would -- it does include all procedures both scheduled and unscheduled. Under risk-based inspection, and Mr. Smith will talk about this, under risk-based inspection, there won't be scheduled versus unscheduled inspection tasks anymore. That's a concept that will go away, and Mr. Smith will talk about that. But in these calculations, yes, we looked at the NRs that were written in all -- as a result of all inspection procedures performed.

MS. BEALS: And just a question. Is the Agency going to share this calculation with the designated plants once that number is calculated for them? We just want to see how close we just came on our own best guess.

MR. SMITH: I believe we stated in the public paper that you will have the factors. You know

the factors and you know through the paper. If you have any questions, we'll certainly, the local people can work -- demonstrate what numbers we're using, you're using and if there's a difference of opinion, that can be resolved through the appeal process.

MR. TYNAN: Okay. Ms. Mucklow?

MS. MUCKLOW: Rosemary Mucklow, National Meat Association. I'd like to frame the same question for Don Anderson that I asked Matthew Michael, but I didn't like Matthew's answer very much, and that is, what is the policy behind putting volume in the inherent risk category rather than as a risk control factor? And I don't want the repetition or what I can read on a piece of paper. I want to try to understand why you made that policy decision. And if I don't like your answer, I'll be back to ask Bill Smith. Thank you.

MR. ANDERSON: I think that part of the answer, and if I went too far astray, there's some people in the room I know that are formal risk assessors, but having exposure in volume is an often used proxy for exposure. Having volume or exposure in

the inherent risk or the risk calculation is the traditional, it's the conventional way to handle that factor. It is -- it does go to inherent risk. This is, this is basically the risk that an establishment poses to the public by the virtue of what they produce and at what volumes they produce it. An establishment with a very large volume of a relatively risky product, if you will, can have very, very good risk control or vice versa.

MR. MICHAEL: I can add, too, if you look at the categories of product we use now in the inherent risk expert elicitation and when you tie that to a -- category, you do see that at least for the category of ready-to-eat product produced without further exposure to the environment after lethality, we are accounting an inherent risk for something the plant does. As we get more data, you know, once, and if we consider plan intervention, it could be that we would expand the number of product categories in which case volume would be tied to something the plan is doing. I mean it's tied to that one category now for ready-to-eat product that's produced without exposure to the

environment. So you're getting, if you had more categories than the volume when, in fact, expressed things that the plant did.

MR. TYNAN: And I'll just ask Bill to be prepared for that question as well.

MR. SMITH: I thought Don did an excellent job.

MS. HOFFMAN: Sandy Hoffman from Resources for the Future. I just have a clarification question. I'm also still trying to understand this pie chart and where it comes from. Is, is this an example of a theoretical plant? Is it -- or is it the -- representing the maximum, you know, an example where a plant gets maximum points and has all categories?

MR. ANDERSON: It is the latter. It is an establishment that produces products that have a *Salmonella* verification category because of what they produce. They have RTE and/or O157:H7 lab results and they have an RTE *Lm* alternative. So that particular pie chart shows the relative contribution of the seven factors in an establishment that has all seven types of data. If an establishment has fewer than those

types of data, each piece of the remaining -- each remaining piece of the pie would get bigger, but they would remain roughly proportional to one another.

MS. HOFFMAN: And then are the actual percentages because this plant has maxed out on the score on each of those categories that again kind of --

MR. ANDERSON: No, it's the base score. So an establishment that has had a lot of RTE testing done in that plant in the last 12 months, then they get a maximum score of 9 points. So that brings down their score. Only if they accumulate positives do they get 3, 6 or 9 points.

MS. HOFFMAN: I guess what I'm trying to understand is whether this is some kind of a benchmark like this is a plant that gets -- has performed very well on a measures and this is what they get or whether this is you've just created some kind of --

MR. ANDERSON: No, no. This pie chart --

MR. MICHAEL: You could have two plants that each have the seven factors, but they have very different risk control scores.

MS. HOFFMAN: Right.

MR. MICHAEL: But these percentages would still hold.

MS. HOFFMAN: Okay.

MR. MICHAEL: These percentages are based on the fact that they have the same denominators because each of these factors is measured.

MS. HOFFMAN: Thank you.

MR. TYNAN: Caroline, just a moment. Felicia, I'm going to go to the phones in just a second. So you'll have to hold your question.

MS. NESTOR: I can.

MR. TYNAN: Caroline.

MS. SMITH-DEWAAL: Am I --

MR. TYNAN: Yes, please.

MS. SMITH-DEWAAL: I just -- I have a couple of comments and one question but having lived through the Supreme beef case, I would urge that your scientists actually talk to the lawyers involved as well because I am a little worried here that these -- the facts that these percentages, these weights are going to be variable depending on how much data the

Government has may not have legal mustard, that you might have two similar plants, one of whom only has -- meets four categories and one who meets six, those we saw, and the weights in those categories are going to change. That may not work. I think you need to consult the lawyers on that.

The second issue I want to comment on is on behalf of CSPI's 900,000 consumer members, at least 800,000 of which are in the U.S., we do support having food safety consumer complaints considered as part of your algorithm. However, we do want to know, and I don't need an answer today unless you've got it, what verified means because I think that's critical both for the industry and for consumers. But we do believe the consumer complaints should be considered in this algorithm.

MR. TYNAN: I think we have an answer for the verified now maybe. Bill, if you can --

MR. SMITH: Again, what we're using for verified criteria is we have evidence that we can track directly back to a plant that then associates that piece of evidence with illness or injury.

MR. TYNAN: Okay. I'm going to ask the folks on the phone, the technician to maybe hook us into those on the phone. Are there any questions from those that have called in?

(No response.)

MR. TYNAN: One more time.

(No response.)

MR. TYNAN: Okay. Ms. Nestor, we'll let you have the last word.

MS. NESTOR: Thanks. Felicia Nestor, Food and Water Watch. I've got a comment and a question. I speak with inspectors all the time, and they tell me that there are other things that go into writing a NR such as like Stan mentioned, how much time they have, but also some of them have been instructed, don't, don't bother with the inconsequential NRs, just do the most significant NRs. I mean and I've been hearing this for years and from a lot of people. Have you done any outreach to the field to determine whether that is true and where it's true?

MR. SMITH: Felicia, as you know, all our policy is very clear and directives that inspectors

are to document all findings of noncompliance. Our front line supervisors look for them to be doing that when they assess their performance and so that's part of supervisory controls and management control systems.

MS. NESTOR: Okay. And then I have a question. On the bottom of page 6, above figure 3, it says, "In effect, an establishment with no positive 0 tolerance samples based on only 1 or 2 samples will not have a risk control measure as low as an otherwise identical establishment from which the Agency has 3 or more samples."

MR. TYNAN: Felicia, this is page 6 on ours. Is that what you were looking at?

UNIDENTIFIED SPEAKER: She's looking at the paper.

MR. TYNAN: Oh, you're looking at the paper itself. I'm sorry.

MR. ANDERSON: And if you'll repeat it, I'll try to answer your question.

MS. NESTOR: It's basically saying that if a plant has a lot of RTE negatives, they do better than

if they have only a few RTE negatives. And so I'm just wondering how much and how can that impact the whole number?

MR. ANDERSON: Yeah. Actually that is a true statement but it's only to an extent. We have a number of establishments that because of the frequency with which they produce and ship certain types of products, they may have, even in a year, they may have only one or two or three types of a sample taken, a RTE sample. I mean it's not very prevalent but we do have some establishments that in the course of a year, they may only have two RTE samples. So let's say an establishment has two RTE samples, and they both come back negative, and we have another establishment that in the year, they had 20 or 40 or 60 RTE establishments, and they all come back negative, that establishment with more samples would have a lower score -- that establishment with fewer samples would have a lower score than an establishment with only one or two samples.

MS. NESTOR: And what's the maximum?

MR. ANDERSON: The maximum?

MS. NESTOR: The maximum number of points?

MR. ANDERSON: The maximum number of points is 9 points --

MS. NESTOR: Okay.

MR. ANDERSON: -- which is -- yeah, 9 points.

MR. TYNAN: Okay. We have two last questions. We'll start with Mr. Painter, and then we'll go over to --

MR. PAINTER: Yes, Stan Painter with the National Joint Council, and I'll try to make this quick. Bill, in the comment that you made regarding the NRs and every NR is supposed to be written, personally as an inspector, I've been told from my supervisor, you're doubling, you're tripling, things of that nature, that you should insure regulatory compliance has been made, and if you don't have time to write the NR, just insure that the compliance has been met and move on.

And then regarding the consumer complaints and the weighting, you know, I could just imagine that if a person had lost a relative due to eating

contaminated product, you know, maybe calling in to report a consumer complaint may not weigh heavily on their mind at the time.

MR. TYNAN: Okay. Thank you, Stan.

MS. SCOTT: Jenny Scott, GMA/FPA, and it's not a question. It's a comment on this whole issue of volume being applied to the inherent risk versus the risk control measure.

We agree with you that risk is hazard times exposure. Volume can serve as an exposure measure. But I would remind you that it's the risk control measures that are put into place, that impact the presence of the hazard and therefore we really need to see this volume issue addressed on both sides of the equation.

MR. TYNAN: Okay. Thank you, Jenny. One item before we pass onto the next topic. So we're going to close this out right now. Since we're having a little bit of difficulty of audio, Dr. Raymond made a good suggestion that, we try and have an e-mail box. It'll be a little bit difficult for us to set that up so that we could take questions as we go. So I'm

going to give you mine, and it's going to ring in, everyone will hear it buzzing up here, and I'll probably get a callous, but at any rate, it's robert.tynan@fsis.usda.gov. So I'm going to turn my Blackberry back on so in case there's some questions. But in that regard, I would suggest just a quick stretch break, not coffee break or anything like that, but just to allow everybody to stand up and kind of stretch just a little bit before we get Mr. Smith here.

(Whereupon, a short recess was taken.)

MR. TYNAN: Okay. We're going to get started. Before I do though, we did a little discussion here about the volume because it seems to be causing a little bit of confusion here. I'm going to let Matthew again clarify how the volume ranges will be applied.

MR. MICHAEL: I just wanted to mention, as you saw on the one chart with the squares, the ranges are divided into quintiles by color code, and those quintiles are based on the hypothetical scores we can get given the ranges we've given the inspectors.

We're going to look at that and if it turns out they, in fact, don't create a differentiation between the smallest plants and the largest plants, we can adjust using the real volume we've received. But those quintiles, the reason we've divided those ranges of scores into quintiles is to, in fact, make that differentiation. But we can revisit it if in practice it doesn't work as it did in theory.

MR. SMITH: Okay. Now we want to move onto how these two different components come together to establish a RBI measure.

And really what we've been talking about, risk-based inspection level measure, what we've been talking about is combining the inherent risk and the risk control measure and we're treating them equally. So it's 1 plus 1 and then dividing by 2.

The IRM, the inherent risk control and the plant risk control measure are on 100 point scales, and this will also be based on a 100 point scale.

So essentially the inherent risk contributes 50 percent. Like I said, the risk control 50 percent. You determine an RBI measure and for what we're

looking at presently would place the plant in one of three levels, 1, 2 or 3.

So the level of inspection for each establishment is derived by the risk-based inspection measure. And by statistical design, we are starting with 60 percent of the plants under Level 2, 20 percent under Level 1 and 20 percent under Level 3. We've talked in the paper we've presented, also we had some references there, for a hypothetical set of establishments. So those that were between the risk-based inspection measure, 24 to 55 were in 2, and so forth.

This is just demonstrating again how the two come together from the information you've seen earlier. We have the inherent risk measure which for this particular plant had an inherent product hazard of 10, volume range of 3. Their measure was 30. Then we have our actual risk values for the data in the establishment. That totals 25. We add the two together, 30 plus 25, divide by 2, we get 27.5. So according to our hypothetical limits that we have established in the paper that we used, that would be

inspection level 2.

And here we have a very, very small plant that has an inherent product hazard of 6 and a volume range of 1 which give them an inherent risk measure of 6, and then a very good compliance rate of the factors that for risk control measure, that totals 9.4, and again, we add those two, divide by 2, and we have a risk control measure or risk inspection measure for that plant of a level 1.

So really what are we talking about here? Because this gets into what is this system actually going to look like?

So level 2 mirrors what we are currently doing in PBIS today. We will be turning off the scheduler but the instructions to the inspectors will be to perform the procedures at the frequencies they do today in the PBIS system. So that's what we'll be looking at. So what does that mean?

For HACCP 01 procedure, just like we're doing today, we schedule that once per week, and the HACCP again 01 procedure for those of you who don't remember, that's a random verification of the five

features of a HACCP control program. That includes monitoring, verification, corrective action record keeping and reassessment. So one or more of those are done in that procedure.

And the HACCP 02 procedure today currently they're doing two per week per processing category, and again that is the inspector verifies all five components of the HACCP program on a specific production. And so that's done two times per week.

Pre-operational and operational sanitation procedures are done daily and the SPS stands for sanitation performance standard procedures once per week.

This includes some establishments who because of their inherent risk cannot under, as it's presently designed, we have some prototype plants that may not be able to achieve level 1 because of their inherent risk score.

In a level 1 RBI plant, what changes then is we have the HACCP 01 procedure. They do one per week in one processing category. The HACCP 02 procedure frequency stays the same, and we either do a pre-

operational or an operational sanitation procedure daily, and again the sanitation performance standard procedures stay as one per week.

Under level 3, the HACCP 01 procedure we are now doing is two times per week. The HACCP 02 procedure stays the same as two times per week, and pre-operational and operational sanitation procedures are done daily, same as in level 2, and the sanitation performance standard procedures we include one more per week. Again, we have in the prototype, we have very few establishments in that prototype grouping that because of their inherent risk are presently going to be assigned to level 3 until we have the outcome of further discussions here, but that is where we are today, a very small percentage.

So I wanted to give you an example in a real life plant, and here we have a plant, XYZ, and so they have SSOPs and they have raw ground HACCP. They have raw not ground HACCP process, and they have one ready-to-eat HACCP category. And so today, the system would schedule inspection procedures this way, and this would be what the inspectors will be doing under level

2. And so as I said earlier, the pre-operational, it would be record verification or observation and record verification, once per day. Same thing with the operational. The raw ground 03B01 is once per week. Same thing for the Raw not ground and same thing for the 03G01 ready-to-eat HACCP and then as we said earlier, that the 02s are all done at the frequency of two times per week.

Our other consumer protections, those are scheduled at the frequency of once per week. We will do our sampling as directed, and there is the sanitation performance standard procedure of once per week.

So on under level 1, what changes is that grouping as I said earlier, the pre-op, you either pick one or the other of the pre-operational or the operational, you perform one or the other, once per day, and the only other thing that changes is that the 01 HACCP inspection procedure, they will perform that once and they will chose that either from 03B or 03C or 03G. And then everything else remains the same as level 2.

For a level 3 plant, then all the pre-operational and operational sanitation inspection frequencies return to each one being done once per day. What changes is the 01 inspection procedures for raw ground, raw not ground and ready-to-eat goes to two per week. And the 06 sanitation performance standard goes to two per week.

So that is basically when we talk about what we'll be doing in this system, those are the changes, those are the things we're talking about based on their score.

MR. TYNAN: I'm going to try one more time with the phones if you don't mind, Felicia. I didn't get any e-mails, so that's a good sign. I'm told that we are connected. So the folks on the phone have the opportunity to contribute if they would like to do that. So I'm going to allow at this particular point once again to ask the phone calls in, if they have any questions to offer them now.

(No response.)

MS. MUCKLOW: Robert, do they know the number to call?

MR. TYNAN: I'll give you my home phone as well. I think they're out there. They just decided not to contribute. I think Patrick's told me he can hear them on the line. Hopefully they're not telling any bad jokes.

MS. MUCKLOW: Why don't you give them the number to call?

MR. TYNAN: They're already on the call.

MS. MUCKLOW: They're already on the call?

MR. TYNAN: Yes, ma'am. Okay. With that, I'm going to start. I think Felicia was up first, and if you could identify yourself again for the transcriber.

MS. NESTOR: Felicia Nestor, Food and Water Watch. Okay. Bill, I want to ask you about this -- the total algorithm here and the 60/20/20. The 60/20/20, if I'm not mistaken, is where the plants would be today based on their current performance. Is that right?

MR. SMITH: No.

MS. NESTOR: Because some of your factors have to do with where the plants are today like the NR

factor, the percentage of public health NRs.

MR. SMITH: It went into the calculation, but we did a total -- you do both the inherent risk and the risk control measure. And then we had -- we know the numbers for all the total population of the plants, and then we chose based on as a starting point the 20 percent would be level 1, 40 percent or 60 percent level 2, and 20 percent level 3. So it's a statistical design. It's just a statistical starting point. And as soon as the first month's calculation is applied, that can change.

MS. NESTOR: Okay. So, in other words, you know, Dr. Raymond's talking about the radical improvement in *Salmonella* numbers in the poultry plants, conceivably six months out, everybody could be in level 1?

MR. SMITH: As I had on my slide earlier, that's not possible.

MS. NESTOR: Because there are some that cannot.

MR. SMITH: That's correct.

MS. NESTOR: Everyone could be in level 2.

MR. SMITH: As I said in my other slide on -- that I had, there couldn't be because their inherent risk value as calculated today, they can never obtain level 2.

MS. NESTOR: So there are some plants that will never attain level 2? They will always be --

MR. SMITH: As we currently have it configured today, and that's not because they don't have risk control measures because they could have a value of 0 for the risk control measures which means excellent and still when you do the calculation, would take it above where the level 3 cut is today.

MS. NESTOR: Okay. But the 60/20/20 is not a constant. So in other words, if a bunch of plants improved, it's not going to knock some of the plants that are in level 1 down to level 2 because --

MR. SMITH: Correct. It's only a starting point.

MS. NESTOR: Okay.

MR. TYNAN: Ms. Hoffman.

MS. HOFFMAN: Thank you. Sandy Hoffman from Resources for the Future. I have a couple of general

comments actually. One is on the scoring of relative risk of illness per serving in the expert elicitation, I think one issue as you're trying to implement this further, there's a lack of transparency in what that means, that I think may cause you problems as you move on. And since you're still under review in the new expert elicitation, I think something that had a more concrete end point, health end point, such as illness, hospitalizations, deaths, that gets that a comparable measure across different hazards, would probably serve you better, that you'll be able to compare it with more types of databases and it'll be more meaningful to you over a long period of time. So that's just a general comment on that measure.

The other goes to this issue of volume, as whether it's an inherent risk or a matter of control. And I generally -- I mean I think you're absolutely right, that you're doing what's traditionally done in risk assessment, that volume is a measure of exposure. But I know Richard Williams and Kim Thompson have a recent paper in risk analysis, and I would agree with them, that volume is something that firms control, and

what you're doing effectively is making an assumption that your inspection and scoring system is not going to be so onerous that it's going to affect their choice about volume. And that may or may not be true. It's kind of an empirical question. So it may end up being something that they try to gain you on. And I think that that will, especially as you think about categories and as you think about the size of those volume, those quintiles, you might want to think about whether you're setting them in ways that may encourage people to shift their volume around a bit to affect the kinds of scoring they get. So it is exposure, but people's behavior can affect exposure.

MR. MICHAEL: If I can respond to that quickly. In our first elicitation, we did, we asked only for a probability of illness per serving from the experts. We received many, many comments asking that we also inquire about severity of illness that could come from contaminated products, and we are in the next elicitation. In the first one, the reason they limited it to probability of illness per serving, with all the constraints on production or assumptions we

give the experts, which was precisely to get at what you mentioned which was comparable data.

But now that we're expanding it with a second instrument, that's by vulnerability, I think we will.

In regard to your second comment, you know, we have heard the comments on volume, we've received them since the October meeting, and we are looking at it. I think along with the idea of volume being a proxy for exposure in the general calculation for risk, we're working with this idea that inherent risk is, in fact, inherent. So if you have a high volume of risky product, you have a volume of risky product regardless of how you control it. It doesn't mean when it comes out of your plant it's still risky, and I think we can look at ways to account for that in the formula. But right now, we're working with the idea that inherent risk is inherent and it doesn't change because of your process control. Otherwise, it wouldn't be inherent.

MS. HOFFMAN: But their behavior is going to affect volume. I mean --

MR. MICHAEL: It could, sure.

MS. HOFFMAN: It could.

MR. MICHAEL: Absolutely. Yeah.

MR. TYNAN: Thank you, Ms. Hoffman.

Mr. Waldrop.

MR. WALDROP: Hi, Chris Waldrop, Consumer Federation. I had a question about the inherent risk and the establishment of risk control. Why are they both 50/50? Why not 60/40 or 30/70?

MR. SMITH: The Agency based on the information and notice today, that was a policy decision to treat them equally.

MR. WALDROP: Okay. So it was just a policy decision within the Agency.

MR. MICHAEL: I think if you go back to my previous comment, we've been working with the idea that inherent risk is, in fact, inherent, and it doesn't change because of your process control. Inherent risk is what's coming into your plant, and that's not changing. Therefore, we gave it an equal weight.

MR. WALDROP: Do you anticipate that ever

changing, maybe once you get some more information coming in?

MR. MICHAEL: It could. Sure. Sure.

MR. WALDROP: Okay.

MR. TYNAN: Ms. Buck, I think you were up next, and then we'll go to the left side.

MS. BUCK: Patricia Buck from CFI. I am curious about the 60/20/20 split as well. What's going to happen when a plant moves from a higher level down to the lower level? In other words, you have a plant that's ranked at level 3, and then it's going to move down to level 2 or from level 2 to 1. Are you going to maintain that 60/20/20 split? And if you do maintain it, would you not expect some resistance from the industry because then somebody obviously in the lower level has to be bumped up to the higher one to maintain this?

MR. SMITH: Again, as I stated, I believe it's a starting point. The first time it's applied, it'll be 20/60/20.

MS. BUCK: Oh, you're going --

MR. SMITH: From that point on, the

calculation will drive the level.

MS. BUCK: Okay. The other thing I'm curious about is what about recurrent problems. It doesn't seem that there's anything in here that addresses recurrent problems, or are we just going to -- I mean it seems to me that every six months this slate sort of get wiped clean and then we start afresh. Or am I just misconstruing that?

MR. SMITH: I think Mr. Anderson said earlier, it would be a running six months. So --

MS. BUCK: Sort of a rolling type?

MR. SMITH: So it's rolling, correct. Plus, again, enforcement actions in a plant, actions to take for corrective actions for noncompliance records, actions taken because of positive laboratory results, all of those things are ongoing also, and if there's reoccurrence, then the Agency will use its enforcement strategies to deal with those.

MS. BUCK: Okay. And as a general comment, I'd just like to once again voice my displeasure at using a consumer complaint file as a major component in your, you know, tools. Not that it should be

discounted. I don't mean it that way. I just mean that it is such a small file, such a small amount of information, and I believe it was Chris or Tony or maybe Stan Painter that pointed out people do not routinely go to a consumer complaint file to go through that process to report a sickness, an injury or a death from a foodborne disease. Thank you.

MR. TYNAN: Thank you, Pat. We're going to go over here. Mr. Painter, if you would identify yourself again.

MR. PAINTER: Stan Painter, with the National Joint Council. In listening to everything that gone on, a lot of the people that have been here have been a part of the process from the very beginning. And I'm going to lead into that to training. What type of training does the Agency propose to do for the inspectors in what has been categorized as the 30 prototype locations?

MR. SMITH: I'm going to let Dr. Peterson address that.

DR. PETERSON: Ken Peterson, FSIS. A couple of things, Stan. As you know, we're in the middle of

Article 6 negotiations with the Union where that very topic will be discussed.

In general, what the inspectors will be trained on is there will be a FSIS notice that lays this out. We'll lay out the work that Bill described. And so they will be trained on, now that I don't get my schedule, here's the work I have to do, how do I know which level the plant's in, and once I know that, you know, what work do I do. So that's really the nature of the training. What we're currently thinking for the initial training would be classroom training for the first group of inspectors, first group being those in the 30, that are in the prototype locations with their supervisors. So face-to-face training to get everybody oriented.

So they're going to do the same work in the same way. It's really how do I get my work, and then enter my procedures as unscheduled procedures. That's how we intend to start out.

MR. PAINTER: Well, the concerns that the Union has is if most of us who have been involved in this process are having trouble understanding it, how

are we going to get the people who should be implementing this in the field to understand it. And I'm going to turn it back on you, you said as I know, we're in Article 6. As you know we're in Article 6 regarding midterm bargaining on this issue. But as you know as well, the Union has no right under the law to determine training, and what the Union was told, it would be handled in a manner such as a team inspection where you will be called in and you would sit down with your circuit supervisor for a short period of time, maybe an hour, maybe two hours, and having that said, the Union feels as though that's not adequate to be able, for the inspectors that should be involved in this, to understand it.

And then in the same token, you have your 30 prototype plants. What, what meetings, if any, is the Agency planning with these 30 prototype plants to inform, involve, to train, those plants?

DR. PETERSON: Okay. The last one first. The plants, this is about how we apply inspection methods. So the plants need to understand and that's why their representatives are here, have some

understanding of the process.

For the inspector, and I agree with what you said on training. They need to know the level so that they can go to the appropriate source, the notice, and say here's the level, here's the work I do. We don't intend to train them on the nuances of so many points for this, so many points for recalls, so many points for that. They don't need to know that in phase one to know how to do their work. They need to know what level the plant's in.

The team training, yes, was a work unit meeting. Most of those ran anywhere from four to eight hours. As I said, the initial training will be what it is which is classroom for the first group of inspectors.

MR. PAINTER: Well, the team training did not run from four to eight hours, and in my Council, I can certainly say that, but I'm going to close by saying this and step away from the microphone. You know, a lot of the plants train their people better than we're trained, and it should not be the plant's responsibility to train us and in the same token, it

shouldn't be our responsibility to train them. But I go into a number of plants and they have more information than I do in a lot of cases, and that shouldn't be the case. The Agency should do what it takes, if it wants to implement a process, and expects the people to be able to perform a job, the Agency needs to train us. Thank you.

MR. TYNAN: Thank you, Stan. Dean, nice to see you.

MR. BERNARD: Nice to be here.

MR. TYNAN: Will you introduce yourself?

MR. BERNARD: Dean Bernard with Keystone Foods, and thanks for the opportunity to be here and to comment. A question for Bill Smith.

Carrying on from your statement about certain establishments that do their inherent risk don't have an opportunity to move from say a level 3 to a level 2. Is the Agency contemplating any incentives for someone in that category to improve their food safety systems?

MR. SMITH: Well, a couple of things. Dr. Raymond, and he's right behind you, has always

talked about his nano system with nine boxes of inspection. Again, we're starting here for the prototypes to learn and with the information we have now. So it is contemplated as we develop this, that we will be able to get industry information and then be able to use that to adjust that. Dr. Raymond, do you want to --

MR. BERNARD: I yield the microphone to the Under Secretary.

DR. RAYMOND: Thanks, Dean. For the record, Dr. Raymond. And, Bill, the real reason I'm here is I'm blocking you from the person behind me because you know what she's going to ask you. So this is to give you a little time to come up with an answer better than Michael's and Donald's so far.

MR. TYNAN: We still have Charlie down at the end. So there's still a chance.

DR. RAYMOND: Charlie's going to run us right to 1:00, and head out the door.

There's a couple of comments I want to make before it gets close to the noon hour and people maybe start leaving for other things. There's several

comments, and I'll make them very brief.

One is the verified consumer complaints. I'm a little bit -- I'm not understanding the concerns, Pat, that you and some others have about the verified consumer complaints. So I would like to have further conversation, not today, but I need to know what your concerns are, whether we give it more or less points, et cetera. As you may know, I'm going to have a cup of coffee with Barbara Thursday morning at 7:30. So maybe she could bring some information to me at that particular time.

Verified consumer complaints so that you know, last year we did verify about 120, 130, somewhere between 100 and 150 were verified. We only had 20 positive *E. coli* samples unfortunately. So, you know, there is a place for the consumer complaints, verified consumer complaints. You guys talk to me and let me know how to work that one out. I'd be happy to move it up or down the scale.

Secondly, the biggest reason we're doing this is to make the food supply safer, and the way you do that is to incentivize industry to get even

better than they already are. And I am troubled, Dean, by the fact that there are some plants that will be in category 3 for all of their lives unless they reduce production. I don't think there's anybody out there that's going to reduce production if they've got a great product. And I also know as we do the math and look at this, we have some small plants that can have a significant number of points in the plant's ability to control risk but because of volume, they'll get less inspection than a large plant who maybe had no -- got 0 for NRs. I shouldn't say had no NRs, but they're in that 0 category. Their samples all come back positive, et cetera.

So we don't maybe have time today, but you guys be thinking about this and for the volume meeting on the 25th, and that's why we're having separate meetings on volume. That's about half of what we've talked about today is volume, and it's very contentious. It's very debatable how to use it. And I'm still all ears on this. That's one of the reasons I've told the Agency we're not going to roll this out in April because there's too much debate

going on. We need to reach some compromises. And one of the things I'll throw out on the table so you can think about the next three weeks, if volume stays where it's at, I don't -- I'm not comfortable with the plants being locked into their category for the rest of the plant's life. They have no incentive to try to do better as far as the level of inspection. They do have incentives, of course, because of the pride they take in their product, et cetera. But I want incentives. It would really be nice if they all got into level 1 eventually. How would we handle that problem? It won't happen while I'm here, I'm sure but, you know, that would be -- that would say this thing was a huge success. We'll cross that bridge when we get to it.

In the meantime, we I think need to develop ways that we reward good behavior. So far we basically have been talking about penalty boxes. You get points in that penalty box for things that didn't go well, and what happens when a plant comes in on a *Salmonella* set, two consecutive sets in a row, under 5 percent. They don't get any points out of this

penalty box, but maybe if they're that good, they ought to get some points taken out of the penalty box which would allow them to move from category 3 to category 2 to category 1.

Maybe for plants that hold the product and retest the product, they should get a point taken out of the penalty box for good behavior. Then we wouldn't have recalls based on our testing at least because right now when we do a recall based on our testing, that means the product's out there, the consumer have it in their hands, they probably have already ingested most of it.

So hold and test is a -- I know all plants are not set up to do that today. I'm not that naïve, but this would be an incentive for them to figure out ways to hold and test, if they could move from category 2 to category 1, because of good practices.

There are probably other good practices out there that I'm not thinking of today and others here representing the industry, but if you can come up with rewards for proven, proven success, and all I can think about right now is laboratory tests which

is indisputable, positive or negative, if there are other ways that we can take a look at this, I'm all ears for rewarding good behavior as well as penalizing bad behavior, and I'm trying, Bill, but she's going to get to the microphone anyhow. So I might as well let her step up now.

MR. SMITH: Okay.

MR. TYNAN: Thank you, Dr. Raymond. And before you start, Ms. Mucklow, is it true you're going to ask the question?

MS. MUCKLOW: Of course, but I've got a preface to it first.

MR. TYNAN: Please introduce yourself.

MS. MUCKLOW: Rosemary Mucklow, National Meat Association.

First of all, I'd like to thank Stan Painter for the indirect compliment to the training that the industry is doing. Thank you, Stan. It was worth coming all the way to Washington to hear that, just as it was worth hearing Caroline Smith-DeWaal tell the produce industry, they ought to do what the meat industry has done, which she did a few months

ago when they were in the middle of their problem. We appreciate that, and we appreciate that people in the greater world know that the meat industry has done an incredible amount of training of its people. And if we could recruit these nice people as honorary members of our organization, they'd also get all the benefits of our advice.

So back to the question for Bill. Bill has actually conceded in what he said by saying that some plants can never make level 1 given the algorithm. And that should be a big message to him, you know. He's now got an unattainable goal and the unattainable goal is mostly unattainable from the large plants.

Michael has told me that volume represents exposure. Don has told me that the policy decision behind that was traditional and conventional. I've heard Bill that he's got an unattainable goal. So now I want to know how he's going to fix it. Thank you.

MR. SMITH: Well, I think as we've said here, we're going to have a separate meeting on

volume.

MS. MUCKLOW: I'm not going to be here. I'm going to be at the Grand Canyon that day.

MR. SMITH: And as Dr. Raymond also said, we do need to incentivize how we can impact that score so we can get plants to move from one level to another using industry information.

MS. MUCKLOW: All right. I'm going to leave you with a fix, Bill, and it'll just be between you and me, before God and everybody.

MR. TYNAN: Did you say that was the bill for the inspection training the industry does? I don't recall who was up first but -- okay. Ms. Foreman, would you like to introduce yourself please and pose your question?

MS. TUCKER-FOREMAN: Carol Tucker-Foreman with Consumer Federation of America, and I would hold my comments if I can be assured that we're going to have one more comment session before we end today.

MR. TYNAN: We'll have another comment session in relation to the next speaker, but this is where we're going -- if you have a question to

address Bill's comments.

MS. TUCKER-FOREMAN: I have questions to address the scope of the -- most of what's happened today. So should I do it now or hold it.

MR. TYNAN: Well, again we have time limitations. So if it's a couple of minutes, it'll be great.

MS. TUCKER-FOREMAN: Foodborne illness is a serious public health problem, and everybody wants to reduce the number of people who get sick and die. I'm afraid that nothing I've learned about risk-based inspection or any of the risk measures today makes me think that this can do it, and I want to address a few reasons why.

First of all, everything you're doing is based only on data that FSIS already has and most of those numbers were collected for reasons that did not have to do with reducing foodborne illness, and in no case, do you have any data that you can say we know what this contributes to the problem of foodborne illness. You've never ever collected the data that say if we change this, the number of illnesses are

down. If we change that, the number of illnesses go up.

Now you purport to say that your reductions in carcass contamination relate to reductions in foodborne illness, but number one, the Office of Inspector General says you can't use numbers that way, and number two, since 2001, foodborne illness has stopped dropping off, and in some cases has gone up.

So you don't know that anything that you're proposing here, you don't have any databases that say this will make a difference. It's not reassuring to hear that this staff thinks or believes that this is the way to go here. The problem is you don't have any numbers. You cite PBIS as the base for much of this. PBIS was developed before you even acknowledged you had authority to control pathogens in raw meat and poultry. It's been adjusted but it was certainly never set up because you knew that if you did the things in PBIS, you would have an impact on foodborne illness. We need to see the data that show the relationship.

There are a number of terms that you use that don't have definitions. I know you know what they mean but you have not set forth definitions for them. I don't know what a typical plant is. I'd like for you to say a typical plant is specifically one that -- first, how can you decide what's a typical plant out of all the plants out there. I'm not sure. Is that an average? Is it a medium? What is it?

I don't know why there are three levels of inspection. How did you come up with three? Why not five? Why not two? I can't find anything in the papers that say we have health related data that show we should have three levels of inspection.

Finally, with regard to that 2005 expert elicitation, I'm distressed to read through these papers and find that all of them reference still the 2005 expert elicitation which was roundly criticized, obviously was severely flawed, and you say that you're going to do another one. And I have some questions about that.

One, will you put the methodology for that

out for public comment before you begin it? It might be a good way to avoid some of the problems that you had with the 2005 one. So far, it's my understanding that you've got it well down the pike but, of course, nobody knows anything about it.

Will you have it please peer reviewed by people who do not work for the United States Department of Agriculture. I know they're outside FSIS but I don't think peer review standards would accept all USDA employees.

Will you please bring them together and put them in one room? That was an industry suggestion that was made at an earlier meeting and I think is absolutely essential to coming up with something.

Our organization will continue to object vigorously to basing all of this solely on expert opinion. It is expert, but in the end, it's still opinion and we need to see data that show if you do "X" it will have "Y" impact on public health, and so far there is nothing like that.

Now until you have that, we'll have to go forward on the assumption that all of these things

that you're proposing may make the problem worse because we have no data that we can use to assume that it will get better. I'll be glad to take responses to that.

MR. TYNAN: I'm not sure where I heard the questions though.

MS. TUCKER-FOREMAN: Oh, there were several. Going back to can you define a typical plant for me?

MR. MICHAEL: When you say typical plant, are you talking about in the instrument or the instructions to experts?

MS. TUCKER-FOREMAN: No, no, no, no. I'm talking about the papers earlier today where they kept making reference to a typical plant does this, and a typical plant does that, and I don't know what a typical plant is. I'll go find it in the paper if you want.

MR. MICHAEL: I think we presented a variety of examples and given the data we have, both risk control and inherent risk, they are fairly typical plants in that context. They have a certain

number of factors or certain types of factors.

MS. TUCKER-FOREMAN: How do you know they are typical? And let me tell you that when I was going to school, you could not define your terms solely by example. You had to lay out a definition and then use an example to illustrate it. I'm just getting examples.

MR. MICHAEL: Well, I think we used typical a number of times in both Don and mine and I think Bill's presentation, and typical probably meant something different each time. We have looked at the data. When we've presented example plants, they're usually examples that represent a large number of plants that have those factors or have that data. So typical, whether it works out to be an exact average, I don't know, but it's something we saw and it's something we see very often.

MS. TUCKER-FOREMAN: Now I'm going to have to have definition and that's the lack of specificity that I think plagues this whole process. Do you put the peer review out for public comment before you --

MR. MICHAEL: We don't have plans to do

that, no.

MS. TUCKER-FOREMAN: I mean the expert elicitation. I urge you to do that because otherwise you're going to keep going forward on something that may have terrible flaws in it, unintentional flaws.

MR. TYNAN: Bill, did you want to respond to that comment?

MR. SMITH: -- to go back and look at, I don't know if we --

MS. TUCKER-FOREMAN: Thank you.

MR. TYNAN: Felicia.

MS. NESTOR: Felicia Nestor, Food and Water Watch. Following up on what Carol was -- make a note of what they're basing their opinion on?

MR. MICHAEL: In the first elicitation where we queried for their opinion, the probability of risk per serving, we did have a column where we asked them to put in comments as to why they gave it a particular score relative to the other scores. We're doing that again. Of course, the instrument is different in that we're asking about severity of different populations. In the severity instrument,

at least the latest one I've seen, we don't just ask, we demand that they tell us why. In the risk of illness per serving, I don't believe we've done that. We could. Of course, we can't make the experts do anything.

MS. NESTOR: Right. I think it's a good idea. I went to the risk analysis meeting up in Baltimore and someone gave a presentation and the whole problem with -- well, one of the problems with expert elicitation is you do it when you don't have data but what the experts are relying on is the best data that you have at that time.

MR. MICHAEL: That's right.

MS. NESTOR: So it would be good to know for the future what their estimations were based on.

Bill, can you, can you just give me a quick example of a plant that cannot go to level 2? Why could it not go to level 2, because if it's zeroed out on the inherent risk, and it just happened to be a high, you know, sorry about the plant control risk, but it was just high inherent, you get to 50 which is level 2. So --

MR. SMITH: Well, again, those numbers and that's why -- those numbers that were in the paper, and the paper does provide for that, so that means the Agency is thinking that way, did provide for a means for a plant in the paper, because it was hypothetical, to go from level 3 to level 2. What I was saying today, the actual number was based on the 30 prototype locations we know now, and the establishment of 20/60/20, that we have one or two scenarios where it is not possible today because the number -- the value of that has been set at the 80th percentile.

And we know we need to look at that, and we know that we're going to talk about that at the volume, and we know we're going to get continual feedback and we know, just like we have to again get data from the industry in order to affect and make decisions on the scoring. We also know that we need to get illness data and how we're going to use that information and we're setting up our systems to do that now. I just can't tell you how we're going to do it today, but we're certainly looking into that

for the next phase of risk-based inspection also.

MS. NESTOR: But can you give me, why could a plant not move from 3 to 2? Give me an example of a kind of plant? Where would the factors fall?

MR. SMITH: That would be a high volume beef grinder.

MS. NESTOR: Okay. A high volume beef grinder gets you to let's say 100 on the inherent risk and what about the other side?

MR. SMITH: It would be 0, and that would be a score of 50.

MS. NESTOR: Right.

MR. SMITH: And what I'm saying, the 80th percentile for the prototype locations, that number currently, I can probably share that, is 28. And so as you can see, 50 --

MS. NESTOR: Okay. I'm going to have to ask you about this later because when I see 50, I see 50 right between 24 and 55.

MR. SMITH: Again, that was for purposes of the paper, and that was based on 500 plants, but that was a hypothetical collection of plants for

demonstration purposes.

Now I'm talking about live prototype locations and the 20 and 80th percentile are different than those numbers. So --

MR. TYNAN: Can we hold your follow up questions for after? And before you do that, if I could ask you to give way. We're right at 12:00. Mr. Johnson has a question. So we'll let him go and --

MR. JOHNSON: This is Dennis Johnson, Olsson, Frank and Weeda. Caroline, I want to make this perfectly clear. I want to put this issue to bed once and for all time. The Agency has the statutory authority to vary the inspection at the establishment. That is industry's view. That is the Agency's view. The statute allows them to do that. We don't need to talk anymore. All right. I'm on record, aren't I? There's absolutely, positively no way we can sue the Agency for varying the level of inspection intensity at an establishment. It was tried in 1983. Harrison Brothers v. USDA. I can file for the record that decision in that case. This

is over with. This isn't Supreme Beef. They can vary. Can we end this one once and for all because Bill, when you start implementing this, am I going to have a boatload of questions for you, but until we start implementing it, they're all hypothetical. That's my two comments. Thank you very much.

MR. TYNAN: Thank you. Felicia, I'm going to give you the last word but it has to be a quick one.

MS. NESTOR: I've got questions. I mean maybe this meeting is not long enough. I think people have said that.

Can an inspector do all the procedures in a plant except for sanitation on one day?

MR. SMITH: I'm not sure what you're asking.

MS. NESTOR: Can an inspector go to -- say he's got five plants. He goes to the ground beef plant on Monday. Can he do all of the HACCP procedures at the ground beef plant on Monday and then only have to go back to that plant for sanitation?

MR. SMITH: Again, the level 2 is what the PBIS system is scheduling today. So it would mirror what they're doing today. If they have to make choices because they have to take a laboratory sample, one or more, if they have to initiate an enforcement action, if they have to take regulatory control action, that affects the time.

MS. NESTOR: Yeah, but now they get an assignment. I mean now they are told on Tuesday, you will do this procedure, and on Thursday you are going to do this procedure. Whereas, under RBI --

MR. SMITH: They will get the same amount of procedures and my guess is they will have the flexibility how they apply that --

MS. NESTOR: To do it all in one day.

MR. SMITH: -- as long as by the end of the week, they get that number done.

MS. NESTOR: All right. I've got more questions, but I'll save them for the next comment.

MR. TYNAN: You'll have to table them because we need to move onto the next topic. Let me see if I can -- Mr. Charlie Gioglio who is going to

talk a little bit about the noncompliance records of public health significance.

MR. GIOGLIO: Okay. Thank you, Robert. And I guess good afternoon.

I wanted to -- I guess I thank you for the opportunity here, and what we're intending to do with this presentation is really to drill down into part of the presentation that Mr. Anderson had made earlier this morning.

And if we take a look and you remember the bubble chart that we had and he talked about the risk factors in risk control measures, okay, and then we did have some discussion about NRs of public health control. He also touched on how -- just generally how we come to that or how we decided which NRs should, in fact, be factored into the risk control measure and are, in fact, a public health control.

Don mentioned earlier, and I'll just remind us, that I guess about a year and a half ago, we did make some changes to the PBIS system, that automated the system of inspectors, for inspectors to actually cite the regulations that would be associated with a

given NR. Okay. So previous to that, inspectors were, in fact, requested to write onto the NR which regulations were, in fact, associated with it.

Now what we do is we give the inspectors a drop down menu, that are specific to that given procedure, okay, that lists out the regulations specific to that procedure and allow them to pick from that menu which regulations they have found to be noncompliant. Okay.

This doesn't change any of the enforcement actions that may be taken in a plant. It does not change any of the follow up actions that would be expected of establishments or anything else, but it does allow the inspectors something that's more user friendly and allow our analysts more access to the data.

And just to make the point, that was earlier in Don's slide, there are presently 564 regulations that could be associated with any of those NRs or any of those procedures.

Okay. So the question was how would we go about rating those regulations, okay, to come up with

a measure of what the public health risk was. And what we did was develop criteria to assign a weighted value to each of the regulations that are currently in the system, okay. And we developed a scale from zero to three, zero meaning that there would be no adverse health impact if that particular regulation was, in fact, violated and the inspector needed to write a NR. And three would indicate the higher level. In other words, it would indicate that there was a definitive loss of the food safety system's process control.

We took those criteria, and I'll get to those specifically in a minute. We took those criteria and we gave them to nine of our Headquarters staff officers. Those folks have a diverse background, most of which -- most of their backgrounds deal with working either with the regulations as regulators in the field for some portion of their career, some actually working here in Headquarters, writing regulations or instructing people through directives, notices, how to apply the regulations, and basically had backgrounds in either

food science or related public health fields. Okay.

We gave them the criteria and asked each one of them to go through, look at each one of those regulations that might be associated with the PBIS procedure, and give a rating either zero, one, two or three. Zero meaning no health risk and three being the most significant health risk.

Those scores from each of those raters then, from each of those people, we calculated a mean value, okay, and that value is then what is being used to calculate the weighted NR rate in the algorithm that goes in. When you go back and think about the bubble, that one factor that informs the risk control measure. Okay.

Now the criteria that we use were category 3 indicates a definitive loss of control of the food safety system, and an example of that would be -- this happens to be a HACCP regulation, 417.3(a), corrective actions after a deviation of a critical control point, meaning that the establishment experienced a deviation of one of their CCPs. Something was not right when they did their finding,

but they did not, in fact, take the expected or the required corrective action that is laid out in their plan.

Category 2 indicates a reasonable probability of a loss of control, and an example of that might be 416.13(a) which is the conduct of pre-operational sanitation procedures.

Category 1 was a more remote probability of a loss of control of the food safety system, and this got us to, if you're familiar with the regs, 416.2(a) is about the establishment's grounds and facilities, something that may be happening or some conditions that may be outside of the establishment that could, okay, if one thought it through, have an impact, in fact, on the establishment's food safety system. Okay. But there was, in fact, a remote probability.

And the 0 category is there's no bearing on the food safety system. So the example there is a standard of identity, 319.307, and that's how much meat is in the meat sauce, and we could have picked any number of those types of regulations.

So again, the key point I think is to

remember, we didn't rate specific NRs but we did, in fact, look and rate the regulations that inspectors would go ahead and cite on those NRs based on their findings at the plant level, at the given time that they did their PBIS procedure.

Okay. And these were the results of that scoring. We had 53. These are the actual numbers, okay. We had 53 that scored in the category 3 or the most severe, 140 in category 2, 175 in category 1 and actually 196 in the 0 category or regulations that don't have a food safety impact.

And the next slide here just basically it down in terms of percentages, and we have approximately 9 percent, okay, of the regulations that we could cite on a NR would indicate a definitive loss of control, 25 percent in category 2, 31 percent and 35 percent in the category 0.

A couple of things that I would add is that the factor or the category that is used to inform the risk calculation or that goes into the algorithm rhythm as it were, and this actually gets back to a question I guess Bill had answered to Mr. Painter

earlier, an inspector could cite a number of different regulations that may have been, in fact, not complied with on a given NR. Okay. What we're going to use from that list of regulations is, in fact, the one that falls into the most -- the highest category, or the most severe category or the one that would indicate the most loss of control of the food safety system. Okay. So the inspector is not being asked to make a judgment about whether or not the NR is food safety or not but, in fact, by their findings and the regulation that they're describing as not being complied with, is what ultimately informs the algorithm. And that is all as far as the presentation. Not quite. Questions?

MR. ANDERSON: The list is on the web.

MR. GIOGLIO: Oh, I'm sorry. Yeah. Mr. Anderson just reminded me. The list of all of the regulations that we work through is, in fact, posted up on our website, okay, with the scores that we found, and I think they are rated probably from the most severe to the least. Thank you.

MR. TYNAN: I was looking the other way.

Who got up first? Mr. Painter.

MR. PAINTER: Stan Painter with the National Joint Council, and I'm here on a repetitive issue just like Ms. Mucklow from earlier. I'm still interested in knowing the type and amount of training that's going to be given to the inspectors in these particular locations in the beginning, in these 30 "prototype" plants.

MR. SMITH: Well, Stan, we'll certainly get back to you on that. You do know that, as Dr. Peterson said, we are in -- until we can complete the negotiation process, so we know what the actual process is going to be, then we can finalize the methodology, then we can finalize the training, and discuss that with you.

As we've done with HACCP, the 5000.1, we want our folks knowing what they're doing, how they have to do it, how they're going to record things, how they're going to determine their work, how they apply the methodology. That would all have to be part of a training packet. How much that is, I don't know until we know what the final method that's in

the process comes out.

MR. PAINTER: Well, regarding the negotiation portion of it, under 7(a)(106) of the law, the Agency has the right to train, not only the right to train, the responsibility, and we continue to be reminded of that sitting at the negotiation table, that that's basically none of our business as the Union. But I'm still curious. I mean we're not in a negotiation setting. So that being the case, it's none of my business at the negotiation table. It's my business here, and I would like the Agency to explain. I mean have you given no thought to the amount of training that will be given and what type of training will be given to the inspectors?

MR. SMITH: I can only answer that now that they will be equipped to do their job, to carry out their method and to report the information through the systems in order to be able to carry that out, whether that is one day, one week, two weeks, I can't sit here and tell you today. You will, before we got to implementation, know that.

MR. PAINTER: But you don't have anything

now to say that we have this amount of time scheduled?

MR. SMITH: We're still -- again, we will share that -- we will get that information back to you if you need an exact timeline.

MR. PAINTER: I understand that, but you don't think the rest of the people here would be interested in knowing how the inspectors that's going to work in their facilities are trained?

MR. SMITH: And again, we've committed, I just said, I'll say it again, they will know how to do their methodology. They'll know how to apply it. They'll know how to report it. They'll know how to -- they already know how to actually do the inspection procedures. They already know how to document noncompliance. They already know how to verify HACCP, SSOP, OCP, sanitation performance standards regulations and since this only applies to processing, there is no slaughter involved. So they have all those requisite skills that they have been trained up to six weeks on already, and so now we're talking about how do I get once a month, my schedule

or the list of activities to be done, we're going to train them to do that. Again, any questions they would have on reporting information, any and all of that will be in the training program.

MR. PAINTER: Two weeks of HACCP training, three weeks of FSRE does not add up to six weeks of training, and that would be six weeks of training since 1998. Thank you.

MR. TYNAN: Thank you, Stan. Jenny, identify yourself again and ask your comment or ask your question or make your comment.

MS. SCOTT: Jenny Scott, GMA/FPA. A question for Charlie, with respect to the NRs and how these regulatory citations are categorized. Do you plan on doing a QC review of this or a validation and adjusting some of these? Let me point out a couple of issues.

Hermetically sealed, contaminated containers shall be examined, rehandled under FSIS supervision, 31814.C. That's for red meat, beef. That's a 3. The same provision for poultry is a 2. There is one dealing with lethality of products

produced -- lethality and stabilization processes other than HACCP for cooked poultry is a 3.

The same provision for beef is a 2. Foreign material, foreign material per se is not necessarily a food safety hazard. It's really dependent upon the nature of the foreign material and maybe someone needs to look at how you might categorize certain foreign -- hazardous foreign materials would be a 3. Non-hazardous would go somewhere else.

Thermal processing, critical factors in application of the process schedule was given a 2. It seems to me that if you lose control of a critical factor, that more appropriately belongs in a 3.

So I would suggest the Agency may need to look at these and make some adjustments.

MR. TYNAN: Thank you, Jenny. Ms. Buck?

MR. GIOGLIO: Robert.

MR. TYNAN: Oh, I apologize.

MR. GIOGLIO: I want to respond to Jenny. I guess the short answer to your question is, yes, in fact, we're working back through these. These were

done first to make sure that both the meat regulations and then the parallel poultry regulations are, in fact, exactly the same, so that, you know, the same factors would be applied in both cases. Okay.

To I guess your other point, anyone of us can look at any one of these regulations and may come out with a different, you know, opinion than the nine raters here, but that's why we use nine different people with the backgrounds that they had.

But to your first point, yes, in fact, we are working back through that now and the plan is to go back to those same people to go ahead and adjust one way or the other.

MR. TYNAN: Thank you. Ms. Buck?

MS. BUCK: Patricia Buck from CFI. I have a question, two-part question for you, and one is on the nine raters. My daughter, as you know, is involved in statistics and clinical studies which do an awful lot of rating of unusual categories. You have 564 NRs that have got to be weighted. Did you have any training for your nine experts that you used

to rate it, to check if there was inter-reliability, meaning within that particular rater or intra, that's intra-reliability or inter-reliability to check between the nine of them to see if there was a, you know, agreement on their responses to either the questions or to how they would score the questions? So I mean did FSIS pursue doing that type of thing which is standard evidently in clinical trials where you actually go and consult with the experts before you have them rate it so that you can have a certain amount of confidence that they're reliability is at a certain level.

MR. GIOGLIO: Let me address that. You have a couple of points there that I want to address first. The folks that did the ratings here are, in fact, FSIS employees that were selected because of their background and knowledge in working with the regulations.

MS. BUCK: That's wonderful, but did you go to this step to do this type of reliability rating?

MR. GIOGLIO: We did provide them with the criteria, okay, with the criteria and had worked

through with any of them, with some examples that senior management had selected as far as being examples of the types of regulations that would fall under each one of the categories.

MS. BUCK: With all due respect, now I'm in the category where I'm starting to lose confidence because I'm not a statistician, of course, but it seems to me that what is being referred to here is something that's done a little more in depth like what you would do for a clinical trial if you follow my meaning. And I would hope that FSIS, since you're NRs are such a huge and important factor would have this type of research behind it before you would go further down the line. Okay.

The other question I have which is probably as important, you have these things rated zero, one, two and three. Now as was pointed out to me, the difference in those violations may not be weighted as clearly as what FSIS has expected that they weighted them. The difference between a 0 and a 1 rating is infinite percent if you follow that. But the difference between a 1 and a 2 rating is 100 percent,

and the difference between a 2 and a 3 rating is 50 percent. So as you keep going up your scale, you may not be giving a full weight to the citations simply because you've included I think zero in there. I'm not a mathematician either. Okay. But this is one concern that has been raised by the people who do know this that they are concerned that FSIS may not be giving the full weight to the most serious problems. And we would like you to take that into consideration when you are putting your scale together. Thank you.

MR. TYNAN: Thank you, Ms. Buck. Ms. Nestor.

MS. NESTOR: Felicia Nestor, Food and Water Watch. I had a similar question to Jenny Scott's and to Pat actually.

A lot of these particular regulations are very similar. Like you have SRM regulations in category 3 and you have SRM regulations in category 2, and, you know, the 416 and 417, I mean I was reading through those regulations. They are very -- there's a lot of minutia you have to know to know

whether you're hitting 417.2(c) or 2(d). Have you done any checks to make sure that your inspectors, that there will be no variation whatsoever on the way inspectors are going to assess what a violation is, which category it belongs in?

MR. GIOGLIO: You're asking a question at the field level, the inspectors -- okay.

MS. NESTOR: How usable are these categories?

MR. SMITH: Again, the inspector will be using the methods that they've been in 5000, on how to verify the HACCP system and then how to determine noncompliance. Their instruction now has been when they find a noncompliance, to document the regulatory site. Then the system takes over from there on the value that's been assigned to it. They're responsibility is verifying regulatory noncompliance, not to assign weight.

MS. NESTOR: I didn't ask about assigning weight. I asked what category it's in, whether it's a 417(c) or a 417(d)?

MR. SMITH: And I believe that the training

they've received in 5000 and FSRE on sanitation, raw, ready-to-eat and shelf stable, provides them with that background and knowledge.

MS. NESTOR: You believe that. Have you done any study to determine if it's correct?

MR. SMITH: We evaluate our training constantly. Training is a condition of employment.

MS. NESTOR: This particular -- on this particular -- gee, Bill, you know, I'm sorry. I really just don't want double talk. I'm asking you, have you done this specific assessment with regulations and your workforce? You're putting out these 500 some regulations, you are categorizing the NRs by them. I am asking you, have you done a survey, have you done tests to find out that these categories are usable by your inspectors and that there is not significant variation in which regs they're citing?

MR. SMITH: Okay. Again, I am telling you that they -- we know through supervision, management controls, their training, training is a condition of employment, that they're trained to identify the non-

compliance and document that and apply the regulatory site. They do not have to assign those values.

Can they determine a HACCP system failure? Yes, we have plenty of experience in that.

Can they determine if there's direct product contamination for a sanitary noncompliance? Yes, they can do that and have demonstrated that on an ongoing basis.

MS. NESTOR: Well, that still doesn't answer my question.

MR. TYNAN: May I interrupt just a second. I saw Mr. McKee get up. Mr. McKee is with our Association of Technical and Supervisory Professionals. He's also one of our field supervisors in California, and so apparently he got up with --

MR. McKEE: Well, perhaps we can help a little bit, Felicia. We correlate with our people on an ongoing basis. Frontline supervisors are out just about daily into the plants. We review the work the inspectors do. We compare the write-ups and the NRs to the regulatory citations, and that's also an

activity that's conducted monthly through all of our district offices. So there is very strict oversight and comparison between the content of a NR, the actual finding, and the regulatory site they choose to support it.

MS. NESTOR: Okay. That might be sufficient. I'm not sure. But I mean, let's face it, the OIG and GAO have gone out there and found tremendous variations between one district and another about what they're understanding of huge policy issues are. So I mean I'm talking about the minutia here. I wouldn't, I wouldn't assume that the FSIS field gets it better on the minutia than they do when they can't keep the large policy issues straight, but --

MR. TYNAN: Felicia, I'm going to ask you, there's a gentleman that's standing behind you and he's looking real tired. So we don't want him to -- come on up.

MR. SMITH: Let me just add one thing. We know we need to look at these things as part of the evaluation package of the implementation of this

system, and we will certainly -- this is one of the critical factors that we'll be looking at in that evaluation.

MR. SEWARD: Skip Seward, American Meat Institute. Bill, I know this issue has come up before. It's similar, and that is the training issue and the consistency in the field and by and large your inspectors probably do an admirable job, but the quarterly enforcement report are the only data I know -- I'm aware of that are public data that illustrate that, you know, there are issues out there and NRs get appealed and they get rewritten. So there are some data out there that suggests that, you know, they have a tough job. And so I would encourage you, like the other folks have, to work hard on the education piece and provide that to them.

My question is, on the drop-down menu that they have to select from, will all of the regulatory citations which have been identified to be associated with that be randomized in the drop down menu?

MR. GIOGLIO: No, Skip, they're not randomized. The, the regulatory sites are, in fact,

associated with a given PBIS procedure.

MR. SEWARD: Right. But within that drop down menu for that particular procedure --

MR. GIOGLIO: I believe they are listed --

MR. SEWARD: Alphabetically or --

MR. GIOGLIO: -- in the order of --

MR. SEWARD: Numerically I heard back here.

MR. GIOGLIO: Yes, numerically. So that if the inspector knows he or she is looking for a given regulation which is going to what Bill has been saying, they've been trained and through --

MR. SEWARD: It's driven by their normal practice. Okay. Thank you.

MR. GIOGLIO: Exactly.

MR. MICHAEL: One more question and then actually I have an e-mail question that came in from one of the folks on the phone.

MS. NESTOR: Okay. I know we're on this topic until 12:45. So -- Felicia Nestor, Food and Water Watch. Bill, I asked you before about whether you've done an assessment about whether the inspectors think that the NRs reflect the conditions

in the plant, and you gave me an answer that the circuit supervisors go out there and management controls and they verify, blah, blah. Now here's the issue. Have you gone to the circuit supervisors and asked them do these NRs reflect the condition in the plant?

You know, if you were to tell me that your circuit supervisors could come to you and tell you, you know what? I'm short 25 percent of my inspectors, and we can't do the work we have to do with the budget that you've given us and you would make an adjustment based on that. Then I might say your circuit supervisors could assess that. But basically you have told them you will get done everything you need to do given the limitations, and we don't want hear if you can't actually do the job.

So my question is, have you gone out and done the assessment? Have you asked them? I know of EAIOs that say they go into a plant and the NRs in the plant do not at all reflect the condition of the plant. You have tremendous variation here, and I just wonder what have you done besides assume that

your system is working properly. I mean this is the same issue we have with daily inspection. You assume that plants are inspected on a daily basis, and you publicly state the plants are inspected on a daily basis, but you refuse to record whether plants are inspected on a daily basis.

MR. TYNAN: Ms. Nestor, I think you've made your point. Bill will respond.

MR. SMITH: Yes, I mean a number of things again. We ask our people, whether it be inspectors or supervisors to again prioritize their work to get the most important things done if they have a shortage situation. And that has been the standard direction to people for a long time.

We changed our supervisory system so that we could have a review system that actually looks at each and every one of the components of the method, was the method applied right? Was the decision making based on the applications of that method right to determination of compliance? Was it documented properly or not and with the right regulatory action? That's been standard practice in the last three

years. In the last two years, field operations has spent hundreds of thousands of dollars in being able to collect that information and set performance criteria for things like HACCP, SRM control, sanitation, so that they can get information at all levels of the organization so they can make a determination from a management control standpoint whether things are meeting the expectations of the organization.

Now there's been quite a commitment. If you're asking how do I know their assessment, all I know is that the tools are in place. They're collecting the data. There is a recognition that if somebody gets sick in the middle of the day or sick in the morning, we have to double assignments. Yes, a lot gets done then, you know, four establishments go to six establishments because you're doubled up. We know we've prioritized for them to do the food safety and not necessarily some of the other things, and what we use as our supervisors to see that they're making those right choices. That's what I can tell you exists today.

MR. TYNAN: Okay. I have two questions from the phone. If you don't mind, let me start with those. I have one from Dr. Rex Holt with our Georgia State Program, and he has a comment and a question.

It's too bad there is a resistance -- there is such resistance internally and externally to RBI. Dr. Holt points out, Georgia, as a state programs, could implement in selected establishments very easily.

His question for the group, is there any interest in including either state plants or TNA plants. Georgia does not have a unionized workforce in your initial plants. And that's his question. I'll turn it over to Bill maybe for a quick response.

MR. SMITH: We have an interest and again, we need to learn from this experience and everybody's telling us we need to take small steps. So that's the 30 prototypes, learn from that and then we expand from there. I'm not sure -- I don't have the 30 prototype locations, all the plants that are in there. So there may be a TNA plant already in it.

MR. TYNAN: Okay. Thank you, Bill. And I

have another question, an e-mail question that came in from Dana Vetter who is sitting in for the NAFE today. She has three questions or he has three questions. I'm not sure of the spelling.

Considering that the field level supervisor will have to have biweekly work unit meetings in these prototype plants, participate in training and insuring individual inspectors understand and implement this system, perform increased data analysis of PBIS to insure NRs are being cited appropriately, and therefore weighted properly, has the Agency considered the effect that this will have on already overburdened field level supervisor position? And I may ask Mr. McKee to respond to that after Bill takes a crack at it.

MR. SMITH: Yes, we are aware that we ask a lot of our frontline supervisors and a lot of what we're trying to do with the data systems is provide them information so they can collect information, and make decisions before they go out and have to interact with the people they direct. So we're constantly trying to improve that interaction.

We know there's additional work. I believe some of the things the districts have been doing for a number of years is take the administrative workload off the supervisors so they can spend more time doing this and my understanding is that that is also underway.

MR. McKEE: This is Bob McKee again. What we really experience out there with the teams is that it's a little different type of oversight, but we're actually getting help from within the team with data collection, things like that. As we work with the team and they become more efficient at it, it's taken a little of the burden off. So while it may look a little different, we get support from the Agency in terms of administrative reduction, things like that. Hopefully it's all going to work out, and I think it's heading in a good direction.

MR. TYNAN: Thank you, Bob. There was a second question that Dr. Vetter had. How will or will linkage affect weighting of NRs? Will linkage be a factor in RBI? Does anyone want to -- Bill.

MR. SMITH: Linkage plays its critical role

in making determinations about enforcement action. It does not have a role in this calculation.

MR. TYNAN: Okay. And the third and last question from Dr. Vetter is not all regulations can be cited in the drop down list. For example, 416.1. Will this be included in the drop down list as RBI comes into play? Charlie, can you --

MR. GIOGLIO: I guess off the top of my head I'm not exactly familiar with the entire list or 416.1.

MR. TYNAN: You don't have all 546 memorized?

MR. GIOGLIO: Not memorized exactly, but I will say we do have a system set up to, in fact, update that list as we need to. So that as, you know, either new regulations are promulgated or potentially even oversights or whatever it happens to be, are brought to our attention that a given regulation, in fact, need to be cited under a given PBIS procedure, those are then called to our attention and then we can add those into the system, as well as we threw in those that are, in fact, no

longer applicable for any given reason can be dropped out. So it's not a static list that we expect to be, you know, 564 regulations, you know, for eternity.

MR. SMITH: Just for the record though, Robert, on that one, 416.1, if they don't have it, they don't operate because that's a requirement to have a SSOP, and no plant in this country can operate without a SSOP.

MR. TYNAN: Okay. I didn't have the 460 some odd -- 564 memorized myself. Thank you, Dr. Vetter, and thank you, Dr. Holt for that, and I'm going to turn it back over to questions from the audience. I think, Mr. Waldrop, you were next.

MR. WALDROP: Chris Waldrop, Consumer Federation of America. In response to Felicia's concern, Bill had mentioned about how that was one of the issues you were evaluating, you were looking at. I want to know if the Agency has an evaluation plan for all of RBI, to look at all of these different issues, you know, complete with your objectives up front so kind of we know how to measure the success of this plan and also know, you know, how we're going

to evaluate all these different elements that are being put in, and if you could share that with all of us.

MR. SMITH: We're developing the plan now to accomplish exactly what you're saying, and I don't know how we could not share.

MR. WALDROP: And will that be shared before the implementation of the pilot?

MR. SMITH: Yes.

MR. WALDROP: Okay. Thanks.

MR. TYNAN: Ms. Buck, I think you were next and then we'll go over here to you, Stan.

MS. BUCK: I just -- first of all, in response to the gentleman from Georgia, I think that all of us in the room here are very interested in risk-based inspection, and I don't think that there's a sense of resistance for risk-based inspection. I think it's more a question of how we're putting it in place. So I think that all of us here, industry, consumer groups, everyone, FSIS is interested in risk-based inspection because we have to do something to meet the challenges of providing safe food to a

growing and large population. So while I understood his comments because we all seem to be taking negatives here, I think we are all interested in risk-based inspection.

And I'm really here just to give a little -- I promised my daughter I would ask this. Last October, we had two days to discuss two papers that FSIS put out. You've given us four hours to discuss a lot more information that is much more complex than what we had before. I don't know if this particular four-hour session is enough to resolve all of the issues. In particular, my daughter is concerned with there does not seem to be a valid statistical justification for the algorithm that FSIS has developed. We would very much like to investigate further with FSIS, and I've already asked this before, and you responded that you would provide additional time. In particular, Barbara would like to include people like Joseph Glover from the Economics Department of USDA and also Beth Johnson if that would be possible.

In conclusion, I think that what you are

trying to do here should be very, very much applauded because I see this as a positive investigation into the next steps that FSIS has to take in building risk-based inspection. However, this is not enough and I hate to keep going back over and over and over again, but I do not see with all due deference to Dr. Raymond, how we are going to put this in place starting in July until we resolve some of these major issues. Thank you.

MR. TYNAN: Thank you, Ms. Buck. Mr. Painter, if you would introduce yourself again.

MR. PAINTER: Yes, Stan Painter, with the National --

MR. TYNAN: Not that we don't know who you are, but --

MR. PAINTER: I'm telling you. Stan Painter with the National Joint Council. I need a clarification on the question that came in from Dr. Holt. Was that Dr. Christian Holt that used to be an FSIS employee?

MR. TYNAN: No, it's Dr. Rex Holt from the State of Georgia.

MR. PAINTER: Which used to be a circuit supervisor, that was a FSIS employee in the Atlanta District.

MR. TYNAN: As long as I've been in the Agency, I couldn't recall whether he is or he isn't.

MR. PAINTER: He was a circuit supervisor in the Atlanta District, and was a FSIS employee.

Regarding the comment regarding the frontline supervisors being hands on and what have you, take a survey of your second and third shift processing inspectors and ask them how many times they have saw their frontline supervisor in a year? When your frontline supervisor says swing by here on the way and we'll do your progress review at McDonald's or swing by here and I'll meet you at a gas station, and we'll perform your progress review or your rating on the hood of the car, you're not seeing that supervisor. So supervisors are, especially on third and second shifts, are not visible to the inspectors in these processing locations. Thank you.

MR. TYNAN: Thank you, Stan. And I'm going

to let Ms. Mucklow have the last question, comment for this period.

MS. MUCKLOW: I always like to have the last word. Thank you.

FSIS is a billion dollar program almost, give or take. It impacts the livelihoods of a multibillion dollar industry, and I just want to say again as I said at our last meeting, that the interactive process that you have set up to develop risk-based inspection is appreciated, and Ms. Buck just applauded the effort to reach out.

I will also tell you that if you had solved the inconsistency problem, there are several of us in this room that would be unemployed. We earn a living finding your inconsistencies and I see no threat to our future employment.

(Laughter.)

MS. MUCKLOW: We want to work with you in this process because we have a self-interest to solve the problem. Will it be solved? Not in my lifetime, and I plan to live quite a few years yet. You haven't fixed it in the 48 years I've been here, but

you've got a heck of a lot better, and I have to applaud that. And, sure, I can pick problems with algorithm and so on and I'm not a statistician and not that good at that. We'll work them out. I know we will but you are -- you've opened yourselves up to work with us, and for that, we appreciate it. Thank you.

MR. TYNAN: Well, thank you for that nice closing remark.

I think we're at a point where we're closing out this portion. I think it's 12:45 in the agenda, and I believe the next speaker is Dr. Goldman for some discussion of next steps.

DR. GOLDMAN: Thanks, Robert. I really want to thank all of you. I think we are between 50 and 75 percent of the way toward a successful meeting, and I say we're not 100 percent because you've given us a lot of work to do. I'm very impressed with some very thoughtful and constructive questions and comments. And now we're on the hook to respond to those, and we'll do that. We didn't come here to hear ourselves talk, that is FSIS. We came

here to hear you engage with us, and I think the fact that you're here after you were here in October, says a great deal that you are indeed, as we've heard from several speakers here toward the end, committed to helping us, as we've asked you to do, to make this the best system that we can. So I really do appreciate that. It makes a difference as we move forward.

I know sometimes you didn't get an answer to your question or the answer you would have liked to your question, and I think you will all appreciate that sometimes we -- in whatever we do, you can't anticipate all the questions you're going to get. You can't possibly do that. That's another reason why this kind of a forum is very constructive and helpful to us, but as I said, we will get answers to your questions. We will get responses to your comments.

There will be a transcript available as was said earlier. It'll be a matter of some days, I think, but just a few days, and then as Robert said, I want to reiterate, we really want you to look at

the transcript, want you to share the transcript with people who weren't here or calling in, and we want to get some further comments, and we want to keep that period open for about 30 days. We will work through those comments as we get to them.

So I do appreciate exactly what you've attributed to the success of this meeting here.

As I said at the beginning, this is the first in a series of technical meetings. We'll continue to need your participation in the meetings that we have lined up. I want to spend just a couple of minutes here to kind of outline some of those meetings.

We have one coming up later this week, and so hopefully many of you can attend, or if not, you can send representatives who can represent your interests and concerns.

The first of the meetings that's next in the series is a technical summit on foodborne attribution. Some of the comments that Carol Tucker-Foreman made, get right at the attribution issues. So for those who were interested in her comments, I

think underlying her comments at least in part were concerns about attribution.

This meeting will be slightly different in a couple of ways. One is although it will be here I think in this room, in fact, it'll be a long meeting. So brace yourself. It's going to be eight hours. It's going to be roughly divided into two parts. You're going to hear from a variety of speakers about what they think attribution is and how it might be used and then in the second half of the meeting, we will hear folks presenting -- scientific representatives presenting on their work, their own work on attribution and I hope you'll be impressed as I am in looking at the agenda. There are people who have spent several years on this issue. That should give you an indication about how complex the attribution issue is, and again, we need your assistance and contributions to that meeting.

Just briefly, there will be a third meeting in this series on April 25th. As Dr. Raymond pointed out about halfway through this meeting, much of the comments at least early on were about volume. That

will be a whole meeting devoted to the volume issue. We've already heard a lot today that will help us hone our thinking a little bit about the use of volume data.

The fourth meeting will be on the use of industry data in the risk algorithm. We've had a few brief discussions about that as we've -- in the various meetings, but we'll devote sometime there to the pros and cons of including industry data, some of the concerns that there may be about including industry data from various angles. So I'll invite you to that meeting as well.

The last in the series of meetings, again as was mentioned, is the meeting on expert elicitation. As was noted, the expert elicitation is due back to us, in its final form, the first week of June. We will have a meeting soon thereafter to again engage you, our stakeholders, in a discussion of the results of that expert elicitation and how we might employ that in the algorithm. We're still working out the details in terms of the time and date of that meeting. We'll continue to keep you posted

as we do through our website, constituent and other fora.

With the exception of the meeting concerning foodborne attribution, we will also offer a one or two or sometimes separate page issue paper on each of these topics, so that it will help you to focus your thinking in advance of the meeting, and it may elicit some questions from you as you read those papers, and hopefully you will bring those questions to the meeting.

As I said, we'll accept comments on each of the meetings for 30 days after the completion of the public meeting.

At the last meeting of the National Advisory Committee on Meat and Poultry Inspection, which was to remind you in October of 2006, it actually followed the two day meeting we had that RESOLVE hosted, we asked the members of that committee to begin looking at risk-based inspection slaughter operations. This summer, we plan to hold a public meeting, again the date will be determined in the future, but likely in July, in that timeframe,

and we will have a public meeting again to engage a wider discussion about that issue and to get your feedback on the plan that we have as of that time.

Risk-based inspection in processing establishments has benefited from your input to this point. Obviously not only your input and your opinion, but the expertise represented collectively by those of you in the room. We will continue to accept and incorporate this input as we move along. You've heard that over and over. It's important for us to say that over and over because we do mean that.

We will continue to use RESOLVE, the third party contractor, who will help us to assess and take in stakeholder input as we continue our deliberations on RBI processing, and we'll also continue to use them for the RBI and slaughter proposal, which is up and coming.

I think you can take away from today that we have been listening to your comments. Again, you have my commitment as the Acting Administrator to continue to listen to those comments, to respond to your questions. I know you know that you have the

commitment of the Under Secretary, Dr. Raymond, to do the same, and as we move forward, we will continue to need the input of all of our public health partners, consumer groups, the industry from whom we didn't hear a whole lot today, and our own employees. We need those three groups to continue to help us make this RBI system as good as it can be.

So with that, I will conclude and thank you for your participation.

MS. BUCK: I do have one question.

DR. GOLDMAN: We do have three minutes, so in fairness to you. Yes.

MS. BUCK: At the last FSIS meeting with the Safe Food Coalition, I asked about the timeline of these meetings, and you said to me, Pat, we'll discuss that today. And I just would like to know, this timeline that you're putting out of these meetings backed up one right after another, is onerous and I get the feeling that it is almost too much for anyone of us, whether we're in industry, FSIS or the consumer groups to manage. Has there been any thought to expanding this timeline out just

a little bit? Thank you.

DR. GOLDMAN: Well, I'll respond in part to your question. This original set of meetings, excluding the expert elicitation, was set up with the idea that we would begin implementation in April. So we started to set those dates sometime ago. So some of those dates have been set. We've got people committed to presenting data, people committed to coming in from out of town, and the contracts with the University to have the meeting space. There's lots of things that went into place in terms of scheduling those meetings.

I will reassure you though by saying that you've heard earlier, at the very beginning, that we will not begin implementation until after the last of those meetings. So whereas we've said you'd have 30 days to comment and lots of opportunity to read transcripts, come to meetings, to have other meetings with us, you can be assured that until we have that last public meeting on expert elicitation and have the comment period, we've said we won't be ready to implement. So you've got that time period and you

can, you know, once we set that meeting, then you'll know exactly what the lay of the land is. So I appreciate your comment.

MS. TUCKER-FOREMAN: Carol Tucker-Foreman with Consumer Federation. A very quick question please. Did I understand you to stay that you would have completed the expert elicitation in May?

DR. GOLDMAN: It's underway in April, in this month. I'll let Matthew give you the details of that.

MR. MICHAEL: The contractor is still recruiting experts now, and we're finishing up the instruments. The contractual timeline calls for it to be conducted this month, I think a little into May. The contractor is to deliver the results as well as the contractor's analysis, June 8th I believe.

MS. TUCKER-FOREMAN: So there is no opportunity for public comment on your methodology in this one? You've already got it or is there still time to have public comment on the methodology?

DR. GOLDMAN: Well, there may be time in

certain venues. One of the concerns, and Matthew can elaborate on this, the idea if you put the instructions and the methodology out, that those who are actually asked to be the experts may be influenced by having that out in advance and for all the stakeholders to know that it's out in advance. So we're just concerned about the bias that might be created by putting all of that out, but there may be some other venues in which we could have that discussion.

MS. TUCKER-FOREMAN: There's not a bias I think if you make the name of the experts available at the same time. Then everybody would have the same information, wouldn't they? We don't know either who your experts are or what the methodology is. If they were both out there, then everybody has the same information. Are you afraid I might influence an expert? Heaven forbid.

MR. MICHAEL: We are committed to putting the names of the experts and their comments, although not associated with the individuals out after the process.

MS. TUCKER-FOREMAN: Well, I would really urge you to make the methodology available. I think you could have avoided some of the problems with the 2005 expert elicitation if you had gotten it outside the closed box of FSIS. That's number one. Number two, I find it really amazing that you done this methodology and have really just come close to finishing before you had the food attribution meeting at which -- as I've gone through, you're going to get a lot of comments about the best way to use that expert elicitation, but you've already decided how you're going to use it. You've decided how you're going to do it.

DR. GOLDMAN: Well, the attribution meeting is this week.

MS. TUCKER-FOREMAN: You haven't decided how you're going to use that.

MR. MICHAEL: I will say that the instrument we're working on now with the contractor contains many changes that came about as a result of comments at the October meeting, comments after that, comments from the Advisory Committees and now

comments from our peer reviewers. So --

MS. TUCKER-FOREMAN: And are your peer reviewers from outside the Department of Agriculture this time?

MR. MICHAEL: Two are and two are not. But none are in FSIS.

MS. TUCKER-FOREMAN: Outside the Department helps. It really would be nice if you had the opportunity to hear from the widest range of people about the nature of the methodology. It might reduce the number of people who say, you didn't get this one right either. Thank you.

DR. GOLDMAN: Thank you. And thanks again to all who participated today.

(Whereupon, at 1:00 p.m., the meeting was concluded.)

C E R T I F I C A T E

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

USING THE RISK ALGORITHM
IN DETERMINING THE CATEGORIES OF INSPECTION
IN 30 PROTOTYPE PROCESSING PLANTS

Arlington, Virginia

April 2, 2007

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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Andy Vogel, Reporter

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