UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

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RISK-BASKED INSPECTION

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EXPERT ELICITATION

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June 26, 2007
9:00 a.m.

USDA
Jamie L. Whitten Building
12th and Jefferson Drive, S.W.
Room 107A
Washington, D.C. 20250

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FSIS, OPAEO

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I-N-D-E-X

I-N-D-E-X

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

(9:09 a.m.)

MR. TYNAN: I'm sorry to be starting a little bit late. We had a couple of things we had to work out in terms of our sound system.

Welcome to the FSIS meeting regarding the expert elicitation. My name is Robert Tynan. I'm the Deputy Assistant Administrator in the Office of Public Affairs, Education and Outreach, and I'm going to be moderating today's session. I think for some of you, you're probably getting tired of seeing me, it's been so many times I think now that I've been moderating meetings.

In addition, to the audience we have here in the room, we also have folks on the telephone. We, as a practice, have been including folks on the phone, and so we'll be going to them for questions and comments at different times during the session.

For those of you that are on the phone, I want to remind you that all of the material for today's meeting, the handouts are posted on the FSIS website, and there's a link on the front page of our

website that you can get the press release. There's a link there, and it will take you to the handouts for today's meeting. Alternatively, you can simply type in risk-based inspection on that home page and that will take you there as well.

I want to take just a minute to walk you through the agenda, and talk a little bit about what we're going to be doing today.

We'll have, as you can imagine, our normal welcoming remarks at 9:00. Then we're going to follow by some remarks by Dr. Raymond. Then we'll have an introduction to the 2007 elicitation by Matthew Michael in our Office of Program Evaluation, Enforcement and Review. We'll follow that by discussion by Dr. Mary Muth from Research Triangle Institute. Did I get that correct?

DR. MUTH: Yes.

MR. TYNAN: And she will be talking a little bit about the RTI process for the expert elicitation. We'll have an analysis of the responses by Chuanfa Guo. He is with our Office of Public Health Science, and he has a Ph.D. in Biostatistics.

Is that correct, Chuanfa?

DR. GUO: Yes.

MR. TYNAN: Okay. He has several Ph.D.'s as well. Is that right?

DR. GUO: Yes.

MR. TYNAN: And then last but not least, we'll have the elicitation and its role in risk-based inspection and in the Agency in the future. And that will be Dr. Dan Engeljohn who is with our Office of Policy, Program and Employee Development.

We'll have comments after each of those presentations for just a few moments, and then we'll have public comments probably about 11:15, and then we'll open it up for general remarks on everything that's going on.

And then last, but not least, we'll have closing remarks by Dr. Goldman.

So that's sort of our agenda. Any questions at this point on how we're going to proceed?

(No response.)

MR. TYNAN: Okay. I should point out that

the focus of our meeting today is the elicitation. So I know that there are other topics that may be touched on during the day, but we don't plan to discuss those in depth. So everything is going to be pretty much focused on the elicitation. Things like the algorithm or volume, we touched on it at previous public meetings. If you have specific comments or you want to go into those in detail, I would remind you that we have a risk-based inspection e-mail box that you can send some more lengthy comments to that.

Before we start, I also want to mention that I'd like you to, when we do have the comment periods, the shorter comment periods and the public comment period at the end, if we can make the comments as brief and concise as possible. We have a lot of people here and a good number of people on the phone, and so we want to give everybody an opportunity to make some comments.

For the post-presentation part, we're not going to impose any limit, but when we get to the public comment period, I'm going to impose probably a two minute timeframe for comments. So you'll have to

make it short and sweet. That's not because we don't value your comments. Again, we want to hear all of the important things that you have to say regarding the elicitation. Point of fact, as I say, we do have a number of people. So we want to give everybody an opportunity to comment. So I may stop you in mid-sentence and remind you, you have to close out pretty quick. So again that's not because we don't value your comments. It's just a time issue.

We'll have a microphone when we get to the public comment period that we'll be circulating around, and we'll have a couple of our staff that will be taking that for you.

I'd ask you when you get to the public comment period, to state your name and your affiliation, and that will help our transcriber. The meeting today is going to be transcribed, and we will put that public record up on our website when we have that back, probably a couple of weeks, maybe three weeks after today's session.

We'll also be alternating between the folks here for questions and comments with the folks on the

phone. So the folks on the phone should be thinking of their comments as well.

We also didn't build in a specific break time as you can see on the agenda. So we'll just leave it up to you all to take a stretch break or grab some coffee whenever you need to. There are restrooms outside adjacent to the patio. So as you face the patio area, on the right is the ladies' room, on the far left is the men's room, and that's a simple right, left. If you know that, we won't have any difficulty.

We also have a small cafeteria downstairs on the lower level that you can either take the elevator down to the lower level or there's a stairway across the lobby.

And that's basically it. So those are sort of the rules of the game, and I'll remind you when we get to the comment period how we're going to proceed.

So with that, I'm going to introduce Dr. Goldman, our Acting Administrator of the Food Safety and Inspection Service to come on up and make some initial remarks.

DR. GOLDMAN: Thank you, Robert, and let me add my welcome to all of you who are joining us in the nearly full room here, and those of you on the phone. I think there are quite a few people as Robert said who have joined us by phone.

I also want to welcome you now to our fifth in a series of technical summits that we have been hosting over a period of several months now on issues concerning our creation of a more robust risk-based inspection system. I am again pleased to see so many of our consumer and industry stakeholders as well as our representatives from our employee associations.

We've got Stanley Painter here on the third row from the National Joint Council of Food Inspection Locals.

We have Frank Bush over here to my left, representing the Association of Technical and Supervisory Professionals.

We should have Pat Basu who was invited to represent the Asian Pacific American Network in Agriculture. He may not be here yet.

And I know on the phone we have Dana Vetter

who is representing the National Association of Federal Veterinarians. So again, I want to welcome all of our important stakeholders.

I want to let you know that today represents another example of how seriously FSIS is taking its invitation early on to listen to our food safety stakeholders, not only using their expertise to further refine, but also to improve this initiative as we go along.

A central component in creating this dynamic risk-based system is to first take into account the relative risks posed to public health by various types of processed meat and poultry products.

FSIS' two most recent expert elicitations to get at this risk posed by various meat and poultry products were both conducted to collect important data on the relative risk of products independent of a plant's ability to control those risks.

You remember the inherent risk is on one side of an equation and the risk control measures are on the other side of the equation that we're using presently.

The format and methodology for the 2005 elicitation received a number of serious criticisms from our consumer organizations. These concerns were taken very seriously by FSIS, as were the possible ways to address them. These points were taken into account as we developed the methodology for this most recent expert elicitation, which is the focus of our meeting today.

There are a number of important changes that I want to outline before I turn the podium over to Dr. Raymond.

The first change was that we made sure that we asked the experts to use a simple scale ranging from 1 to 10 in order to rank the hazard that the product represented. As you may recall in the 2005 elicitation, we left the scale up to the experts and we ended up receiving less usable data in that way.

Secondly, this time we included a category for canned products on the list that we were asking the experts to rank. This helped to insure that this elicitation covered the wide range of products regulated by FSIS.

And finally, we wanted our experts to also look at the hazards these products posed to the most vulnerable populations when it comes to foodborne illness. So we asked them to rank the products by risk of illness per serving posed to at risk populations, such as the elderly or women who are pregnant. This was in addition to their ranking of a risk these products represented to health populations.

These and other changes have all been made in an effort to gather the best possible data.

Your input in today's meeting is important as we work toward our shared goal of protecting the public health and improving the safety of our food supply. I'll look forward to your comments today and our discussion.

And now I'd like to ask Dr. Richard Raymond, our Under Secretary for Food Safety, to provide his comments. Dr. Raymond.

DR. RAYMOND: Thank you, David, and I want to thank you and the Agency for taking the time to outline a few of the insights that we received from

the consumer groups that the Agency has taken to heart in designing this most recent expert elicitation. I believe that our confidence in finished product had been greatly enhanced by everyone's willingness to share their concerns and to share their possible solutions with us.

As we expected, the results of this more refined and more focused elicitation still closely matched the previous rankings. This didn't surprise me at all, and I don't think it surprised very many people in this room, that they would be about the same. After all, I think we all agreed that ground poultry proposes more risk than cooked canned hams.

But as a physician, I also realize that common sense sometimes needs to be confirmed by testing these notions and using science, and that's why we did the two expert elicitations on this area. And it's through this process of testing that we can move from accepted common sense ideas hopefully toward scientific consensus of those that are working with us on risk-based inspection.

The consensus of our experts combined with

research and other empirical data can be used as the basis for the sound policy that we'll be going forward with. This is absolutely critical as we work to enhance our science-based inspection programs to insure the continued safety of the United States food supply.

Everyone here knows that I believe very strongly in the importance of a more robust risk-based inspection system and the public health benefits that such a system offers to us.

I want to ask everyone here today to remember that we're here to focus on the FSIS most recent expert elicitation results today. Today is not the time to discuss some of the subjects that we've had the other technical forums on, but we still welcome your input on those subjects, and you can get those to us by using the FSIS website which continues to receive input.

I also want to thank everyone here today for coming, and I look forward to working with all of you today and in the future as we continue to work to further improve the safety of the United States

supply of meat and poultry products.

It is my sincere hope that after today's discussion about the hazards of the various products that we regulate at FSIS, that we can then begin to focus on the critical work of reducing and minimizing the risks posed to us by those hazards in the plants that we inspect every day as we move risk-based inspection forward in processing.

So thank you for the time and, Robert, we'll turn it back over to you and get on with the program.

MR. TYNAN: Thank you, Dr. Raymond, for your remarks and, Dr. Goldman.

The first presenter we have today regarding the introduction to the 2007 elicitation is Matthew Michael again of the Office of Program Evaluation, Enforcement and Review.

MR. MICHAEL: Good morning. This morning I'm going to talk about the need for an expert elicitation in developing RBI, how we'll use the data obtained through the elicitation, the history of the 2007 elicitation, and a little bit about the

elicitation itself.

There are a number of reasons to conduct an expert elicitation. You might want to conduct one to forecast future events. Maybe to learn about what is currently known in the field of knowledge. Or even to learn how experts make decisions, but the quote referenced here gives another reason, and it applies to why we conducted the elicitation.

The quote is, "Expert judgment is frequently needed to organize qualitative information or mixtures of qualitative and quantitative information into a framework for making decisions."

And it's just this sort of mixture we have in regard to processed meat and poultry products, in regard to the risk to the public health posed by these products. That's exactly what we have.

In some cases we have a wealth of data regarding specific products, the pathogens they might carry and the illnesses they might cause. Consider, for example, ready to eat products and *Listeria monocytogenes*, where we have risk analysis data, paraplin (ph.) modeling data, enough data that we are

able, in fact, to promulgate regulations specific to *Listeria* in ready-to-eat foods, and those are the regulations in 9 C.F.R. 430.

In other cases though, we have esoteric or novel products, the processing methods, emerging pathogens or changes in consumer habits, and we know less about the risk imposed by the specific products.

So because we have this mix of data about the products, an elicitation is what we needed to give us a comprehensive characterization, of the risk posed by all the processed meat and poultry products that we regulate.

The expert elicitations we've conducted allow us to determine the scientific consensus about relative risks from all the processed products by tapping into the collective expertise of the public health community, academia and industry experts. A comprehensive view of risks based on this consensus allows us to more effectively allocate our resources and inspection otherwise toward the products and processes that pose the most risk to the public health.

Ideally, of course, you want empirical data as opposed to expert data or even modeling data. So as science progresses and more data is collected and analyzed, we can refine our approach to food safety and in many places replace our expert data with empirical data.

So what does the expert elicitation provide for RBI? It provides the hazard component portion of the risk-based inspection algorithm.

The hazard component is the relative value for the risk of illness per serving of each category of processed meat and poultry product. And that value is determined by the experts, taking into account the species and animal processed, the type of processing and other assumptions regarding production, shipping and handling that we laid out for them in advance or rather RTI did.

The 2007 elicitation, as Dr. Goldman mentioned, provides us value for both healthy populations, healthy adults specifically and vulnerable populations and as you'll hear in detail from Dr. Muth and Dr. Guo, the 2007 elicitation also

provided attributes and specific illnesses to specific product types.

So the expert values themselves are the hazard component in the algorithm.

The hazard component, and possibly a factor for production volume, together provide an individual measure of inherent risk for all the processed products produced in each official establishment. I say possibly here because, as you know, we've discussed various ways to incorporate volume into the RBI calculation at the last few meetings. I mentioned it here anyway because up until now, inherent risk has been calculated using both production volume and the hazard component, the expert elicitation value.

This next chart which probably looks familiar, this shows you the hazard component and volume up until now are combined to create the inherent risk portion of the algorithm, and the hazard component again are the expert values.

Inherent risk and a value of risk control, that is a relative value representing how well an

establishment controls food safety risks, are combined to give us a score, for lack of a better word, for each plant, a risk in RBI score. That allows us to determine the level of inspection, or intensity of inspection that that plant needs under RBI.

Here's another volume chart, a bubble chart rather, showing how that works. So in short, the hazard component is part of the inherent risk factor, and the inherent risk factor with the risk control factor provide a score, for lack of a better word, the RBI score for each plant. And that score, then tells us what intensity of inspection that plant needs under risk-based inspection.

I'm going to talk a little bit about the history of the 2007 elicitation. In developing risk-based inspection over the last few years, we have conducted three expert elicitations, in 2001, 2005 and 2007.

Back in October, at the workshop, I discussed the 2001 elicitation to show how it led to the 2005 elicitation. In that elicitation, we

categorized hazards using HACCP inspection categories and used separate values for species and processes and we collected less than comprehensive data and some questionable values, and it led us to some major improvements in the 2005 elicitation.

Because that 2001 elicitation was so different, the date it yielded is now inapplicable to what we're doing in RBI. But it's important to mention because it's really part of the evolution of the expert elicitation instruments that we've developed.

There's significant agreement between the '05 and '07 results, and Mary and Chuanfa will talk about that in detail, but I think that agreement shows that we're on the right track in developing elicitation instruments, and this slide really shows that it's been an iterative process over time.

Another contribution to the process has been peer review. We have the 2007 expert elicitation instruments and instructions peer reviewed under the OMB Information Quality Act Guidelines. The reviewers were a senior advisor for

regulatory support, a veterinary epidemiologist, a deputy director for research and senior scientist, for four different agents, the Food and Drug Administration, Environmental Protection Agency, USDA's Economic Research Service and APHIS, USDA's Animal and Plant Health Inspection Service.

Also in accordance with those guidelines, we will be publishing the reviewers' comments and our responses soon. We're working on that now but the comments led to changes to the instrument, and I believe improved it.

Another input to this 2007 elicitation, of course, was stakeholder comment, and we incorporated changes suggested by the stakeholders at the October meeting and subsequent meetings, as well as changes suggested to us by the National Advisory Committee on Meat and Poultry Inspection.

And then here is a list of specific changes that you heard briefly from Dr. Goldman and you'll here again in more detail from Dr. Muth.

One is we specifically recruited experts in three categories, public health, state health

officials, epidemiologists, academia and industry. And I'll note here that, and Dr. Muth will talk about it as well, RTI recruited 45 experts to participate, but ultimately only 17 agreed. And so in order to have equal representation from each group, we ended up with a total of 12 experts in this elicitation. But three groups, that's one of the major changes.

Another that Dr. Goldman mentioned, we included a risk ranking for our vulnerable consumers as well as healthy adults. And a lot of you will recall from the public meetings, that there were concerns about the 2005 elicitation, because we didn't ask questions about severity. And that had been intentional in '05 because it's difficult to ask questions about severity and a way to elicit comparable responses. But more important, there's ample empirical data on the severity and illness.

What we don't have, however, is a risk ranking for vulnerable consumers, and this new elicitation provides that. We asked them to rank the risks per serving for each of the products, not only for healthy adults, but for vulnerable consumers, and

that would be the young, the old, immunocompromised and pregnant women.

Another change, we have a third form in the instrument in the 2007 instrument where we asked the experts to attribute illness caused by specific pathogens to each of our product types. And this gave us some unsurprising results, but useful results, and I think in this form we were attempting to mirror the type of information that was given to us in the RFF, Sandy Hoffman's elicitation that was conducted either last year or this, on food safety. In that elicitation, however, the categories for meat and poultry products were very broad. We asked the same kinds of questions now in this one to our very specific categories, which cover all types of processed meat and poultry and got some good data.

We collected confidence ratings in this elicitation, and again, that tells us a little bit about the quality of individual rankings and a little bit about uncertainty in the rankings, probably not stochastic uncertainty but state of knowledge uncertainty. And again, we took a cue on that one

again from Sandy Hoffman's work. But I will remark that in 2001, we had a confidence rating as well.

And then finally as Dr. Goldman mentioned, we asked about canned product in this elicitation. We hadn't in '05 precisely because in '05 we had no upper bound on the rankings, and we thought that canned product is so safe, relative to the other products, we'll get these skewed ranges. So we just assumed in '05 that they would be the safest product.

So in '07, we asked about canned product, and sure enough, every expert listed it as the safety product. So it was good to confirm that.

Future use of the expert elicitation, and Dr. Engeljohn will talk about this as well. The elicitation results regarding healthy adults from this '07 elicitation could be used in our current RBI algorithm immediately. The data is comparable. Even though it was collected on a slightly different scale with an upper bound, it's comparable type of data and Chuanfa will tell you how he's correlated the two using rankings.

The other data though involving vulnerable

consumers and attribution is more complex, and the Agency is considering ways now on how to use that data in risk-based inspection and, of course, we will welcome comment on that data. Thank you and I'll take any questions.

MR. TYNAN: We have on the agenda as I mentioned earlier, a few minutes after each presentation for some comments and questions. The focus obviously for these small comment periods is the presentation. So what we would like to do now is open it up to the folks here in 107 and then I'll go to the folks on the phone to ask any questions, and Sally and LaVonne have microphones if we -- do we have any questions. Stan, I can see you're on the edge of the seat.

MR. PAINTER: Yes.

MR. TYNAN: If you could state your name and your affiliation that would help.

MR. PAINTER: My question is regarding the testing that was done. You said there was testing that was done in 2001, 2005 and 2007. Let me back up. Stan Painter with the National Joint Council.

I'm sorry.

Where was the testing done in each of those years? What type of product was being tested during those time periods? And what group and/or organization done the testing?

MR. MICHAEL: In regard to the three elicitations, they were all conducted by a contractor, by RTI, and in each case I believe they were letter reviews and peer reviews. I believe we sent out individual instruments to experts and asked them to respond to it with the rankings for each of the products.

In 2005 and 2007, the list of products were essentially the same with the exception being that in '05 we did not include canned.

In 2001, as I mentioned in my presentation, we used the HACCP inspection categories of products and separated those from the species, which caused -- counting and that was the improvement made in '05.

But essentially the way the elicitations were conducted, the three elicitations, was the same. A contractor did it with a group of experts who were

recruited. They were instructed in the methods and in the instrument and sent in their values and then the contractor followed up with them if there were any questions and whether they understood the instructions.

MR. TYNAN: Does that answer your question, Stan?

MR. PAINTER: Not really.

MR. TYNAN: Then you do you have a follow up?

MR. PAINTER: Well, yes, I did. In the original question I asked where were the locations that were tested. I guess I'm alluding to did this have anything to do with the Hemp Project and especially in the 2001 or 2005? Where did you do these tests or where were these tests done?

MR. MICHAEL: We didn't conduct any tests. We just elicited data from experts.

MR. PAINTER: From where?

MR. MICHAEL: From the experts themselves, the individual experts.

MR. PAINTER: Okay. You had to have a

location from somewhere that it came from, did you not?

MR. MICHAEL: Well, that's wherever the experts responded from.

MR. PAINTER: And that's what I'm asking you? Where were they responding from?

MR. MICHAEL: We can elicit the experts and tell you where they work. I mean if they were in industry, academia, public health, so it would be from their offices where they were filling out the form and sending them to us. They weren't in plants if that's your question.

MR. PAINTER: That was what I was getting to.

MR. MICHAEL: Okay. No.

MR. PAINTER: So it wasn't the plants?

MR. MICHAEL: No. No, these are experts from academia, from the private sector and public health.

MR. TYNAN: We can get you a list of their locations if that would be helpful to you.

DR. RAYMOND: Carol Tucker just e-mailed me

and said those that are on the phone cannot hear. The phone connection cuts out about every 10th or so word and the speaker is speaking so softly it's hard to hear when the voices do come through.

MR. TYNAN: Okay.

DR. RAYMOND: So if you, on the phone, let them know that we got the e-mail.

MR. TYNAN: Okay. For those of you on the phone that can hear, hopefully I'm speaking loud enough so that you can hear me, we're going to ask the gentleman, our technician, to see if he can help with upping the sound between us and the telephone. That would be great.

In the meantime, I'll take one more question from here, and then we will go to the folks that are on the phone. Is there another question from our audience here in 107 regarding Mr. Michael's presentation? Yes, Ms. Donnelly. If you'd introduce yourself and your affiliation.

MS. DONNELLY: Nancy Donnelly with STOP. I actually have two. One is one of the points that we brought up in the last meeting was the fact of having

the expert elicitation done as a cumulative group, meaning that the experts would all be there together, where they could then share concerns, questions, ideas, that could be interchanged of information, and I'm curious why the Agency didn't take that suggestion.

And then the second thing is more of a comment. That's the question. The comment is that without getting into the very specifics, I think if FSIS, if they really want to stand true to their position as a public health and safety agency, that they need to put the vulnerable consumer category as the basis of all their decisions for RBI.

MR. TYNAN: Matthew.

MR. MICHAEL: In response to your question, the main reason that we queried the experts individually in '07 was to insure that the data we received would be comparable to '05. We had some other concerns about having them meet in a group. Often when you have a group dynamic like that, you'll have some people who are louder than others, et cetera. It's more difficult sometimes to insure that

you, in fact, get the opinions of each expert. That is a method in expert elicitation. It's probably more akin to a focus group. But the main reason is we wanted to make sure the data we received in '07 would be comparable to '05 to determine whether the data we received in '05 was good, and I think it did.

But we do aggregate the answers we received in '07. We ended up taking median -- short term of those expert answers and we found agreement among the experts. So we did find consensus among them even if they didn't get together to score the products together.

MR. TYNAN: I want to take two quick questions from the folks that are on the phone. Operator, could you query the people on the telephone for questions? Operator?

OPERATOR: Barbara Kowalcyk, you may ask your question.

MS. KOWALCYK: This is Barbara Kowalcyk from CFI. Can you hear me?

MR. TYNAN: Yes, we can. Thank you.

MS. KOWALCYK: I had a couple of quick

comments and a question and maybe it's more appropriate later. I wanted to also reiterate what Ms. Donnelly had said, that if you're going to take the conservative approach of protecting public health, you would want to use the vulnerable population as opposed to the data from the healthy adult risk ranking.

Also I'm a little bit concerned about the poor response rate and whether or not this was consistent with the response rate, if you recall, in 2005 and 2001.

And finally, I don't know if this is going to be covered later, but the expert elicitation is very important in terms of calculating the magnitude of risk because as I understand that's what they're going to be using in the RBI formula. And if you could expand on that a little further, I don't know if that's going to happen later, I can possibly wait if it is, but I just wanted to know a little bit better about how you were going to use the risk ranking in the RBI, because it does matter in terms of what kinds of methods were used in terms of

aggregating and eliciting the information, and what you're going to get out of it, matters depending on how you're going to use the data.

MR. TYNAN: Okay. Thank you. Matthew?

MR. MICHAEL: I think we got a response in 2005, if I remember, we had 23 experts and we recruited approximately the same number, 45 or 50. And this time around, we recruited 45 and we had, in fact, 17 agreed. It's just in order to have equal representation from each of the 3 groups, we had to with 4 from each group and we ended up with 12. So there was a slight decrease from 23 to 17, and then we went down to 12 experts just to get equal representation in each group.

In regard to the magnitude of risk, in one sense, because we put an upper bound, we put a constraint on the answers in 2007, we lose one measure of magnitude. In 2005, the experts could give us a ranking or an estimate of proportional risk, proportional relative risk among the products. In one sense we agree with that, but because we now have the ranking for the vulnerable populations, I'm

not a statistician, but I'm assuming we can compare those rankings with the healthy rankings, and with all of our empirical data, we can maybe get some kind of an estimate of magnitude of risk. I'm not quite sure what you mean by magnitude, but we can certainly compare that data and come up with various types of conclusions that we wouldn't be able to come to with just one of the instruments.

MR. TYNAN: Okay. Thank you, Matthew.

One more question from the folks on the phone, and then we'll go to our next presentation. Operator, is there another caller that has a question?

OPERATOR: Yes. Carol Tucker-Foreman, you may ask your question.

MS. TUCKER-FOREMAN: Thank you. My first is a comment. I am having a terrible time. One microphone basically cuts out about every third or fifth word. And so I have very little understanding of what was done in the last presentation. There's one microphone that cuts through and one speaker very loud and clear, but we'd ask everybody to speak up

and I think you need to have your technical people check. I'm on a high quality landline and we're having real problems here.

MR. TYNAN: Okay. We'll do that, Mrs. Foreman. Thank you.

MS. TUCKER-FOREMAN: Let me ask my question please. There's been a couple of comments about the nature of the elicitation. It is I think much better. However, there is still a problem with the composition of the group. FSIS defines academic as only those people who are involved in meat science and food technology, and public health experts are only those people who work in the Department of Public Health.

You have excluded anybody who is a public health academic. There is no one on here from a school of public health. These people bring a very different perspective to looking at these issues.

In addition, by deciding it as somebody who has an understanding of meat process, you are including a lot of public health experts and orienting the elicitation to those who come into

problems from a point of view of what is it reasonable to expect from the industry rather than what is necessary to protect public health which might require major changes in the process. If you had asked this group of people in 1992, they would have told you that *E. coli* present in the intestinal track of all bovines can't be controlled unless the consumer cooked the product well done. That obviously reduces the assumption of risk here. When you ask people, you begin a catch-22. But I'm really very disappointed and I think that it really handicaps the project that you have no people in public health, only health department people who are not involved in public health research.

And the second one is the vulnerability still does not consider the severity of illness and all of us have pointed out again and again and again, that this public health project has to talk about the severity of illness. And in order to keep it parallel to 2005, you excluded that and -- The 2005 effort was admittedly very broad, and now I think that you have made this one substantially --

MR. TYNAN: Thank you, Mrs. Foreman.

MR. MICHAEL: Let me just respond by saying that we have a standard pool of experts, the type of experts and we have seen significant agreement in the answers among those experts. Could we expand it further? Sure. Sure, we could. But I think we made a real leap here by including the state epidemiologist and seeing comparable answers. We've seen some confirmation of our original data.

In regard to talking to people, I understood your comment about what they think should be done as opposed to what the state of knowledge is. That really wasn't what we were intending to do. We're trying to collect scientific consensus on risk posed to consumers by various products, not their opinions on how we should deal with them. We're going to make those decisions, but we're going to make it using a variety of data including the data we elicited.

And then the final comment about severity, the main reason we didn't use severity in '05 and again in '07, is because we have ample empirical data

on the severity of illness. And we are going to use it in risk-based inspection, and we are going to use the inspection. And we already do make decisions about inspection based on what we know about the severity of illnesses. We don't need to do an expert elicitation on severity because that data would be of a lesser quality. We have real scientific data on severity.

This time around, of course, we did ask for a ranking on vulnerable consumers, and that gives us some new valuable information and it's relative to severity, because often vulnerable consumers have more severe illness. So it's not completely unrelated. Just because we didn't ask about severity in '05 and '07 in the elicitation, doesn't mean we're not going to use the data in inspection. We already do. You do an elicitation when you don't have empirical data. We have empirical data on severity. So we don't need to ask about it in the elicitation.

MR. TYNAN: I'm going to ask you to hold any further questions. I'm going to remind maybe the speakers as well as the folks out in the audience who

will be making comments to speak up so that the people that are on the telephone can hear.

And with that, I'm going to switch over to Dr. Mary Muth from Research Triangle Institute, to talk a little bit about the conduct of the expert elicitation.

DR. MUTH: Thank you, Robert. I'm very pleased to be here to tell you about the process that RTI followed for conducting the elicitation. I'll give you some highlights of the results.

I'm the Director of the RTI Student Agricultural Policy Research Program. I also wanted to acknowledge Shawn Karns, who is here today and managed the expert elicitation process at RTI.

Matthew talked about the history of the expert elicitation. So I'll just touch on that briefly. I'll also talk about the development and content of the expert elicitation worksheets, the process that RTI followed for recruiting members of the expert panel, the process we used for conducting the expert elicitation and then some highlights of the results.

So a little bit on the history. Matthew has already gone through this. I'll just touch on this very briefly. RTI did conduct an initial expert elicitation back in 2001. However, it separated the processes from the species, and so it's not directly comparable to this expert elicitation.

In 2005, we conducted the expert elicitation ranking the relative risks, post-public health by various types of processed meat and poultry products, and then based on comments received during a public workshop, FSIS contracted with RTI and we revised that process and conducted the new expert elicitation.

So the primary modifications compared to the 2005 expert elicitation, as has already been mentioned, the experts were equally divided among public health, academic institutions and industry. There were two additional worksheets added to the expert elicitation, one that included a risk ranking specifically for vulnerable consumers, and a third worksheet that addresses attribution of foodborne illness to individual product categories. And again,

as has been mentioned, the scoring in this case was limited from 1 to 10, instead of open-ended scoring.

So I'll go through the process that we used to develop the expert elicitation worksheets in collaboration with FSIS. RTI and FSIS held a series of conference calls to discuss the required modifications, to address some of the comments that had come up in the public meeting. The initial draft of the worksheets was peer reviewed. The peer reviewers were mentioned by Matthew. They came from a variety of Government agencies, people who have experience with previous expert elicitations in their agencies.

We modified the worksheets in response to the peer reviewer comments and then worksheets were internally reviewed at FSIS, and they were pilot tested with scientists at FSIS. And then based on one of the primary things that came out of the pilot test was that we added the worksheet on attribution of foodborne illness to various categories of processed meat and poultry products. And then RTI made final changes to those worksheets.

So as I mentioned, there's now three worksheets. There's the first one that's very similar to the previous worksheets that had been used for the 2005 expert elicitation. That's for healthy adults. We added essentially the same worksheet that asked the experts to rank for vulnerable consumers, and then the third worksheet was on attribution of illness, and that's for five different foodborne pathogens.

So the primary differences compared to the 2005 expert elicitation worksheets, we added the worksheet for vulnerable consumers in the attribution worksheets. As Matthew mentioned, we added an additional product category for thermally processed, commercially sterile products. We limited the scoring from 1 to 10. The experts could score multiple products with a 1 and they could score multiple products with a 10, and they could use fractions in that range. We asked the experts to consider only bacterial hazards, not viruses or physical or chemical hazards. This is another difference from how the expert elicitation was

conducted for 2005. And then finally we asked the experts to rank or indicate their level of confidence in their estimates that they provided on the worksheets.

Next we're going to switchover and talk about the recruitment process that we followed for the expert elicitation and the members of the panel. We initially started with a list of 45 potential experts. There were 15 each in public health, academia and industry, and the criteria for including those experts were that they had to have advanced knowledge and professional recognition in a branch of science related to public health and food safety. They also had to have an understanding of food science, meat and poultry processing and foodborne illness.

So this list of 45 experts was generated by FSIS, RTI from a pool of experts that we work with frequently on a lot of our projects related to food safety, and suggestions from the National Advisory Committee on Meat and Poultry Inspection.

So of that group of 45 that we contacted,

14 declined or dropped out primarily due to scheduling difficulties and then 14 were not responsive to our repeated phone calls and e-mails over a 4 week period.

So ultimately we recruited 17 experts, 4 in public health, 5 in academia and 8 in industry. All 17 of these recruited experts completed their worksheets. The names of all of those experts and their affiliations are provided in the draft report that's posted on FSIS' website.

And to ensure a balanced panel, FSIS decided that we would use information from four experts in each of the groups to allow equal representation. So we randomly selected from those groups to have four from each group in the results that were generated from the expert elicitation.

I'm going to move on to describing the process that we used for the expert elicitation. So we contacted the experts and provided worksheets or provided the experts with the following materials: the 3 worksheets to be completed, the list of 25 products and examples of what those products contain.

They're essentially the same list of products that were included in the 2005 worksheet, and the same list of examples except that we added thermally processed, commercially sterile products. And we also provided to them a list of assumptions to be used while assigning their risk scores in the first two worksheets.

So that process, once we had provided the materials to the experts, we scheduled and hosted a series of teleconferences based on their schedules with groups of experts. We talked about the purpose of the data collection. We reviewed the worksheets with them and responded to their questions. So the purpose of this teleconference is to insure that they understand what the assumptions are when they're completing the worksheets and how to complete the worksheets.

We asked the experts to complete their worksheets within one week after the teleconference. We also asked them to provide any scientific documentation that they thought would be helpful in understanding their responses. And once we received

their worksheets, we entered the data into the spreadsheet.

So why don't we go through the assumptions that we provided to the experts and discussed with them by teleconference. There are nine different assumptions that we provided to them. Again, these are the same as the 2005 expert elicitation with the exception of the first assumption.

The first assumption is to consider only bacterial hazards in indicating the risk rankings, and to exclude viruses, chemical hazards and physical hazards.

The second assumption that we asked the experts to take into consideration is that products would reach consumers without further processing at another establishment or at retail. So the consumer would be purchasing this product and preparing it and consuming it without another intermediary after the processing plant.

The third assumption is that all products are produced in an USDA regulated plant with HACCP and SSOPs.

The fourth assumption is that the incoming source material comes from a supplier with average or typical food safety controls. We asked them not to think of extreme circumstances when they were assigning the risk rankings.

The fifth assumption is that we asked them to assume that the processing plant's food safety controls are average or typical, again not extreme situations.

The sixth assumption was that products received typical handling from the time they leave the processing plant until they are consumed, that the consumer's handling of the product is typical, again not extreme situations.

The seventh assumption is that raw products are cooked before consumption.

And eighth is that no products were irradiated.

And then the ninth assumption is really a set of three assumptions for ready-to-eat products in particular. And that's these products are exposed to the environment after lethality treatments, unless

it's specifically noted in the product description that was provided to them, and that the products do not contain additives to inhibit growth of *Listeria* nor do they receive post-lethality treatment to destroy *Listeria.*

So next I want to go through some highlights on the expert elicitation results. Chuanfa will go into a lot more detail on these. So I'm just hitting the treetops in terms of what the results are.

The expert scores for product categories with the highest likelihood of illness among healthy adults receiving a median score of 10 on our scale of 1 to 10 was raw ground, comminuted or otherwise non-intact chicken, followed by raw ground, comminuted or otherwise non-intact turkey, and then followed by non-intact poultry other.

I did want to note, too, that the next set of products in their rankings, all with a median score of 8 were raw intact chicken, turkey, other poultry and then raw ground, comminuted or otherwise non-intact beef. So those are our top ranking

scores. You can see from the range of scores that there's quite a bit of difference in the individual experts' rankings.

Then moving onto the lowest likelihood of illness among healthy adults to be expected, with a median score of 1, was thermally processed, commercially sterile product, and then followed by RTE meats and poultry fully cooked without subsequent exposure to the environment.

Moving onto vulnerable consumers, again the same risk ranking but just for vulnerable consumers. We have in that case raw ground, comminuted or otherwise non-intact chicken again scoring a 10, the same as for healthy adults, followed by raw ground, comminuted or otherwise non-intact beef which is different from the healthy consumers, and then followed by raw ground, comminuted or otherwise non-intact turkey. And there are a series of products that also have relatively high rankings following immediately at 9, 8.5 and 8 which are raw ground, other poultry, raw intact chicken, raw intact turkey and raw intact other poultry.

And then with the lowest likelihood of illnesses among vulnerable consumers, the same products are on this list. The rankings are just -- the scores are just slightly different as for healthy consumers.

So sort of summing up between the two risk ranking worksheets, the results were very similar between healthy adults and vulnerable consumers. The scores are slightly different, and there's slight differences in the ranking but they're very similar. Raw products, as one would expect, were assigned higher risk rankings compared to RTE products. Poultry products were assigned higher risk rankings than red meat products, and I did want to note that the opinions of the experts varied substantially for some products, and you can see that in the wide range of scores that are indicated.

So moving onto the highlights of the expert elicitation results for attribution, I wanted to talk about what the highest attribution percentages were for the five pathogens that we asked about in the expert elicitation, and again these percentages are

the relative percentages of illnesses for meat and poultry products. So this is out of the category of meat and poultry products. If we had all 25 products listed here, these percentages, the mean percentages would add up to 100 percent.

So the highest attribution percentages for *Salmonella,* non-typhi, with an average attribution of 22 percent for raw intact chicken, followed by raw intact turkey at 14 percent and then raw ground, comminuted or otherwise non-intact chicken at 9 percent. And here we have a mean level of confidence of the experts of 2.2, which is a medium slightly better than a medium confidence level.

And then for *Salmonella*, multidrug resistant, here the average attribution percentages are 20 percent for raw ground, comminuted or otherwise non-intact beef, followed by raw intact chicken at 19 percent and then raw ground, comminuted or otherwise non-intact chicken at 8 percent. And here we had a slightly lower mean level of confidence compared to *Salmonella*, non-typhi.

For attribution percentages for *E. coli*

O157:H7, at 57 percent, we have raw ground, comminuted or otherwise non-intact beef, much higher than any of the other product categories. Raw ground, comminuted or otherwise non-intact other meat is 14 percent, followed by raw intact beef at 8 percent. And here we have a relatively high mean level of confidence.

For the highest attribution percentages for *Listeria*, the mean percentages for RTE fully cooked meat was 30 percent, the highest percentage, followed by RTE fully cooked poultry at 25 percent and at a much lower percentage, RTE acidified/fermented meat, without cooking, and here a relatively high level of confidence among the experts.

And then finally, the highest attribution percentages for *Campylobacter,* raw intact chicken at 36 percent, followed by raw intact turkey at 13 percent and raw ground, comminuted or otherwise non-intact chicken at 12 percent with a medium level of confidence for this pathogen.

And I did want to note, and I don't have a specific slide for this, but across all of these

attributions, across all of these pathogens, the thermally processed, commercially sterile product had the lowest mean attribution for every single pathogen. It was 0 percent or 0.1 percent for each of the pathogens on the worksheet.

So with that, I'll address any questions there might be.

MR. TYNAN: Okay. If you could identify yourself and your affiliation, and I'm going to ask Dr. Muth if she could sort of pull a microphone over just a little bit and speak up in response.

MS. SMITH DEWAAL: Caroline Smith-Dewaal with the Center for Science in the Public Interest.

Mary, I appreciated your presentation. But I would ask, if possible, one of my questions at least may also go back to Michael.

MR. TYNAN: Okay.

MS. SMITH DEWAAL: First of all, did you have any academics in your panel who had a medical expertise as part of their academic background?

DR. MUTH: I'm not actually prepared to answer that off the top of my head, but I can provide

that answer to you.

MS. SMITH DEWAAL: Okay. I would appreciate that, and a similar question among your public health officials, did among those state public health officials that were included, did they have experience with outbreak investigations?

DR. MUTH: That's another question that I'll have to get back to you on.

MS. SMITH DEWAAL: That would be fine. My next question has to do with the fact that you surveyed I believe all 17 experts but included 12 in your final results. Among the 17 experts surveyed, did you have outliers?

DR. MUTH: Among the 17 experts?

DR. SMITH DEWAAL: Yes. Both you and Matthew have stated that there was substantial agreement among the experts, but I wanted to know, were there outliers?

DR. MUTH: Yes. I think it's correct to say that there are some outliers in the report. We do provide the ranges for all of the responses that were received. So you can see that there are in some

cases the full range was used for --

MS. SMITH DEWAAL: And did you make the decision about whether to include or exclude the outliers among the experts that you chose for your 12 that were used?

DR. MUTH: In the summaries RTI did, we randomly chose which experts to include in the summary statistics. We did not make our selection based on outliers or excluding outliers or their levels of confidence. We did it on a random basis.

MS. SMITH DEWAAL: And would your results have been significantly different, if you had chosen different or different groups of experts had been randomly selected?

DR. MUTH: We haven't done that analysis but that's something that we could look into.

MS. SMITH DEWAAL: I would urge you to do that analysis because from what I could see in terms of your minimum and maximum, there appeared to be some outliers in your group that you're including, and I would be interested whether that's a large number of outliers or small, how your results might

have been different.

Did Sandra Hoffman participate in the peer review of the expert elicitation, either in advance or following?

MR. MICHAEL: No, she did not.

MS. SMITH DEWAAL: Is there a reason for that given that you cited her work several times and she presented at your initial meeting?

MR. MICHAEL: No, I can't think of a reason. It was a full peer review -- who had experience in expert elicitation in their own agencies. An EPA expert, Ms. Soaper (ph.), recently completed an expert elicitation on mortality and air pollution. When we chose our peer reviewers, we wanted people with expertise in data collection analysis and expert elicitation, and not necessarily expertise in food processing or public health because what we really wanted comments on were would the instrument work and give us data that's accurate and data that we can use. They didn't have to be able to fulfill that.

MS. SMITH DEWAAL: Okay. My last question

is kind of a little more of a comment. Matthew suggested that -- actually I'm going back to CSPI's comments on the expert, the initial expert elicitation. We ask that you give the experts the best available public health data to consider, including product attribution data. It strikes me that that wasn't done.

MR. MICHAEL: No, that was not done. We depended on the experts' own knowledge and we chose them because they had expertise already in these fields. That is a method used in expert elicitation but that's not the method we used.

MS. SMITH DEWAAL: And, Michael, you made the comment in response to an earlier question about the results regarding vulnerable population, that you could look at the results from this expert elicitation and the vulnerable population and other data.

MR. MICHAEL: Sure, we could.

MS. SMITH DEWAAL: When are you doing that? Because I think we have data to provide that would help to test this.

MR. MICHAEL: That would be great. I mean the expert elicitation was recently completed. So we're just now considering, or we've been considering for the last few weeks that data we received and the focus in the last few weeks has been comparing the first instrument from the '07 elicitation to the '05 results because those are the most comparable. And as I mentioned earlier, that was the agreement. The agreement is between only the first instrument in '07 and the instrument in '05 is very comparable and Dr. Guo will talk about that in correlation with using the rankings.

MS. SMITH DEWAAL: We've been urging the Agency to also look at actual data that's available, and now you've got these two sets of expert elicitations. I think it's time to really narrow down with available data to --

MR. MICHAEL: Sure.

MS. SMITH DEWAAL: -- to making your, not necessarily basing it on one expert elicitation or another, but basing it on the best data available.

MR. MICHAEL: Absolutely. Absolutely.

MS. SMITH-DEWAAL: Thank you.

MR. MICHAEL: As I mentioned in my --

MR. TYNAN: Your timing is perfect. I'm going to -- I know there's more questions here. We have another comment period. I'm going to take one question from the phones first, and then if there's an opportunity, we'll catch it at the end. I apologize.

Operator, can you see if there's any questions from the folks that are on the phone please?

OPERATOR: Thank you. If we have any questions on the phone, please press *1.

And I do have a question from Carol Tucker-Foreman.

MR. TYNAN: Okay. Mrs. Foreman.

MS. TUCKER-FOREMAN: Yes, I would really love to know what Caroline wanted to ask you.

MR. TYNAN: I'm sorry. Caroline had a whole series of questions that she was --

MS. TUCKER-FOREMAN: Those of us on the telephone could not hear. The primary microphone is

working fine. Could at least the person who is making the question repeat the question because right now you've got us on the phone and we've taken the time to do this. We've just not been able to get any information.

MR. TYNAN: Okay. Well, Ms. Dewaal has come up and she's going to repeat just her questions. We're not going to go through the answers again.

MS. SMITH-DEWAAL: Carol, I'm sorry if I'm at fault for that.

MS. TUCKER-FOREMAN: I don't believe you are.

MS. SMITH-DEWAAL: I asked whether the academic experts had medical expertise.

I asked a follow up on whether the public health officials had experience in outbreak investigations.

I asked a question about whether there were outliers among the 17 experts because based on the data we saw here, there was clearly some evidence that there may have been an outlier included among the 12 that they chose, and then we discussed the

randomness of how they chose 12 of the 17, and they did admit that there were, in fact, 1 or more outliers.

Sandra Hoffman, I asked if she had done the peer review on either of the instruments or there results. The answer was no.

And then I asked a more general question on Matthew's response to the vulnerable population saying they would look at that, they would look at the standard results and also external data, and I urged them to do that.

MS. TUCKER-FOREMAN: Thank you. I appreciate it.

MR. TYNAN: Again, I apologize to the folks on the phone. We are going to see if we can't get the sound one more time to be a little bit more robust, and we're also going to ask our commentors here in the room to speak a little louder and maybe closer to the microphone. That may help us a lot.

And with that, we're a little bit overtime. So I'm going to go to the next discussion which is the analysis of responses of the expert elicitation,

and I'm going to introduce Dr. Guo.

DR. GUO: As the previous two speakers, you know, the 2007 expert elicitation is improved, enhanced design, not only peer reviewed but also take many input from comments, previous public meeting comments. And the new expert elicitation, 2007, have two additional worksheets and 2007 data rank the public risk posed by the bacterial hazards in each of 25 product categories. And the 2007 elicitation data score 1 to 10 for the likelihood of illness for consuming and handling meat and poultry products for both healthy adult consumers and the vulnerable populations.

And the -- we do look at and compare healthy adult consumers and vulnerable consumers, see what is the relations of the two rankings.

And also additional, in addition to the vulnerable consumers, we also in the new elicitation also collect attribution data for the following areas of specific pathogens, for the consuming and the handling processed meat and poultry products. So this is the slide that I just talked about.

This slide show you the results of the likelihood of illness among healthy adult consumers, and as Dr. Muth's presentation, the top here is the top seven ranking product categories. And Dr. Muth mentioned that is the raw ground chicken, turkey and other poultry product at the top, very top, and followed by the intact chicken, turkey and other poultry. And the raw ground beef is tied with at the fourth place with the intact chicken, turkey and poultry.

For the healthy adult consumers, the results from this year's elicitation, so the raw product of chicken, turkey and other poultry have higher risk ranking. And the poultry products generally were ranked higher than red meat products. And as we know, ready-to-eat product have the lowest rankings.

And as mentioned by the earlier two presentations, the 2007 expert elicitation data is used to compare with 2005 elicitation results.

In analyses conducted, we found that this new expert elicitation for the worksheet one, that is

healthy adults, is consistent with the 2005 result.

And here is a correlation plot, plot both 2005 results and 2007 results for the median ranking score. And we see the line, that is the dots represent the 25 product categories in both 2005 and 2007 elicitations. And sum dots, the points in the graph represent multiple pair values. And we see that the line here is the -- line for this data. You can see the two elicitations as correlated is quite along -- appear along the line. And a statistical analyses is coefficient correlations that is experiment correlation coefficient for this kind of data, give our value .95. As you know, correlation coefficient could have ranged from 0 to 1. Zero means no correlation. One means perfect correlation. So our data is 2005 and 2007 is a .95 correlation. So it is a quite high correlation here.

So the conclusion is the two elicitation data is correlated and the result is consistent.

Next I want to show you the additional data we collect in this new elicitation, that is in response to the comments to our previous elicitation,

that is for the vulnerable consumers. The same group of experts used the same ranking score, so that is the same score, and they rank 25 product categories. And you can see here the same seven product category is at the top ranking, and the raw ground chicken, poultry and the chicken, turkey and poultry and the intact chicken, turkey and poultry is the same here, at the top seven. The only change is the raw ground beef now is more up in the second place for the vulnerable consumers.

And in summary, I will say the pattern of risk ranking scores for the 25 product types in this elicitation for both healthy adults and the vulnerable consumers are similar. When I say similar, it means there are ranking scores between healthy adults and the vulnerable consumers are correlated and the same product generally held higher risk ranking for vulnerable consumers than for the healthy adults.

And on this page, we have a scatter plot to show the correlation between healthy adult consumers and vulnerable consumers, to show the relationship

between the two rankings. There are two lines here. The right line at about the top is the -- line. That is so the scores, the two set of scores is correlated since they are next to each other close to the best -- line. The lower one is green color, is the equal risk line and here you can see all the points is above the green line, that means vulnerable population always have a higher risk than healthy consumers, adult consumers. And they are correlating to each other.

So this finding give us a -- we can use this, I think we address some -- about why since earlier the 2005 elicitation, we have rank healthy adults. Now consider what has happened, should we take consider reason of vulnerable population, vulnerable consumer. So this results, so they are highly correlated and again, the correlation coefficient here is .96, is very high. So in other words, if you know score for health population, you can well know what can happen to vulnerable consumer. That is a --

Next five slides is the same message

Dr. Muth have presented in her presentation, attribution of the foodborne illness to specific pathogens, to meat and poultry products, but here it is presented in a pie chart. The whole chart represent 100 percent and the distribution to the 25 categories, and for the *Salmonella*, non-typhi, the top attribution resulting is raw intact chicken is about 22 percent followed by the raw intact turkey and the raw ground, otherwise intact chicken. So this is *Salmonella*, non-typhi.

The next slide is multidrug resistant *Salmonella* and here we show the top three are raw ground beef, raw intact chicken and raw ground, non-intact chicken.

The third attribution graph show you the attribution of the *E. coli* O157:H7, and the top one is raw ground beef. That is account 57 percent of foodborne illness based on expert elicitation data, and followed by the raw ground, otherwise non-intact meat, not beef and pork, that is 14 percent, and then followed by the raw intact beef.

The fourth one is the *Listeria*, here is the

top three are ready-to-eat products, Mary already presented and the graph give the whole what is other attribution is.

And this is the last one, is *Campylobacter jejuni* and *coli*, and the top one is raw intact chicken. That is 36 percent, and followed by the raw intact turkey, 13 percent and the raw ground non-intact chicken, that is 12 percent, and this is the pathogens we have in this new elicitation, that we have collect data on attribution.

And before the end of my presentation, I want to give you a summary. And besides we have looked at rankings for healthy adults, for vulnerable population, and we have collect attribution data, we compare the current, the new expert elicitation to the previous one, that is 2005 data, and to look at comparative data. We found the new elicitation results are consistent with the 2005. So the two elicitation is consistent, the result is consistent, is correlated the score.

And also we have looked at for this elicitation, we look at the risk ranking for the

healthy adults and vulnerable consumers, to make comparison between two risk rankings, and that the result are highly correlated. Thank you.

MR. TYNAN: Thank you, Dr. Guo. I was going to start with the phones but I have a lady out here in the audience who wanted to ask a question before. I'm going to start with a question here, and then I'm going to ask Dr. Guo to pull the microphone over so it's nice and close, and we'll start with a question here. If you would identify yourself and your organization?

MS. ROSENBAUM: Yes, thank you. I'm Donna Rosenbaum from STOP, Safe Tables Our Priority, and this question was the same question I really had from the last panel, which really applies to all of the material presented so far.

I would like to know whether we're doing a lot of comparison between '05 and '07 expert elicitation. I would like to know if the new set of experts in the '07 elicitation were given the data from the '05 elicitation to read or review at all, and if not, were these panel of experts screened for

whether they were familiar with that data or had read the data?

DR. GUO: I think I -- my answer is this, that we collect new data as independent. Which one we use this new data to make, since we receive, common from our 2005 elicitation. So this new elicitation data is collect as a new data set to make comparison to the earlier 2005. So they are -- will be -- in the design, the category is comparable, but the expert opinion is, the way we think, is independent to each other. So the current results, our current, the new elicitation, and the earlier elicitation, the two results is consistent, the ranking is correlated. That is one purpose because we want to answer the stakeholder input and the comment.

MS. ROSENBAUM: Okay. I guess what I'm trying to get at is if there wouldn't be some bias, you know, in the second expert elicitation if these experts were already familiar with the first one.

MR. TYNAN: Perhaps we could maybe ask Dr. Muth or Mr. Michael to try and respond to that

question, and we'll give you one follow up.

MR. MICHAEL: We did not give the '05 results --

MR. TYNAN: You've got to speak up, Matthew.

MR. MICHAEL: We did not give the '05 results to the experts in '07.

MS. ROSENBAUM: Were you at all aware if they were familiar with them?

DR. MUTH: We did not screen them specifically on whether or not they were.

MR. TYNAN: You need to speak up.

DR. MUTH: They were not screened specifically on whether or not they were familiar with the previous expert elicitation. We do know that some of them were based on some of the comments they made during the teleconference. It is public information. So there wasn't any way we could specifically look for experts that were not aware of the information.

MS. ROSENBAUM: One really quick follow up to the process itself. I understand that you went

from 17, who were identified in the paper that was given us, down to the 12 when you actually did your calculations. Was that 12 in the entirety? So five people were completely ruled out or did you use partial data from different people?

DR. MUTH: They were excluded in the entirety. We had four public health experts. So all of those were included. We had eight from industry. So we randomly selected four of those, and then we had five from academia, and we randomly selected four of those five.

MS. ROSENBAUM: Okay. Is there anyplace in which those 12 are identified?

DR. MUTH: The list of 12, they're in our draft report that's posted on the FSIS website.

MS. ROSENBAUM: Okay. Because I've only seen the 17 in total, not just the 12.

DR. MUTH: Okay. I guess we don't. Yeah, you're correct. Actually we don't list which 12 were included in the expert elicitation.

MR. TYNAN: Okay. I'm going to go to the folks on the telephone. Operator, can you query the

people on the telephone if there are any questions?

OPERATOR: Thank you. If anyone has a question, please press *1. We have a question from Curtis Travis.

MR. TRAVIS: I just wanted to comment that I can hear perfectly well. So I don't think all of the people on the phone are having trouble hearing.

MR. TYNAN: Well, that's good. We'll have to get the name of the phone you're using so we can all have it. Mr. Travis, could you please identify yourself and your organization and then if you have a question or comment.

MR. TRAVIS: My name is Curtis Travis. I'm with SAIT, and I don't have a comment. I just wanted to let you know that not everybody's having problems.

MR. TYNAN: Thank you very much. Are there other questions or comments from the folks on the phone?

OPERATOR: Yes. Barbara Kowalcyk, you may ask your question.

MS. KOWALCYK: Hi. This is Barbara Kowalcyk from CFI. I did have a couple of questions.

First of all, why did -- this is more for RTI. Why did you use or chose a median when you were talking about the risk rankings, and then switch to means when you were talking about attribution of foodborne illnesses. Furthermore, by asking the experts the sum of percentages of attribution of illness to 100 percent, wasn't RTI implicitly asking them to rank the products in relation to foodborne illness?

DR. MUTH: The first question you asked about in terms of how we presented the data, the reason why we presented medians for the risk ranking because those were scores from 1 to 10. So there were a lot of discrete observations and the mean is less informative when you have people indicating categories of responses rather than a continuous response. And then for the attribution, since they were providing responses, it could be anywhere from 0 to 100 percent. The mean was more informative for the summary we provided.

Now all of the data that we collected from the 12 experts is provided to FSIS and additional analyses could be done to present that information in

a different format if that would be useful.

I'm sorry. Can you repeat your second question?

MS. KOWALCYK: Well, actually I would argue that both rankings were discrete in nature, but by asking the experts the sum of percentages of attribution of illness to 100 percent, wasn't RTI implicitly asking them to rank the product in respect to contribution to foodborne illness?

DR. MUTH: I guess my interpretation of that is that in terms of asking them to specifically rank, it is true that we restricted them to processed meat and poultry products. So it is asking them to provide percentages within those categories of products, but they could provide any response from 0 to 100 percent, and there could be larger percentages attributed to products that had more foodborne illness. So I guess it's not specifically ranking because you do get some indication of the realms of different conditions here, simply the numerical ordering of the data.

MS. KOWALCYK: Yes, but I think that, you

know, for example, if you told people, the respondents that they must attribute the 25 categories, *E. coli* O157:H7 illnesses and the total must equal 100, you know, if they feel that ground beef is the most problematic, then they may say, well, I'm going to attribute 80 percent of the illness to that category and then they would have 20 percent left over to -- I think what I'm trying to get at is for a lot of the attribution illnesses, the minimum scores were 0 percent and this was mainly because, I think, because the respondents in essence haven't been weighing what they feel are more problematic, attributable to foodborne illness. So it might be useful to look and see which ones scored the highest among the 12, consistently among the 12 respondents. And I'm not really sure how FSIS is going to take this attribution data information and combine that with the risk rankings to come up with a hazard coefficient I believe is what they called it. And it's interesting to me that FSIS said earlier that, you know, they're going to put a severity of illness in their RBI algorithm yet we never heard

anything about that before, and I still don't know quite how they're going to do that. I don't know if I really have a question in there but I think that there's still needs to be a lot of details flushed out and maybe someone can comment on that later this morning but I think there needs to be a lot more flushed out. Caroline made some very good points earlier, as many of the other commentors that, you know, FSIS or RTI hasn't really looked at outliers. The Agency has given us part of the data set for each one of the product categories to see, you know, was there a lot of concurrence among the experts or were responses spread out over a range, particularly if there's a minimum of 1 and a maximum of 10, and then the median is somewhere in the middle, I have -- that doesn't tell me a whole lot about the distribution of the responses.

MR. TYNAN: Ms. Kowalcyk, I'm going to interrupt and --

MS. KOWALCYK: -- see all of the data.

MR. TYNAN: Ms. Kowalcyk, I'm going to interrupt for right now, and I'm not going to ask --

MS. KOWALCYK: I'm done for now.

MR. TYNAN: -- the panel to respond to that at this particular point. I'll take one more question from the telephones, and then we're going to go onto our next presenter. Operator, is there another question?

OPERATOR: No, that was the last question.

MR. TYNAN: Okay. Thank you. Is there anyone here in the audience that has an additional question that they would like to ask at this point about Dr. Guo's presentation? Ms. Dewaal?

MS. SMITH-DEWAAL: I have a question just for clarification. In our analysis of the 2005 median rankings, together with the 2007, we identified 13 categories where there was a difference, and only 11 categories I believe where the results were exactly the same. At some point, and in your chart, especially the first one, I'm missing some points, especially in the 2005, a number of products were given 10s, which included ground beef, ground turkey, ground other poultry and then ground chicken. And I'm shortening the product

category names just to make it easier. But those all rank 10, and in your slide, I didn't see those categories enumerated. Because I'm just wondering, and maybe I'm not a statistician and it may be that I don't understand the point .95 correlation. But with 13 categories where there was not -- there was close agreement but not quite exact agreement, and 11 categories, it just doesn't -- I don't understand how you're getting that coefficient. Thank you.

DR. GUO: To make comparisons between the two elicitations, we had to look at the, I will say, aggregated data, that is when we identified median of the score rather than a median of rank, and as you know earlier the two design, two studies, this new one, 2007, is an improved, enhanced design, and that score is only 1 to 10. The earlier 2005 is an open-ended format and that is different scores but the way we use this, we are interested in the relevant risk not to the aggregate -- So we take the rank and that is also aggregated to the median score, the correlation coefficient -- and the result, that is the rank correlation coefficient is .95 is quite

high. So you maybe look at the report, at the whole picture to see what is the -- from minimum to maximum, look at both years' data, at the whole picture.

MR. TYNAN: I'm sure you'll probably have a follow up question but we'll allow you to do that in the open comment period.

And with that, I'm going to close out the comments on Dr. Guo's presentation, and I'm going to introduce Dr. Dan Engeljohn, with the Office of Policy, Program and Employee Development.

DR. ENGELJOHN: Thank you, and good morning. I'm going to talk about the expert elicitation and its role in risk-based inspection.

For its use, we've identified that we're using an expert elicitation for ranking the relative public health risk of FSIS inspected products. And we presently only looked at those products that relate to meat and poultry. We did not include eggs in this particular activity at this time, but it will be our future goal to do so.

The goal of risk-based inspection then is

to allocate FSIS inspection resources in a way that best protects public health. And to do that, we make estimations of the contribution of a particular food to a subsequent human illness, and we know that that's difficult and quite complicated. And there are several ways to contribute food to illness. Each has its own strengths and weaknesses which I'm going to characterize as caveats, and I'll walk you through those just to present some perspectives on what we consider.

In terms of the methods for attribution, the three different methods that we'll be talking about are expert elicitations, which we're focused on today, predictive models and epidemiological data analysis. And all of these we look at by comparing the results of multiple methods and then we can, in fact, improve our own final scores by looking at them in combination. However, the independent means of determining the relative public health risk will be performed as a source of comparison.

For expert elicitations, FSIS has recently conducted two independent expert elicitations to

define the relative risks posed to public health by processed meat and poultry products. From these two elicitations, one had 22 experts and the other one 12, from industry, academia and public health sectors, and both generally defined 24 meat and poultry product categories. Both ranked these foods to relative risk to public health.

The strengths are that they can be performed even when there is little available data, and they can help to resolve discrepancies between other methods.

The caveats are that they're judgment based and they may be less objective than data driven decisions.

In terms of predictive models, this is an estimate of public health of a food based on a variety of data input. We can estimate illness attributed to each product by a ranking of FSIS foods. FSIS has developed predictive models, and we use them today to estimate the number of illnesses attributed to meat, poultry and processed egg products.

The strengths are that they're objective, they're based on observable data, and they can help identify data needs.

The caveats are that there's a reliance on human dose response curves or surveillance data, and this can create uncertainty in the predictions of human illness. And additionally, modeling post-production mitigations is, in fact, quite complex. This would be what happens at the retail level or at the consumer level. And as you know, FSIS products generally are handled and prepared further at retail or in the consumer's home.

A bit about predictive models and molecular subtype data. This would help to better discern the information that we can use to make judgments about attribution. Molecular models from microbial source tracking include PFGE patterns, serotypes, subtypes, phage types and genotype assays. Much of this is conducted by the public health laboratories, CDC in particular, and this can better inform how we, in fact, attribute human health to products that we regulate.

The one example that we find to be most developed and, in fact, quite telling is the Denmark model in which they use *Salmonella* to identify attribution related to foods in that country to this particular pathogen. That country has a very robust means by which they know what's happening on the farm throughout the distribution chain and then with consumer illness.

We can use this as a working model to try to work through the issues related to how serotypes that we have in the products that we currently regulate can attribute to salmonellosis in this country and right now we have the serotype information. We've not yet used greater discernment in terms of other information that may be available to us.

The caveats are that some cases of salmonellosis do not have a serotype or a subtype, that is strongly associated with a single food or a species or source of animal. As you know, many illnesses are associated with the bugs that are, in fact, not just from the products that we regulate or

may, in fact, not be from foods at all.

To give you a little more perspective about how we can use predictive modeling and how we will, in fact, use it to inform the estimates that we get from our elicitations, we can take the human case data by serotype. This would be that information published by CDC Public Health Laboratories, food prevalence data by serotype, and this would be from the products that we do, in fact, regulate and have information for, and this information is presented from 1998 to 2003. And then we have also taken the Pennsylvania Pilots Study on Shell Eggs which is old data but it is the most current and best available data available to us from 1995, to give us a perspective about the contribution of eggs to human health related illnesses.

And then we look at food consumption data provided to us by the economic research service from the same time period to try to get some approximation about the number of culture confirmed salmonellosis cases per year that are attributed to the products that we regulate. And on this chart, and I accept

that it is hard to read, and we can provide greater detail to you if that would be helpful. But this would be actual data compared with CDC data as an example, and the ERS data to show that there have been changes from the year 1998 through the year 2003. The darker red column, if you can discern that on this chart, being the first one visible on the column in the year 1998 is for ground beef. And then on the opposite end in 2003, the column shown there is the yellow column, and that is for the chicken products.

So you can see that there has been a decrease over time in terms of human illness related *E. coli* O157:H7 in ground beef whereas you can also see that there would appear to be a trend in terms of the human illness on the increase associated with chicken products. And this again is not an example in terms of hypothetical data. It is real data.

Another example of how the Agency has used predictive modeling to estimate the contribution of human illness to the products that we regulate was the FDA/FSIS risk ranking that was conducted a couple

of years ago, and then further refined by FSIS. But in any case, from this chart, from the summary of the risk ranking, you can see that deli meats show that it was, in fact, the highest ranked, in terms of contribution from a per serving basis for a food as well as for the per annual basis for a food. And then a number of other products are identified there, but of the FSIS regulated products, deli meats, frankfurters, pates and meat spreads were those that were most likely associated with contributing to human illness associated with *Listeria monocytogenes*.

This would be a further refinement of that risk ranking model to then take information and predict what the impact would be with regards to risk based verification testing. If we focused our inspection resources on certain products, particularly those that present a higher risk for likely contributing to human illness, we can see how we can or should allocate inspection resources with regards to testing and focused by our inspection program personnel with regards to daily observations and food safety assessments, to see whether or not

that impacts public health. So this chart using real data would show the relationship between percent positive results and human illness predications associated with products that we regulate.

Then, for example, the epidemiological data analysis, this uses actual human illness events clinically diagnosed and attributed to a food vehicle by epidemiological evidence. This would be using foodborne outbreak reporting systems, using the CDC FoodNet, which is an active surveillance of foodborne illness in the United States.

And the strengths are that it is an objective measure, and it's based on observed human illness.

The caveats are that foodborne illness grossly is under diagnosed, and uncertainty about the coefficients are used to compensate for this under diagnosis. It's based upon interviews, surveys and case control studies used to attribute clinical cases to foods and relies on human reporting and can be anecdotal. And data sets tend to be small.

An example of how we can take this

epidemiological data, however, and use it to inform the expert elicitations that we have, as well as the predictive modeling, we can take this information and then apply other factors to inform us as to where we might, in fact, want to focus our resources.

In this particular case, we presented information here, which has point estimates. We can, in the future, as we have more data, replace this with uncertainty distributions and run this through simulation models. Expert elicitations could be used as an input into the uncertainty around these points of estimates, and then again, we can allocate resources based on cost to human illness. This gives an example of what, from an ERS perspective it identifies as being a contribution of human illness to cost to the American taxpayers as an example.

It's one consideration that can be given to the overall estimates that FSIS will be using in terms of how we use the expert elicitations and then be informed about how we might make adjustments.

For now, however, in the immediate future, based on the information we have now from the two

expert elicitations and the attribution data that we know that is, in fact, fairly solid that we can use to rely upon, the results that we got from the first estimate gave us rankings for the product categories. And so in essence, the results from that would remain the same as what we have been modeling and using in terms of development of a risk-based model. We will continue to use new information and, in particular, the second elicitation, which will inform us with regards to information about healthy populations and vulnerable populations. And this can help us to make determinations about how and when we should, in fact, make adjustments to the original scores that we've assigned.

We will continue to combine expert rankings with other information, such as the volume, to arrive at an overall establishment's inherent risk.

In addition, we'll continue to assess the expert elicitation results with current knowledge from the epidemiological studies and the predictive modeling, mostly used by risk assessments within the Agency, to better inform us about the attribution of

foodborne disease to the products that we regulate.

FSIS is further assessing, however, whether and how we should collect or expand the 24 food categories from the expert elicitations, into categories more closely informed by other work. And we were presented information at the April meeting from the Center for Science in the Public Interest which provided really helpful and informative information about outbreak groupings that may be, in fact, considered. So that is one thing that we are, in fact, now running through in terms of simulation models to see how, in fact, we could adjust the categories that we've identified.

And FSIS will assess the use of epidemiological data to incorporate severity of illness. This will be a factor of how we go forward. How we do it at the moment is something that we don't have the best information about, but we will continue to look at it, model it and, in fact, run sensitivity analyses to see how things might change if, in fact, we incorporate different factors.

Cost of illness is something that the

Agency at least will look at to see where is the burden of illness in the United States and what do we need to focus on as one factor?

And again, using risk assessments provides us a means by which we can model what components of our algorithm are more important than others and have more impact than others. This can be a factor in how we make adjustments.

We'll continue to have ongoing communication as we become informed about new information or as new information becomes available. We do know that there will be emerging pathogens as time goes along. As control becomes better for various pathogens, we need to be constantly attentive as new issues arise. And so with that then, the Agency will continue to do what it can to make the information available in a transparent mode and to include you in terms of informing us about what we could and should be doing.

So thank you.

MR. TYNAN: Thank you, Dr. Engeljohn. I'm going to open it up to the folks on the telephone and

take questions from them first. Operator, are there any questions from the audience participating by phone?

OPERATOR: Yes. Barbara Kowalcyk, you may ask your question.

MS. KOWALCYK: Barbara Kowalcyk, CFI. The first question I had is, Dan, your presentation is not on the web and would it be possible to have that put up as quickly as possible?

DR. ENGELJOHN: Yes, it will be put up momentarily I would guess.

MS. KOWALCYK: Okay. Because it was kind of difficult to follow along.

Now in terms of the predictive modeling, I mean it sounds to me like this is a lot different than what we had heard before about how you're going to use different forms of attribution data in the risk-based inspection model.

I'm particularly interested to hear about the predictive models, and I know you said that's based on data being developed by FSIS, the estimated attribution of illness, and it relies on

surveillance. Where exactly is that data coming from? Is it coming from a verification testing program?

DR. ENGELJOHN: Yes, this is Engeljohn, and the data that we have inputted into that model is the data that the Agency collects through a variety of its regulatory testing programs. So it mainly is our *Salmonella* data, our *Listeria* data and our *E. coli* data. Factored into that would be any other data that's available in the published literature and in particularly that for which the CDC in terms of trying to make associations, but it really is in the form of our risk assessments, and if there are more specific questions about that, we'd be happy to perhaps in the future provide groups or individuals some forward view of how those risk assessments work.

MR. TYNAN: Operator, are there other questions from the folks on the phone?

OPERATOR: No, sir. That was our only question.

MR. TYNAN: Thank you. I'll take questions from the audience, specifically to Dr. Engeljohn.

Okay. Going once, going twice. Okay. We -- was that a hand in the back or was that just a stretch?

UNIDENTIFIED SPEAKER: Just a stretch.

MR. TYNAN: A stretch, okay. All right. I saw two hands go up. I thought we might have two questions.

With that, we have a period now for open public comment. So we can go back and revisit any issues that you want to regarding any of the topics presented here this morning. And we're going to start here in this room.

Mr. Corbo, if you could identify yourself and your organization.

MR. CORBO: Tony Corbo from Food and Water Watch. Dr. Muth, one of the concerns that we had with the 2005 elicitation was the fact that very few of the experts provided rationales for their rankings. And we notice at least in this draft document, that there were no rationales provided. Is there going to be an additional document that will list why the experts ranked the different foods the way they did?

DR. MUTH: In the information that RTI prepared from those expert elicitations, the experts were given the opportunity to provide rationales and comments along with the worksheets that they completed. So all of that information will be available to FSIS and I guess, I can't respond how that information will be used.

MR. MICHAEL: We will make that information available. We asked for rationales in 2005 as well, and we didn't receive many though we did receive some. We would make that available with the answers, so the answers are -- it won't be associated with the identity, the expert's view, who the experts are, and what the rationales when provided are for individual answers.

MR. TYNAN: Other questions? Chris.

MR. WALDROP: Chris Waldrop, Consumer Federation. I had a similar question to Tony's in that on page 3.3 of the draft report, there's a point that says the products received typical handling -- or one of the assumptions that was made was that the product received typical handling by all parties from

the time the products leave the processing plant through the time they are consumed, and then the instruction to the experts was account for safe handling or mishandling if you believe either to be typical.

A couple of questions on that. One, were the experts -- did the experts indicate whether or not they were thinking that this was typical or this was safe handling or this was mishandling and whether they considered that typical or not? And then if the experts are -- if one expert is thinking that typical handling is safe handling for all product categories, another expert is saying typical handling is mishandling for all categories, or they're changing that characterization for each product, how does that impact or does it impact the results at all?

And then just a second comment is that, you know, I think it's very interesting that the 2007 and 2005 expert elicitations correlated and I just want to reiterate the importance of not relying solely on those. It sounds like from Dan's presentation, we're going to be incorporating as much scientific data as

possible, and not just saying, well, the two expert elicitations matched up, so here we go. So I just encourage the use of as much scientific data as possible to inform your decision-making.

MR. TYNAN: Thank you, Chris. Dr. Muth, did you want to comment on that?

DR. MUTH: Well, we did not ask the experts to specifically indicate whether they were thinking about mishandling as one of the causes or whether it was handling or just typical processing that might be the cause of the foodborne illness associated with the food product. So we did not ask them to do that differentiation. It does point out one of the issues with conducting the expert elicitation is that you try and through your conversations with them, in introducing them to the process of preparing the materials to as best you can, insure that they all are thinking about the same -- they're coming from the same set of assumptions when they're doing the rankings.

So we try to insure that as much as we can but there's a limit as to how much you can do, when

you're bringing together experts from a whole variety of different backgrounds. It's one of the advantages but also one of the disadvantages of expert elicitation. We get all of the information, all of the background in terms of how they provide the response, but they also as a result of all of their background and experience, they have different opinions about what the source of a particular pathogen might be in a food product.

MR. TYNAN: Other --

MR. MICHAEL: Yeah, I would just add to that in general, to what Mary said. You try to get the experts to use values, to use estimates within the same context. We want them to understand the instructions. We want them to think about the products in the same way when they use the estimates. There's always going to be misgivings and there's always going to be outliers. If they didn't have an opinion or there was scientific consensus we knew of, we wouldn't need an expert elicitation. We always see some disagreement. In regard to asking them specifically on these products whether or not they

felt handling was typically good or typically bad, they did have an opportunity, if they chose to put that in the content of the data offhand, but again with elicitation, you want to make sure you collect the best data and you can't ask every question you might want to. You can always return to it and ask it again.

MR. TYNAN: Other questions from the audience?

MS. BEALS: Sharon Beals, Tyson. Just a point of clarification on the attribution of foodborne illness. What timeframe were the experts asked to think about the context? Current day, historical presence. Were they asked the same question in '05 as in '07? What was the frame of reference they were supposed to be referencing?

DR. MUTH: When we spoke to them, it was current practices. Are you having trouble hearing me still? When we provided the instructions for them to do the expert elicitation, it was based on current practices. We didn't give them a specific time period to keep in mind as they were completing that.

MR. MICHAEL: The attribution would be current, the day they filled out the form, and we did not ask about attribution in '05.

MR. TYNAN: Other questions from the audience?

(No response.)

MR. TYNAN: Operator, could you check with the people on the phone please?

OPERATOR: Thank you. We do have one question. Pat Buck, you may ask your question.

MS. BUCK: Hello, this is Pat Buck from CFI, and first of all, thank you everyone for the very informative meeting.

One of the questions I do have may be a little more generic than staying particular on topic, but I still think it's an important question. Given that the implementation of RBI cannot take place until after the OIG completes its report, what future efforts will FSIS be making to flush out the questions raised by today's meeting?

One of the things in particular that I'm concerned about is that some of the methodology used

in those expert elicitations, even though the 2007 one I think is a good improvement, would not meet the requirements of the Data Quality Act, and I think that's a problem in the future for the implementation of our RBI system. So I would like to have some response from FSIS as to what they plan to do over the next 18 months that OIG gets its report together?

MR. TYNAN: Ms. Buck, thank you for your question. I'm going to ask Dr. Engeljohn to perhaps respond.

DR. ENGELJOHN: Yes. This is Dan Engeljohn with the Office of Policy here at FSIS. I can tell you that we have actively engaged in developing the documents to better, at this point, combine all the information that has been presented to the public and stakeholders at this time, so that we will have a concise document that explains what we believe RBI is and should be, that provides all the rationale behind what was a policy decision that was made in terms of decisions that have been made thus far versus what was a scientifically based decision and how was that decision made with regards to the data available.

And so it would provide a description of the statistics and the types of analyses that the Agency has done.

So that is something that's actively under development and you should expect will be made available over the course of time. I obviously don't have a time period, but that is something that we know will be helpful and useful to you to be able to capture everything that has been presented to you thus far.

So there are a number of analyses that the Agency is looking at. As I explained in my presentation, the sensitivity analyses that we would be running in terms of our predictive modeling, is one way to look at everything that we've done thus far and make some determination about what impact that likely would have on public health related to the products we regulate, and then to make adjustments to those decisions such as changing how many establishments may fall within a particular level of inspection and see if that has an effect, or see whether or not increasing the level at testing in

some plants and decreasing in others or changing the focus on particular pathogens would have an equal or lesser or greater than effect on public health. And so those are the analyses that we are, in fact, actively engaged in, in terms of developing more of the rationale that can be communicated to you to have an opportunity to review.

MS. BUCK: Thank you very much, Dr. Engeljohn, but actually what I'm most interested in is what are we going to do to make sure that when you put RBI in place, you will not have difficulty with lawsuits from the various, you know, organizations that find that the ranking is displeasurable to them?

So we have to have to have in place a system that's going to stand up to the rigors of the Data Quality Act. And one of the things that concerns me is that this expert elicitation, both of them, has a very, very small sample size, and that there were some questions as to, you know, the speed at which it was done. And the fact that we didn't include some of the other what I would call food

safety experts, which would include people like the inspectors and people from different consumer groups. I appreciate immensely the amount of work that FSIS has put into putting a second expert elicitation in place, but I would like to see that the Agency continue along this line and keep trying to flush out the experts' opinions that they haven't already gathered so that we can have the best data to match the rigors of what the Data Quality Act is going to be asking people to do, if you are indeed going forward with the --

MR. TYNAN: I'm going to ask Mr. Michael to respond.

MR. MICHAEL: I'll respond --

MS. BUCK: Okay.

MR. MICHAEL: We did peer review this 2007 expert elicitation just as we did the '05. We published the peer review plan on the FSIS Information Quality Act peer review page in either early '07 or late '06, I don't recall the date. The review is what's known as a letter review under the OMB Guidelines, and the expert elicitation data

itself is considered to be influential under those guidelines as opposed to having influential on one end --

And as I mentioned in my presentation, we will be publishing a summary of those peer review comments and how the Agency responded to them, as well as the identity of the peer reviewer. They won't be individually associated with their comments as was provided for -- shortly. We're working on that now.

MS. BUCK: Well, thank you. I have a final question. What about CDC? Has it been involved in the planning and expert elicitation process? I didn't see anyone from CDC on the list?

MR. MICHAEL: There was a CDC expert, I believe it was Robert Tauxe in the '05 elicitation, and we did recruit another one in '07 but he wasn't able to participate because of time constraints.

MS. BUCK: Well, I understand that, but are we going to move forward through this and get as I said, a stronger base from the various other stakeholders that could be involved in helping us

improve what you have already improved through some correlation between the 2005 and 2007. We now need to see if there is any what you would call, you know, other opinions out there that we have missed in this capturing process.

MR. MICHAEL: Again, I'll respond, I'll respond in general. More generally, we do work with CDC and we are working with the CDC. We work with their data and we work with them beyond the expert elicitation.

MS. BUCK: Thank you.

MR. TYNAN: Dan, did you want to make a comment?

OPERATOR: That's the only question on the phone line.

MR. TYNAN: Thank you, Operator.

DR. ENGELJOHN: This is Engeljohn. I will just follow up also to say that the Agency continues to do what we can to work with our public health partners at the state level, local level and CDC. In particular, the information that was presented in the presentation that I had was, in fact, a working group

for which a number of individuals within FSIS are actively engaged in working at CDC to be able to better make associations between attribution of the products we regulate and the illnesses that CDC has information on.

There's more information that we can and should be following up on, and the Agency is taking steps to make that happen, that meaning being able to better try to find associations between the products we regulate and those that are reported to the public health data infrastructure.

I do also want to say, and I would guess that we would also make this available soon as well, that we have just recently received a letter from CDC that, in fact, identifies that they believe that the risk-based inspection system that we have designed and that we're pursuing is, in fact, the right thing to do and that they do support that. So we will make that information available to you.

MR. TYNAN: Are there other questions or comments from the audience? Ms. Dewaal?

MS. SMITH-DEWAAL: Thank you. This is

Caroline Smith-Dewaal from Center for Science in the Public Interest. I hope this will be my last comment.

First of all, I want to congratulate FSIS on what appears to be an improved expert elicitation.

However, I hate to throw out data, and the fact that you have a number of experts who have completed the survey and who are not being considered, I'm wondering if there's some way you could include all that data and then weight the categories.

I'm also concerned in looking at some of the data, that -- I'll hold this closer so my remarks are fully captured, that there appears to be one or more outliers. I was looking at slides that seemed to indicate that some of your experts thought that ground beef posed 0 risk of *E. coli* O157:H7, and that's a surprising finding from an expert working in this area. So there would appear to be some outliers from what I can see in your data although maybe I'm somehow misinterpreting a slide.

I did want to note that we have reviewed

the older median results for the '05, and this will refer to general population, with the new median results for the general population. We found that there were four ready-to-eat categories where your experts believed the risk was higher in 2007. There were three categories of intact meat, including pork and beef and another category, again where it appeared to increase the risk. The experts believed the risk was higher in 2007 than your 2005 panel had indicated.

However, there are six categories where your experts in 2007 believed that the risk was lower, and I have some specific concerns about these categories, particularly raw intact turkey went down, raw ground pork went down significantly really by 2, from 8 to 6, and then a number of the categories for ground product, including ground beef, went down from 10 to 8 in the case of ground beef, ground turkey went to 8.5 and ground other poultry went from 10 to 9.

So we see a number of significant differences, and we believe that some of the product

attribution data that we may have at CSPI would be useful in figuring out what's correct, what's right, in these expert elicitations. We talked at the food attribution meeting that we held, the summit that Dr. Raymond so graciously called and got all the agencies together. We talked about the fact that you can't use product attribution data alone, but I would argue here you cannot use the expert elicitation alone. You need to use all the data. Thank you.

DR. RAYMOND: Can I?

MR. TYNAN: Yes, sir.

DR. RAYMOND: Caroline, we agree with you 100 percent. This is one instrument that we use to get the inherent risk of the product, and I just want to comment a little bit on your thoughts about how some of these categories changed.

First of all, you've got different experts. You have somebody who might move from 8 to 6, but also if you did an elicitation on inherent risk of product, the day after we announced the 5.7 million pound recall of ground beef, you might move ground beef up a little bit in your mind that day. If you

saw a report from us that said that a year ago, two years ago, the fiscal year or the calendar year, I'm sorry, the calendar year of '05, poultry products, carcasses were testing positive, 16.7 percent for *Salmonella*, and then if you read our report last year, it was 11 percent, you might move poultry down a little bit. Maybe that's why turkey moved down.

So '07 should be different than '05. If it's not different than '05, we're not making any progress. And so hopefully in '09, we'll see another re-ranking and we'll have other problems to deal with because maybe we'll be handling the *Salmonella* issues and not the poultry that will continue to come down. So that didn't surprise me that some of those things changed and some of them like I said, it might just depend on what was in the news yesterday.

MR. MICHAEL: If I could add, too, as Dr. Raymond said, you have different experts and also a different range, a different scale for the experts in '07 than in '05. And so as Chuanfa did in his analysis, we want to look at the rankings. What's important is ranking relative to the other products

and not the actual value -- So turkey went from 9 to 7 between the two years, that's not so important. It's not important at all. What's important is where it ranks among the other products as the scale --

MR. TYNAN: Other questions from the audience here in 107?

(No response.)

MR. TYNAN: Operator, any additional questions from the people on the phone?

OPERATOR: Yes, we do. We do have a question from Pat Buck.

MR. TYNAN: Okay. Thank you. Ms. Buck.

MS. KOWALCYK: I'm sorry. This is Barbara Kowalcyk. The question that I had is will FSIS make the actual risk data from the 17 respondents available to the public? And if so, I don't know, you don't necessarily need to match up the respondents with their actual data, but it would be useful to know which results are from public health people, which ones are from the academia people and which ones are from industry, so that everyone -- observations.

MR. MICHAEL: We will make the data from the 17 experts available.

MS. KOWALCYK: Thank you.

MR. TYNAN: Other questions from those on the phone?

OPERATOR: That was the only question.

MR. TYNAN: Thank you, Operator. Questions here in 107? Going once.

(No response.)

MR. TYNAN: Okay. If there are no other questions or comments from either the audience here or the folks on the phone, I'm going to reintroduce Dr. Goldman to come up for some closing remarks. Dr. Goldman.

DR. GOLDMAN: Well, thank you, Robert, and thank everyone for your interesting and informative comments. I think one overriding theme of today's meeting is that this is very much a work in progress. I think that's a reiteration of a theme we've tried to put out there since the beginning of this, going back to February. So your comments today will help us.

This meeting in particular, we just literally received the final report or the draft final report in the last two or three weeks. So a lot of what you've heard is literally hot off the press and our own analysis of that data is also very recent as well.

I think we've heard some comments from various people that we should consider further analysis of the data that we've just gotten, and I think you've heard our response to that. You've asked for raw data to be made available, and I think we can do that to a great extent.

I want to go back to Carol Tucker-Foreman's comment early on that we should be doing what is necessary, and not what is reasonable to expect. I hope that we have been able to make that point all along, and I think that not only with the expert elicitation, but with all of our efforts in RBI, that we are trying to do what is necessary to protect public health.

We have heard several concerns raised about the incorporation of severity of illness into our

further analysis and ultimately into the algorithm, and I think we've committed to do that. We have to determine exactly how we will incorporate that, and that gets to the use of actual empirical data on human illness and the causes of that illness.

We heard today a nice explanation of kind of a continuum of data and information that we are using and would like to continue to use. An expert elicitation, as we said multiple times, is, one, a valid scientific method for gathering data that combines both a qualitative and a quantitative aspect in order to determine in this case inherent risk.

Dan Engeljohn very nicely kind of laid out kind of the other parts of that continuum which include use of various modeling techniques as well as real data when that's available. And you heard hopefully our commitment to continue to refine and incorporate the data that we have available although I think early on we said we would use the results of the expert elicitation at least initially to set our inherent risk ranking. You've heard our commitment to continue to refine and incorporate other data to

make that inherent risk more robust.

I think we also heard a little bit of discussion about use of attribution information. We did get some attribution out of this expert elicitation. We had a little discussion about the absolute importance of attribution information for us ultimately building the best risk-based inspection system possible.

And previously at our summit on attribution, you heard about some of the difficulties in arriving at a consensus about how to obtain attribution information and then ultimately how to incorporate that. But you did hear some discussion about the attribution information that came out of this expert elicitation, and we're still considering how and whether we might use this particular attribution information in the risk-based inspection system algorithm.

Let me continue to remind you as we have on many previous occasions, that your input today is valuable. Your input after today is equally valuable. We do have the e-mail address that was

mentioned several times to you. We will have all of the presentations posted. I think Dan Engeljohn's was the one that wasn't posted. The RTI report is available, and we'll respond to your additional requests for some information, specific information from that report.

So with that, I would like to again thank everyone for coming today to Washington if you came from out of town, and for those of you who joined us on the phone, and to our panel of experts who presented their particular expertise regarding expert elicitation and our analysis of that information. And we will look for you at the next meeting which will be announced sometime in the future. And I think we're probably done with the series of meetings on RBI in processing. And so the next meeting will be about RBI in slaughtering.

So thank you again for coming, and we'll see you at a future meeting.

(Whereupon, at 11:34 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:

EXPERT ELICITATION

Washington, D.C.

June 26, 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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DOMINICO QUATTROCIOCCHI, Reporter

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