

UNITED STATES DEPARTMENT OF AGRICULTURE  
FOOD SAFETY AND INSPECTION SERVICE

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PRODUCTION VOLUME AND ITS ROLE  
IN RISK-BASED INSPECTION

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April 25, 2007  
9:00 a.m.

George Mason University  
Arlington Campus  
Room 244  
3401 Fairfax Drive  
Arlington, Virginia 22201

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(8:30 a.m.)

MR. TYNAN: -- important meeting related to production volume and its role in risk-based inspection. My name is Robert Tynan. I'm the Deputy Assistant Administrator for the Office of Public Affairs, Education and Outreach, and I'm going to be moderating today's meeting. So it's a pleasure to have that opportunity.

I have some things that I want to mention to you regarding the meeting, and we'll go through the Agenda, but before I do that, I wanted to acknowledge we have some of our employee organization representatives here today, and I wanted to acknowledge their presence, and I have Ms. Olga Morales from the Association of Technical and Supervisory Professionals. I have Mr. Stan Painter, who is the Chairman of the National Joint Council of Food Inspection Locals. We have Dr. Pat Basu. Where are you, Pat? I've lost you. He went to the men's room at the wrong time I guess. Dr. Basu is the head of our Asian Pacific -- there he is -- our Asian

1 Pacific American Network in Agriculture, and I have  
2 Dr. Danah Vetter. Dr. Vetter, nice to meet you.  
3 Thank you for coming. And she is with the National  
4 Association of Federal Veterinarians. I was going to  
5 tell you that in addition to our audience here, we  
6 have some on the phone. I think you already know  
7 that.

8 We changed the format for today's meeting a  
9 little bit from those of you who participated in the  
10 April 2nd meeting, and the April 5th meeting. So  
11 we've tried to design this so it's a little bit more  
12 interactive session, in that there's more discussion  
13 among the participants than we've had in the past.

14 The Agenda, I think you all have copies of  
15 it when you came in. Let's take a look at that real  
16 quick and let me go through it for you.

17 In the interest of time, because we've lost  
18 a little bit of time, Mr. Quick was kind enough to  
19 give up his time on the Agenda, and he's going to do  
20 the closing remarks. We'll have some discussion from  
21 Dr. Raymond regarding production volume and how he  
22 sees the role in risk-based inspection.

1           And then at 9:30, we have Janell Kause  
2 talking a little bit about assessing risk and the  
3 value of volume data. Dr. Dan Engeljohn, with our  
4 Office of Policy will talk a little bit about  
5 collecting volume data, the way we do it currently in  
6 FSIS, and then we're going to have a little bit of a  
7 panel discussion regarding approaches to volume in  
8 RBI. In our meeting on April 2nd, there was a lot of  
9 discussion about volume. We've given some thought to  
10 the comments that were made and we have sort of a  
11 different approach that we want to pose today, and  
12 Dr. Joe Harris from the Southwest Meat Association  
13 will participate on the panel. And he has an  
14 alternative approach from the industry's perspective  
15 that will perhaps compliment some of the things that  
16 we're doing.

17           We also had our consumer representative  
18 scheduled to participate. They were unable to  
19 identify a representative or someone to speak today.  
20 So we'll still give them the opportunity to send any  
21 comments, any thoughts that they have to our e-mail  
22 site or in other ways. We meet with them regularly so

1 that we'll hear their viewpoints on that at some other  
2 time.

3           And then the different part for today's  
4 meeting is after we get through our discussions, we're  
5 going to have breakout sessions and we have some  
6 questions for the group to discuss in the breakout  
7 sessions and hopefully we'll get report outs around  
8 11:45 and then we'll have some closing remarks, some  
9 comments and questions, some closing remarks and be  
10 done hopefully at 1:00.

11           So with that, are there any general comments  
12 that you have regarding the Agenda at this point?

13           (No response.)

14           MR. TYNAN: There will not be comments and  
15 questions during the presentations. All of that will  
16 be toward the end of the discussion, and we are using  
17 as three breakouts, and we'll talk a little bit about  
18 that in a few minutes.

19           We're going to get to that point in the  
20 Agenda. The folks on the phone will do their own  
21 breakout session, and again hopefully they will be  
22 able to join us.

1           You'll see on your nametags that there are  
2 colored dots. They're using a very sophisticated  
3 system today in determining what room and what  
4 breakout session. So we're color-coding everybody.  
5 So it's very sophisticated.

6           The last thing I want to do is I want to  
7 point out that there are probably other topics that  
8 you all will want to talk about today that are going  
9 to be touched on perhaps or have been touched on in  
10 previous meetings such as industry data, perhaps the  
11 elicitation. We are planning another meeting on  
12 Monday as you know. That's on our website right now,  
13 and the Agenda should be going up sometime on  
14 Thursday, and hopefully some of the materials will be  
15 up at the same time. But those topics will be dealt  
16 with later. So we'll have to try and confine our  
17 questions to volume today and comments and issues that  
18 are raised during this meeting.

19           Before I start, I'd also like to remind you  
20 all that we have an e-mail site,  
21 riskbasedinspection@fsis.usda.gov. At anytime,  
22 whether something from the meeting or something that

1 you see between meetings, you're certainly welcome to  
2 provide us any comments, any thoughts, any suggestions  
3 you have through that website, and some of our staff,  
4 Ellyn Blumberg takes good care of that. She manages  
5 that and makes sure that the questions get out to the  
6 people that they need to get to.

7           We didn't build in a specific break time,  
8 which is pretty similar to April 2nd. So we're going  
9 to leave it to all of you to decide when you need to  
10 take a break, then go get some coffee and stretch your  
11 legs. There is a small coffee bar down on the first  
12 floor. I think there's some coffee in the Bookstore  
13 but as you get down to the bottom of the elevator, you  
14 take a right, and there's a coffee bar there as well.  
15 So if you need some refreshments or, as I say, to  
16 stretch your legs, you're welcome to do that.

17           And with that, I'm going to introduce to  
18 you, Dr. Richard Raymond, who is our Under Secretary  
19 for Food Safety for some opening remarks.  
20 Dr. Raymond.

21           DR. RAYMOND: Thank you, Robert. I think  
22 the first thing that you all want to hear is it's

1 awfully warm in this room. So ladies and gentlemen,  
2 if you want to take your jacket off, let's get casual  
3 for today and get comfortable because we've got some  
4 work to do and we're more productive when we're all  
5 comfortable.

6           On behalf of the Office of Food Safety and  
7 Food Safety and Inspection Service, I thank you all  
8 for once again coming for our public meeting that  
9 we've convened to discuss a very important topic, and  
10 that's how do we best use volume in the equations for  
11 identifying risk to products in the plants. It's not  
12 a non-controversial issue. We know that. We heard a  
13 lot in February when we first rolled out our proposed  
14 plans, and I emphasize proposed plans on how we're  
15 going to do risk-based inspection. That was a trial  
16 balloon that we sent out so people could see what we  
17 were thinking and get a hold of it and shake it and  
18 tell us what we could do to improve it. And volume  
19 was one of the most frequently talked about things.  
20 We heard about volume, lots of ideas, where we had  
21 good ideas and where we had some not so good ideas.

22           No one ever said volume wasn't important. I

1 think everyone, consumers, industry, employees, the  
2 Agency, they all recognized that volume is important.  
3 The question is how do we best use volume in this  
4 risk-based equation.

5 We recognized at the last meeting that our  
6 initial formulas had some flaws in them. Bill Smith  
7 got up here and acknowledged that if you're in  
8 category 3, sometimes you'll never move to category 2,  
9 and sometimes when you're in category 2, you could  
10 never move to category 1. We had recognized that  
11 earlier and made sure that Bill acknowledged it. You  
12 all heard it and we also said at that same meeting  
13 that we were going to try to correct that.

14 I think one of the best things about risk-  
15 based inspection is there's incentives for plants to  
16 get better in how they do their business. And if the  
17 incentives are not there, how can you expect industry  
18 to continue to try to improve other than the pride  
19 that they take in their product but you could never  
20 get it acknowledged by we went from category 3 to  
21 category 2 because we got better. That's not a good  
22 system.

1           We've refigured our equations. Don Anderson  
2 will tell you about that. I challenged him and the  
3 others that work on this. I said come up with a  
4 solution. I don't care what it looks like. Just come  
5 up with a solution. Don got innovative and came up  
6 with an idea that I do like. I know Joe has spent  
7 time working on the issue with some in industry and  
8 they've got a formula that I also like, totally  
9 different. I really don't care which one we use.  
10 What I care about is we get the majority of people  
11 saying, yep, that is better than what you guys have,  
12 and we'll go with it, and let's move onto the next  
13 topic which will be plant data. So we'll spend as  
14 much time as we need to try to get to that consensus  
15 or at least the majority.

16           We have invited industry to present this. I  
17 know industry was working diligently yesterday trying  
18 to come up with other ideas, solutions and Bryce was  
19 with me on the road, and his phone was ringing  
20 constantly from representatives of industry saying  
21 here's a thought, here's a thought, here's a thought.  
22 So I actually think we might hear a couple of ideas

1 today from industry.

2           And we also, of course, invited consumers to  
3 tell us what they think is the best way to use volume  
4 to make sure that their concerns are met.

5           I hope today that what we hear is some  
6 constructive comments, constructive criticism. I  
7 don't mind criticism. If you've got an idea how we  
8 can do something better, please let us know. That's  
9 what we're all here for. It's getting to be kind of  
10 almost an event. We've had so many of these. I look  
11 around the room and I know 90 percent of you by name  
12 and what you do and who you represent and getting to  
13 learn a little bit about how you think. A year and a  
14 half ago I didn't know any of you. It's really been  
15 an amazing thing of how the group keeps coming back  
16 together to work on these issues. A little smaller  
17 group today. I don't know if that's good or bad or if  
18 that means people are trusting us to do what's right  
19 and don't feel they have to be at every meeting,  
20 whatever. We'll take whatever we get from you.

21           That reminds me a little bit, about five,  
22 six years ago, when planes flew into buildings and

1 anthrax was used to attack the American public through  
2 the mail. CDC came up with, and the Federal  
3 Government came up with a \$1 billion to help states do  
4 bioterrorism preparedness. They had the public health  
5 emergency preparedness which meant you could use it  
6 for other things besides bioterrorism which gave us  
7 some latitude. Nebraska was the recipient of \$8.5  
8 million a year. We formed an advisory committee of 58  
9 people. I could do that in Nebraska. We formed an  
10 advisory committee. The Federal Government, it's a  
11 little harder to form an advisory committee, so we  
12 just have public forums but I consider you my advisory  
13 committee.

14           When we had our first advisory committee  
15 back in Nebraska to talk about how to spend \$8.5  
16 million a year for public health preparedness, we had  
17 58 different ideas. Fifty-eight different people  
18 thought they should get the whole \$8.5 million. The  
19 universities thought they should use it for research.  
20 The laboratories thought we should improve our  
21 laboratory capacity. Emergency medicine folks thought  
22 we ought to buy a whole bunch of new ambulances and

1 helicopters so that when we had the attack, we could  
2 get people to healthcare. Hospitals thought we ought  
3 to have decontamination units in every hospital.  
4 That's where they wanted to spend the money. Every  
5 group had a different idea how to spend \$8.5 million.  
6 And, of course, when we got done, nobody got exactly  
7 what they wanted.

8           We had meeting after meeting after meeting,  
9 and as we got to know each other and trust each other,  
10 we began to say, I'll wait a couple of years for my  
11 piece because your piece is more important than my  
12 piece, but I'm going to keep coming to these meetings  
13 to make sure my voice is always heard. I think when  
14 we were all done, we had a heck of a system in  
15 Nebraska to improve public health preparedness and I  
16 think all 58 of those organizations got part of what  
17 they wanted and recognized the good of the cause was  
18 more important than their individual areas that they  
19 were concerned about.

20           And that's what I hope we're doing with  
21 risk-based inspection over the last 18 months. By  
22 having these meetings, we're coming to know each

1 other. We're coming to respect each other. We're  
2 listening. We are changing. We're evolving as we go.  
3 I don't think anybody can say we have not evolved.  
4 All we have to do is look at noncompliance reports and  
5 what was on the table 18 months ago, and what we're  
6 doing today with the noncompliance reports and how  
7 we're using the eyes and ears of our inspectors.

8           Now this is one example, but there are many  
9 other examples that I could bore you with but you  
10 didn't come to hear me preach. But I just feel the  
11 need to talk a little bit about it. We've had a  
12 couple of budget hearings. RBI has been heavy on  
13 those agendas. Hopefully we've addressed the issues  
14 that Congress has about risk-based inspection.  
15 Hopefully the Office of the Inspector General who is  
16 taking a look at our system will issue a very  
17 favorable report about our data, about our formulas  
18 and about our capacity. We're anxiously waiting for  
19 that.

20           And I look forward to hearing all of your  
21 different plans today and your comments about the  
22 plans that are presented and the comments that they

1 generate.

2 I encourage you all to ask yourself one  
3 question today that I've been asking myself for a long  
4 time, and that is what approach to production volume  
5 best works for the initial prototype locations to  
6 improve our ability to protect the public's health?  
7 And, remember, this is what we're going to do for the  
8 initial 30 prototype locations. This is not  
9 necessarily what it will look like after we see how  
10 the volume issue that we raise today work in the 30  
11 prototype locations. We may have another meeting in  
12 three or four months. Okay. This is what's  
13 happening. Is it working? Is it not working. This  
14 is just for the prototype locations. This is not the  
15 end. It's just the next step.

16 So with that question, think about how we  
17 use volume to further protect the public's health.  
18 That's it. That's the discussion on the table. Keep  
19 that in mind for the next 3 1/2 hours, and if you do,  
20 I think we'll have a very productive hearing, and I  
21 look forward to hearing your answers to that question.

22 Robert.

1           MR. TYNAN: Thank you, Dr. Raymond. At this  
2 point, I'd like to introduce Janell Kause with our  
3 Office of Public Health Science, and she's going to  
4 talk a little bit about assessing risk, the value of  
5 volume data. And my very complex assignment is to get  
6 the PowerPoints up as quickly as possible without  
7 messing things up. You're good to go.

8           MS. KAUSE: Thank you, Robert. I'm Janell  
9 Kause. I'm the Director of the Risk Assessment  
10 Division of the Office of Public Health Science. And  
11 I want to welcome everyone here today to discuss the  
12 use of volume data in assessing risk. The purpose of  
13 my talk is the value of this data to do just that.

14           At FSIS, we utilize science-based tools,  
15 including risk assessment, risk-based algorithms, risk  
16 rankings, attribution models and other systems-based  
17 models to guide food safety decisions predicted to  
18 improve public health. These decisions allow us to  
19 systematically understand and address food safety  
20 issues. There are formal principles guiding the  
21 development of these tools presented by the National  
22 Academies of Science and at the international level,

1 Codex.

2           There's also a very good paper that's out in  
3 publication that was written and prepared by Dr. Frank  
4 Bryan (ph.) in 1997. It's part of the proceedings for  
5 the world commerce and food hygiene that would be of  
6 interest to this group.

7           The use of a structured process insures  
8 objectivity in linking science to predictive public  
9 health benefits. These tools also provide a framework  
10 to structure data in a more transparent manner which  
11 improves both peer review and public input processes.  
12 We want to insure that how we use the data information  
13 is clear so that others can effectively weigh in on  
14 how best to assess risk. The liquid of process is  
15 essential for using science and guiding decisions.

16           It's important to have a common  
17 understanding of the terminology used in assessing  
18 risk in order to have a more comprehensive and in  
19 depth discussion on data used of this process such as  
20 volume data. Risk itself is the likelihood of an  
21 adverse public health impact or outcome resulting from  
22 exposure to a hazard. In food safety, this outcome

1 could be foodborne illness, hospitalization or death.  
2 Exposure could be something like *Osta monocytogenes*  
3 (ph.), and that could be -- that were on poultry, *E.*  
4 *coli* in ground beef and so on. These are just  
5 examples.

6 Risk itself as you can tell from this slide  
7 is both a function of exposure and hazard.  
8 Understanding these terms is important because it will  
9 help when we get down to discussing volume data.

10 The hazard, everyone should know, is a noun.  
11 This is chemical, physical or biological agent of  
12 concern. For more detailed information we have on  
13 hazard, subtyping data or genomics, will help us to  
14 have a little more specificity in what is actually the  
15 agent causing the harm itself.

16 Exposure in the world of food safety is the  
17 likelihood of ingesting the hazard. Exposure itself  
18 has two components. It's the presence and amount of  
19 hazard in each serving of food and when using that  
20 along with hazard information, it gives you per  
21 serving risk. There is also the number of servings  
22 containing an amount of hazard. In the risk field,

1 the amount of hazard or the concentration is  
2 distributed over the servings that are out there in  
3 our society.

4 Now how does this tie in with risk-based  
5 inspection? We all know that public health risk will  
6 vary by product as well as process, and as a result,  
7 the risk will vary by the amount processing  
8 establishments produce of those various products. As  
9 you can imagine, there's variability in the public  
10 health risk posed by deli meats versus chicken breast  
11 versus ground beef.

12 One of the things that also will result in  
13 differences in the risk posed to public health is  
14 really, when I talk about exposure, I'm talking about  
15 the likelihood of contamination, and has to do with  
16 both the product type itself which will support the  
17 survival and growth of the pathogen or hazard of  
18 concern, the processing that occurs with that product  
19 because the time and temperature under which that food  
20 undergoes will influence both the growth and kind of  
21 the hazard in the food. The interventions will either  
22 reduce, mitigate or eliminate the hazards, and whether

1 or not there is an extensive -- that practices in the  
2 establishment, whether it has a HACCP plan, that is  
3 rigorously followed and has great control, versus  
4 another establishment that is struggling with  
5 compliance as indicated the microbial testing data.

6 So establishments who are producing foods,  
7 they give you a per serving risk, basically the  
8 likelihood of contamination in the food. But we also  
9 need to know how much food that establishment is  
10 producing that enters the marketplace.

11 So this is where production volume is the  
12 second part of the exposure equation. While volume  
13 itself is not a predictor of the likelihood of  
14 contamination as we've discussed, the likelihood of  
15 contamination is the function of product type,  
16 process, interventions and practices in the  
17 establishment.

18 However, volume is used to distinguish the  
19 relative risk between two establishments that would  
20 have the "same risk profile," risk profile meaning the  
21 likelihood of contamination of the food that is  
22 produced.

1           Again, if there are two facilities making  
2 similar product with similar processes and similar  
3 interventions and similar compliance histories, the  
4 facility with the higher production volume is the lone  
5 discriminator but again volume itself is not a  
6 predictor of the likelihood of contamination. So you  
7 need to consider volume in context with these other  
8 factors.

9           So the question here today is not whether or  
10 not we should use production volume. I'm just here in  
11 the risk assessment committee. You cannot assess risk  
12 without using production volume. The real question,  
13 and I'm asking a little bit of what Dr. Raymond said,  
14 is really how do you go ahead and weight that volume  
15 so that you're not indiscriminately targeting either a  
16 small business or a large business, but you're really  
17 looking at the servings of food coming out of an  
18 establishment and the likelihood of contamination in  
19 them, and then you consider how many servings that  
20 will be put in the marketplace to look at the  
21 population risk as a whole.

22           As the discussions continue on the issue of

1 production volume, I encourage the public to pose  
2 options for how to scientifically weight production  
3 volume so that it doesn't overpower the other factors  
4 that I've discussed and how do you rate it so that it  
5 accurately contributes to assessing the risk. Thank  
6 you.

7 MR. TYNAN: Thank you, Janell. And the next  
8 person on our Agenda is Dr. Dan Engeljohn with our  
9 Office of Policy, Program and Employee Development.  
10 Let me see if I can get his PowerPoints up.

11 DR. ENGELJOHN: Good morning. I'm Dan  
12 Engeljohn with the Office of Policy. It's my  
13 responsibility as the senior risk manager to inform  
14 how we control risk within the products that we  
15 regulate, and I'm going to present to you some of the  
16 considerations that we have when we undergo collecting  
17 information about volume in the establishments that we  
18 regulate.

19 There's nothing there. I will go ahead and  
20 talk. While they're looking to see if we can find the  
21 presentation, I'll go ahead and talk from the slides  
22 that we have posted on the web page, and that are

1 available out front should you choose to want to go  
2 out and get a copy of them.

3           From our last meeting on attribution on  
4 April 5th, we have identified that one of the goals of  
5 our risk-based program is to collect relevant and  
6 representative regulatory data, volume being one of  
7 those types of data that we want to insure that we  
8 have.

9           We've got two types of information  
10 collection processes that we use, one being using the  
11 OMB, Office of Management and Budget, approved  
12 instrument in which survey industry in order to  
13 collect information. This is a process that is within  
14 the Paperwork Reduction Act of 1995, and the purpose  
15 of that Act really was to insure that there isn't any  
16 undue burden placed upon the regulated industry in  
17 terms of information that the Federal agencies want to  
18 collect from those that they regulate. The second  
19 process then would be one in which the Agency has the  
20 ability to be able to utilize the inspection force  
21 that we have throughout the nation in order to collect  
22 relevant information, that we believe they're capable

1 of generating for us with the constraints that they  
2 have in terms of how they would go about collecting  
3 that. We do that through our Performance Based  
4 Inspection System automated scheduling process in  
5 which we have a plant profile for each establishment  
6 and we ask the inspectors to fill in the various  
7 entries on that form which ask for information about  
8 the production process within that establishment. The  
9 type of product they produce is an example.

10           On the OMB-approved instrument, there are a  
11 number of things that the Agency has to address each  
12 time that we consider asking OMB for approval, and I  
13 should say that the Agency at one time had a very  
14 large information collection process. This would be  
15 back in the seventies and eighties in which we  
16 collected an extraordinary amount of information about  
17 product that are produced by all these establishments.  
18 With the advent of looking at the burden placed upon  
19 industry, it was determined at that time, that the  
20 Agency was no longer able to get the approvals that we  
21 needed to collect that information because of the  
22 burden that was being placed upon the industry, and

1 the fact that we had employees in every establishment  
2 that we regulated.

3           So it's with prudence that we consider  
4 whether or not we seek OMB approval to get Paperwork  
5 Reduction approval for information and we have a  
6 number that the Agency does collect, some being survey  
7 information mainly for economic impact analysis  
8 information in which we collect census or aggregate  
9 data. But the OMB-approved instrument that we use  
10 specific to our purpose today would be one in which,  
11 the example I give would be for our *Listeria*  
12 *monocytogenes* program.

13           In that process, we identify what  
14 information that we believe that we need. We fill  
15 out a form in which we submit to the Department and  
16 to OMB for review in which we answer a number of  
17 questions. In this case, we knew that we needed  
18 information specific to the production practices  
19 related to exposed, ready-to-eat products that were  
20 applicable to our regulation on ready-to-eat meat and  
21 poultry products. And so by regulation, we added a  
22 requirement that industry would submit to us on an

1 annual basis various pieces of information that  
2 addressed the production process.

3           And so with that activity then, each year  
4 the Agency goes back to OMB and justifies the  
5 approval process that we have, justifies how and why  
6 we use the information the way we do and provide some  
7 estimate of how it impacts industry and as an  
8 example, we identify the purpose or the title of the  
9 information collection. We ask then in terms of a  
10 description of what it is that we need the  
11 information for. We estimate the amount of time that  
12 it would take each establishment to fill out the  
13 form. We identify the number of respondents. This  
14 would be in this case the number of establishments  
15 effected. We then have to estimate the annual  
16 response per respondent. This would be as they have  
17 to modify it or each time that they would have to  
18 fill out information related to it. We give them  
19 estimated burden for the total year and then we  
20 actually publish in the Federal Register a document  
21 which asks that stakeholders provide input on the  
22 necessity, the accuracy, the enhancements and other

1 ways to minimize burden on industry, and that  
2 information goes both to the Department and to OMB  
3 for review.

4           And then each year the Agency has to reask  
5 for approval to collect that information. That  
6 process can take months. In the case of the *Listeria*  
7 rule, it took more than a year to be the approvals to  
8 get that information collection process. And we  
9 recently have made it so that it's a web-based  
10 application for industry to submit that information  
11 but it started out as one in which we asked our  
12 employees to collect the information, and then we  
13 then were able to transfer that over to the industry  
14 once we got a tentative approval from OMB.

15           The second way that we collect information  
16 is through our PBIS Profile Extension. This is a  
17 targeted collection of information from the  
18 Inspector-in-Charge within each establishment that  
19 would have the type of products being produced in  
20 that establishment. And then we ask them some very  
21 specific information and because it's in our PBIS  
22 Profile Extension, we're able to identify which

1 establishments make a category of products that might  
2 be applicable and then it tailors the questions to  
3 that operation. So the questions are not asked of  
4 each establishment. It's dependent on what products  
5 are produced in that establishment.

6           Importantly though, if I see notes that the  
7 establishment makes a particular product that is not  
8 listed on the PBIS Profile Extension, then there's  
9 the opportunity to modify the Profile Extension for  
10 that establishment, add that product category to that  
11 Extension, and then we're able to collect the  
12 information about that.

13           The important thing as well is that the  
14 inspectors are to update the Profile Extension if  
15 substantive changes are made within the establishment  
16 with regard to various production processes, and that  
17 at least annually we expect that the Profile is  
18 reviewed and updated.

19           Because we consider this to be critical  
20 information, with regards to informing the Agency  
21 about its risk management practices and policies  
22 under development, we also identify that in order to

1 take time by the inspector to complete this  
2 information, that they then should record other food  
3 safety related procedures that they do not perform as  
4 a consequence of conducting or filling out this  
5 information collection process. Again, we consider  
6 the information to be critical to inform our risk  
7 management activities and therefore we substitute one  
8 inspection procedure for another and in this case,  
9 it's a food safety activity because we consider the  
10 information to be critical to informing risk  
11 management.

12 For the PBIS volume survey that we  
13 conducted, this was initiated just last year.  
14 Primarily it initiated in December, and we again  
15 asked the inspectors to identify whether or not the  
16 product was produced, and if not, then they were  
17 asked to modify that Profile Extension. In the  
18 initial volume PBIS Extension that we collected  
19 information from, we listed 19 different product  
20 classes. At the time, we had various needs for  
21 information on these 19 product classes, and part of  
22 this to inform what was under consideration at the

1 time with regards to development of risk-based  
2 inspection. We were considering designing a risk-  
3 based verification testing program for beef  
4 manufacturing trimmings, and we had need for  
5 information related to imports/exports related to  
6 various products for which we needed to collect  
7 additional information and for food defense  
8 activities and vulnerability assessments, we had a  
9 specific need for asking questions. So the questions  
10 are tailored to the needs within the Agency in a  
11 manner that we get the type of information that would  
12 best satisfy all those needs. So at the time we had  
13 19 product classes that we asked questions about.

14           There were really two questions that the  
15 inspectors had to answer. One was they needed to  
16 record the approximate pounds of finished product  
17 typically produced and shipped in a day across all  
18 shifts. And then we gave them a series of ranges of  
19 products and options to select from ranging from  
20 none, meaning that the establishment doesn't produce  
21 that product for which that would either be an  
22 indication that the profile extension was not updated

1 or that none was being produced at the time, through  
2 various poundage levels, and then finally don't know.

3           As well then we asked how many days in the  
4 last 30 days was this product produced in order to  
5 give us some estimate about the range and amount of  
6 product that would be produced over time. And again,  
7 it wasn't essential to have absolutes, but this was  
8 estimates and again the purpose of this information  
9 is to be able to categorize various information  
10 pieces so that we can at least see the perspective of  
11 the aggregate changes within the industry on various  
12 product types.

13           We were pleased that there was an emphasis  
14 placed by our district managers on insuring that the  
15 information was, in fact, being completed in a timely  
16 manner. The response level was above 96 percent  
17 which we think was extraordinary considering that  
18 this means getting information in there, looking at  
19 this particular piece of information. And so from  
20 our perspective, that was a higher response rate than  
21 we normally get from information collection  
22 exercises.

1           I want to walk through just generally that  
2 we got some partial completion to those forms. If  
3 there were questions about the responses, then we had  
4 follow ups to make sure that we could answer any  
5 questions that the inspectors may have about that  
6 form. We know how many forms are left remaining and  
7 we follow up and try to figure out what it is we need  
8 to do to get all the forms completed.

9           On your presentation, there's a breakout of  
10 the number of establishments that produce the various  
11 categories of products, and again these products  
12 range from raw intact beef through beef manufacturing  
13 trimmings to ready-to-eat products and just to point  
14 one point of clarification between the OMB approved  
15 form and the Profile Extension, the OMB approved form  
16 that we have industry submit information on is  
17 specific to exposed ready-to-eat products that are  
18 applicable to our regulation contained in Section 430  
19 of the Code of Federal Regulations. So that's for a  
20 very specific type of ready-to-eat product, whereas  
21 the question we ask on this survey and as an example  
22 of that which is asked in the expert elicitation is

1 more generally defined as a ready-to-eat meat or  
2 ready-to-eat poultry product. So it doesn't  
3 specifically capture whether or not it's exposed  
4 post-lethality, ready-to-eat product that's  
5 applicable to our specific regulation.

6 From this information, then we were able to  
7 identify how many establishments produce one product.  
8 We have 33 percent of the establishments produce only  
9 1 type of a product contained on that PBIS Profile  
10 Extension, through 14 percent of the establishments  
11 producing more than 5 types of products just to give  
12 you an example of the range of production processes.

13 We were also interested in looking at HACCP  
14 size. For those of you familiar with regulatory  
15 process work, we're required to take into account the  
16 impact upon businesses based on their categorization  
17 or whether or not they're large, small or very small,  
18 and this is dependent upon the number of employees  
19 that work in the establishment, not on the amount of  
20 production or on the revenues that the establishment  
21 produces, but on the number of employees. And so  
22 there is a range that shows that the large

1 establishments do, in fact, produce on average in  
2 terms of monthly production in terms of pounds,  
3 considerably more product than the small or very  
4 small plants.

5           The utility of volume information from the  
6 Agency is that it is a good estimate of production  
7 volume for a variety of products nationwide. Again,  
8 we have right now a 96 percent response rate.

9           With our inspection program, with personnel  
10 assigned to every establishment, we're able to  
11 identify any substantive changes to the numbers that  
12 were previously submitted, and would be able to  
13 readily change those pieces of information as changes  
14 occur.

15           Our FSIS results that we collect can be  
16 shared with the establishment and timely corrections  
17 can be made, and I do want to point out that we  
18 instruct the employees to make their best estimate in  
19 terms of responding to the survey that we have  
20 through this Profile Extension. There are  
21 instructions that they are not to have the  
22 establishment actually generate the numbers for them,

1 and at the end, it requires OMB approval to have the  
2 industry provide the information to us but it doesn't  
3 require OMB approval if, in fact, we collect the  
4 information, make an estimate and share that with the  
5 establishment and ask them whether or not the  
6 information is accurate to the extent that the  
7 establishment wants to make a judgment about that.  
8 So it's acceptable for us to ask and to share it with  
9 the establishment and make corrections, but it's not  
10 acceptable to ask the industry to provide that  
11 information.

12           This gives us relative estimates, which a  
13 relative estimate which for our purposes are  
14 sufficient for discerning differences amongst  
15 establishments with regards to volume, and we can  
16 take this information and use it in a variety of ways  
17 to assess whether or not the ranges of production  
18 volume that we ask for make a difference. We can do  
19 this through a sensitivity analysis in which we would  
20 model that through a risk assessment methodology.  
21 And this thinking gives us estimate of public health  
22 impact associated with volume. Thank you.

1 MR. TYNAN: Thank you, Dan. I want to  
2 apologize for the glitch with your PowerPoints but I  
3 admire your flexibility in being able to deal with  
4 it. We seem to be having a little gremlin or  
5 something that's causing a problem with the phone.  
6 It does not look -- we may have corrected our  
7 problem. So give us 30 seconds so that we can see if  
8 we have.

9 (Pause.)

10 MR. TYNAN: Can you connect with the  
11 Operator?

12 OPERATOR: Can you hear me?

13 MR. TYNAN: There should be an Operator.

14 OPERATOR: Yes. Can you hear me?

15 MR. TYNAN: Operator, it's nice to hear your  
16 voice.

17 OPERATOR: Oh, great.

18 MR. TYNAN: I can't tell you how nice it is  
19 to hear your voice.

20 OPERATOR: And I can hear you as well.

21 MR. TYNAN: Okay. Very good. I hope the  
22 participants can. I want to mention while we had the

1 technical glitch here at the University, I apologize  
2 to the folks that are on the phone, and I hope you  
3 have the group that are still with us.

4           We did proceed and have gone through a  
5 couple of the initial presentations, and we're to the  
6 point in the agenda related to the panel discussion.  
7 I would mention to all the people on the phone that we  
8 do have all of the presentation information on the  
9 FSIS website. You can go to that, and there is a  
10 block on the front page regarding our meetings, and  
11 you can proceed your way through to the April 25th  
12 meeting and the presentations. So if you have not had  
13 an opportunity to do that, perhaps you could do that  
14 now.

15           So we are at the panel discussion portion of  
16 the agenda, and so I wanted to introduce Dr. Joe  
17 Harris, from the Southwest Meat Association who is  
18 going to talk a little bit about production volume.

19           DR. HARRIS: Thank you, Robert, and  
20 hopefully when I push this button, my slides are going  
21 to have not all been erased. I might not be as adept  
22 as Dr. Engeljohn to just go in with a blank screen but

1 at any rate, it's good to be here this morning.

2           The comments I want to share with you this  
3 morning represent a general consensus of a broad based  
4 coalition of industry organizations that have been  
5 working together on this issue. Collectively this  
6 group represents the vast majority of federally  
7 inspected meat and poultry establishments. It would  
8 definitely not be accurate to say that I am speaking  
9 for everyone. That's impossible to do because I can  
10 tell you when I say that we're talking about a  
11 consensus, and Dr. Raymond used the example earlier  
12 about the group coming together and trying to figure  
13 out how to divvy up all the food defense money,  
14 there's a lot of opinions out there. So when I say  
15 industry, that's who I'm referring to, those broad  
16 based group of individuals and associations and  
17 companies that came together and worked on this.

18           A few general comments about risk-based  
19 approach inspection in general. I think it's safe to  
20 say that the industry broadly supports that concept  
21 and agrees with the move toward a risk-based system,  
22 relative to the process that we've been going through.

1 Dr. Raymond talked earlier about the meetings and the  
2 back and forth and the evolution. We do think that  
3 the plant -- that the process has been transparent and  
4 effective relative to being able to evolve the process  
5 and the product over time.

6 And so that it's not just a, you know, put  
7 something out response, but more of a back and forth  
8 situation between the Government and the inspected  
9 industry, the consumers, the employee groups and  
10 everyone that's been involved, I think has made the  
11 process be relatively effective.

12 And finally, we appreciate the opportunity  
13 today to participate on this panel and be able to  
14 share with all you guys our views on how to approach  
15 incorporating volume into a risk-based system because  
16 again, it is definitely an issue that is not uniformly  
17 agreed to in terms of exactly how that should be done.  
18 And so I do think that the dialogue is important here.

19 Specifically related to how do we deal with  
20 volume in the algorithm or in a risk-based inspection  
21 program in general, I think there are two key points  
22 to keep in mind, that we don't want to see an

1 establishment that has an excellent compliance record,  
2 an excellent process, good controls, that's doing  
3 everything the right way. We don't want to see that  
4 entity penalized under a risk-based inspection simply  
5 based on its size. I think Janell kind of touched on  
6 that earlier, that volume has to be considered along  
7 with other things.

8           Just as the other side of that coin, we  
9 would not want to see an establishment rewarded with  
10 some sort of a lower intensity of inspection or a  
11 better risk-based inspection score simply for no other  
12 reason than it had the benefit of being a small volume  
13 establishment.

14           One of the issues that the Agency's first  
15 algorithm that was released back in April, I guess  
16 maybe even before that, I'm trying to remember exactly  
17 when -- February that came out. One of the problems  
18 we had there was that we believed that volume under  
19 that scenario did tend to penalize particularly larger  
20 volume establishments, and I'll show you an example of  
21 how we came to that conclusion.

22           This is using the original algorithm, we

1 have two plants, Establishment A and Establishment B.  
2 Both of them producing raw ground beef. So under the  
3 inherent product hazard in the original algorithm,  
4 that was at the top of the list. So that received a  
5 20. The volume again of Establishment A was in the  
6 smallest volume category. Establishment B was in the  
7 largest one. In the original algorithm, those two  
8 values were multiplied so that the inherent risk  
9 measure for Establishment A was 20, and Establishment  
10 B was 100. Just based on the product that's produced  
11 and the size.

12 Now let's look at the performance data from  
13 those two establishments. All of the things that were  
14 included in that algorithm, data from non-compliance  
15 record, food safety complaints, potential recalls,  
16 enforcement actions and the whole gambit of things,  
17 you can see that the smaller establishment in this  
18 example was hit just about every way you could be hit  
19 on those. I would hope under that hypothetical  
20 example, no plant would ever be worse than that.  
21 While we picked the angelic large plant here, that had  
22 absolutely nothing, none of those things.

1           When it's all said and done and you get to  
2 the bottom line of this, the RBI risk measure, they  
3 came out with virtually identical under the original  
4 algorithm. So that's what really called our attention  
5 that we really needed to address how volume was being  
6 incorporated because that value up at the top, that  
7 inherent risk measure of 100 for that second  
8 establishment, situated in such a way that it was  
9 never -- there was nothing it could do to get up into  
10 even the top half relative to the final RBI score.

11           So that was an example of where we thought  
12 there was definitely some room to, to improve that and  
13 just summarizing that, by having the production volume  
14 be a component, going back, having it being a  
15 component up here of the inherent risk sort of skewed  
16 things so that that establishment was trapped just by  
17 its own size and the product that it was  
18 manufacturing, and there was nothing they could do as  
19 an establishment to get out of that hole that it was  
20 in, no matter how good it was.

21           So that was really what caused us to look  
22 at, what if we try to incorporate volume maybe on the

1 other side of that equation, looking at it more in  
2 relationship to the controls that are in place rather  
3 than volume as a component of what the product is. So  
4 we headed in that direction, and I will tell you that  
5 in looking at it, in looking at the Agency's original  
6 algorithm, the first bullet point there just  
7 summarizes what the original algorithm was and just  
8 having gone over that example, we know what was in it.  
9 Product inherent risk, the production volume included  
10 along with the product inherent risk, and then the  
11 third factor being that it's the establishments  
12 ability to control the risk.

13           So we would like to see a system that has  
14 much more of an emphasis on the establishment control  
15 as opposed to the inherent risk. We think that the  
16 establishment's ability to control whatever risks are  
17 inherent in the product is far and away the most  
18 important determining factor, and it's the only one  
19 that the establishment has direct control over and  
20 conversely, it is the one factor that could be most  
21 impacted by increased oversight by the Agency.

22           So that is where we were, and in trying to

1 come up with alternative algorithms, Dr. Raymond  
2 mentioned that we had one proposed algorithm that I  
3 shared with him a while back. In looking at it  
4 further, we didn't think that was the perfect  
5 algorithm. We came up with a lot of different ideas,  
6 again about as many different ways as you could come  
7 up with. And we finally came to the conclusion by  
8 late yesterday that perhaps us telling the Agency what  
9 its algorithm should be maybe was not the right  
10 approach. Maybe we should talk more about what the  
11 algorithm needed to accomplish. We realize that the  
12 Agency has a lot of expertise in terms of doing that  
13 sort of thing. So we saw that the Agency was going  
14 toward a nine cell Nona Matrix, as we're going to hear  
15 about a little bit later from Don Anderson. So we  
16 took that concept and looked at it, and we came up  
17 with what we're referring to the Nona Compromise.  
18 That's a compromise amongst all of us, and what you  
19 see here differs a little bit from what you're going  
20 to see in a little while from Don, but I want to talk  
21 specifically about some of the characteristics of  
22 this, and while we think that an algorithm should be

1 and can be developed to fit this type of situation.

2           The key ways that it differs from the  
3 existing one is that looking at the three levels of  
4 inspection, the LOI 1, 2 and 3, the box at the top  
5 left and the boxes along the bottom differ slightly.  
6 We think it's important that any algorithm that is  
7 developed has to have all levels of inspection that  
8 could be achieved by all plants regardless of size,  
9 that if I'm a large establishment producing whatever  
10 product it is, there should be a means there in the  
11 system for me to control risk to the level that I'm  
12 eligible for the Level 1. Conversely, regardless of  
13 size, we think that the system has to allow for every  
14 plant to have the highest intensity of inspection, if  
15 the situation warrants. So this is the approach that  
16 we'd like to see. We think that it's important again  
17 to maintain that ability for every plant to be able to  
18 move between all levels of inspection. And with that,  
19 I will stop.

20           DR. RAYMOND: Joe, we called it the Nona  
21 Matrix because Nona is Greek for nine. What's Greek  
22 for 13? Not to have 13 categories.

1 DR. HARRIS: We don't have 13. There's  
2 still only three levels of inspection.

3 DR. RAYMOND: Yeah, but there's 13 different  
4 categories of --

5 DR. HARRIS: That's a Nona Compromise.

6 DR. RAYMOND: Okay. We've got to come up --

7 DR. HARRIS: I didn't know what Greek for  
8 nine was until I was talking to you yesterday.

9 DR. RAYMOND: We'll know by the end of the  
10 day.

11 MR. TYNAN: Thank you, Dr. Harris, very  
12 much. I had this terrible feeling when you started  
13 your presentation, that you were going to try and go  
14 to slide 2 and there would be nothing there, and that  
15 I was positive that my touching it had caused that to  
16 be the case. I keep doing that.

17 I'm going to introduce at this point, Don  
18 Anderson from our Office of Program Evaluation,  
19 Enforcement and Review, and talk a little bit about a  
20 different Agency perspective on the use of volume, and  
21 again perhaps we'll stop after Don finishes his  
22 presentation and maybe take one or two questions

1 before we go to the break out session itself. Don.

2 MR. ANDERSON: Okay. Thank you, Robert,  
3 very much for the introduction.

4 What I'm going to do in the next 10 minutes  
5 or so is remind everybody how volume was used along  
6 with other types of information in the RBI model that  
7 we presented back on April 2nd in this very room. And  
8 then I'll restate some of the volume questions or  
9 concerns that were raised that day by people in the  
10 audience including some of you very folks out there.  
11 Then I'll show an approach that the Agency is  
12 considering that you've already seen from Joe, a  
13 glimpse of, which we developed based on our follow up  
14 to those good comments that we heard on April 2nd, and  
15 an approach that we think is better than the proposal  
16 or the model that we proposed on April 2nd. And I'll  
17 conclude by comparing some of the attributes of the  
18 new proposed approach if you will, with the  
19 attribution of the model of the formula that we talked  
20 about on April 2nd.

21 In the April 2nd model, an establishment's  
22 relative volume, that is the data that we have on

1 establishments' volumes, in a relative sense, was used  
2 for every plant along with the expert elicitation  
3 based inherent hazard for each product to compute the  
4 weighted hazard, a weighted hazard, posed by each of  
5 the plants that we inspect. Then the absolute volume,  
6 that is the total volume of all products produced by  
7 the plants, was computed and that served as a proxy  
8 for exposure as Janell talked about.

9           So we used the volume information from  
10 establishments in two ways in the model on April 2nd.

11 We used it to compute a weighted average hazard for  
12 each plant, and we used it to compute total exposure  
13 or proxy for total exposure to those products.

14           These two factors carry equal weight in the  
15 inherent risk measure. Each establishment's inherent  
16 risk was then combined with the measure of how well  
17 establishments control the risks that are inherent in  
18 their operation. The first two measures were combined  
19 together to yield what we called back on April 2nd, an  
20 RBI measure, which is then used to identify three  
21 levels of inspection, 1, 2 or 3.

22           We heard a number of questions and comments

1 on April 2nd. Several participants that day suggested  
2 or offered that establishment volume has too great an  
3 influence, too much weight, if you will, on the level  
4 of inspection. And the concerns that we heard that  
5 they were, number one, that the formulation is an  
6 insufficient or inadequate measure of establishment  
7 risk; two, that the approach yields inadequate  
8 incentives for establishments, for some establishments  
9 to further improve risk control. And on the flip side  
10 of that coin, that the approach also offered  
11 inadequate disincentives for other types of firms not  
12 to relax controls. And again, this is something that  
13 Joe touched on. We want all establishments, however,  
14 good their controls are, to at least maintain their  
15 good level of controls if not an incentive to actually  
16 improve them.

17 So considering the feedback that we heard on  
18 April 2nd, we asked ourselves how can you more  
19 appropriately use volume information in our RBI system  
20 to more accurately characterize the relative ranking  
21 or the relative risk posed by each establishment for  
22 purposes of risk-based inspection? And, how can we at

1 the same time build into the system a set of  
2 incentives so that all establishments tried better and  
3 better to control the risks in their operations.

4           So as Joe has already reminded us, we've  
5 proposed a matrix that Dr. Raymond had been calling a  
6 Nona Matrix Approach to RBI, and it's called a Nona  
7 Matrix Approach because it's a three by three matrix  
8 with three levels of inherent risk and three levels of  
9 risk control that together identify nine combinations  
10 or nine areas, if you will, of inherent risk and risk  
11 control.

12           This approach just like the April 2nd  
13 approach, still assumes for now for purposes of this  
14 discussion, that there would be three levels of  
15 inspection. So there's no change there. And  
16 furthermore, as with the April 2nd approach, this  
17 approach, the Nona Matrix Approach, generally speaking  
18 assigns more inspections resources to establishments  
19 that, one, produce products that have higher inherent  
20 hazards, two, to establishments that produce higher  
21 volumes of those products and ship those products into  
22 commerce and, three, it applies greater inspection

1 resources to establishments that have less effective  
2 risk controls. So that again is very similar to the  
3 April 2nd approach.

4 In contrast though to the April 2nd model,  
5 this approach does not combine, does not  
6 mathematically combine the two factors, inherent risk  
7 and risk control, into a single measure that back then  
8 we called the RBI measure. Instead, it assigns a  
9 level of risk based on pairings, on pairs or  
10 combinations of inherent risk and risk control.

11 So let's look at this for just a minute.  
12 Let's look at establishments with a medium, what we'll  
13 call a medium range of inherent risk. These are  
14 establishments in category 2. Establishments with a  
15 medium range of inherent risk can be in any one of the  
16 three levels of inspection. It depends on how good  
17 their risk controls are. If a medium inherent risk  
18 establishment has better than average, if it has  
19 really good risk controls, then they can be Level of  
20 Inspection 1. If their risk controls are more average  
21 in a nature, they're going to have a medium range of  
22 risk control, then they would be in Level 2

1 inspection, and if their risk controls need  
2 improvement, they're not as good as they could and  
3 should be, then that same establishment would be  
4 identified or selected for Level 3 inspection.

5           Let's contrast that now with establishments  
6 with what we call or low or relatively low inherent  
7 risk. These are establishes in this lowest category.  
8 Establishments with very low inherent risk would be a  
9 Level 1 inspection. If they have either better than  
10 average or average risk control. However, and if that  
11 same establish with low inherent risk has worse than  
12 average or not as good as average risk control, then  
13 they would be assigned a Level 2 inspection.

14           Contrast that then with the other extreme,  
15 establishments that are large producers with products  
16 with inherently high hazards. These are  
17 establishments with category 3 or what we would call  
18 relatively high level of inherent risk. These  
19 establishments would not be able to achieve Level 1  
20 inspection, but they would be able to achieve Level 2  
21 inspection if they had better than average risk  
22 control, but if they had average or worse than average

1 risk control, then they would be assigned Level 3.

2           We want RBI, okay, to appropriately  
3 characterize the relative public health risk posed by  
4 groups of establishments so that we can more  
5 effectively allocate inspection resources. We also  
6 want the system to give all establishments an  
7 incentive to strive for better risk controls, and  
8 actually I think we want to insure that poor risk  
9 control is always identified and addressed.

10           Let us reiterate then that just as with the  
11 current inspection systems, and whatever ultimate  
12 system we end up with, if it's a Nona Matrix or a  
13 compromised Nona Matrix, or any of those, that we will  
14 always deal with poor performing establishments  
15 through our enforcement system and enforcement actions  
16 to insure the market inspection given to products or  
17 to establishments deserve to have the market  
18 inspection. So that wouldn't change in any approach  
19 we would adopt.

20           So the attributes of the Nona Matrix  
21 Approach, to summarize, we believe that it's a better  
22 way than the April 2nd model that we proposed. We

1 don't necessarily think it's the only way or perhaps  
2 even the best way to approach RBI, but we think that  
3 this approach still uses all three types of critical  
4 information, exposure, hazard and risk control to  
5 determine establishment level of inspection. We think  
6 it has a built-in system of incentives for all  
7 establishes to maintain or improve their risk control,  
8 and it also means that we can't find ourselves, kind  
9 of logistically, in the dilemma of having all  
10 establishments in a single level of inspection.

11           We hope that this system makes it clearer or  
12 that it's more transparent how an establishment's  
13 level of inspection is determined, and I think that  
14 Robert will reiterate this after the break, but we'll  
15 be looking to you for comments today on how we can use  
16 any of the various models that were talked about here  
17 or other ideas that you might have, on properly  
18 incorporating volume information to characterize the  
19 establishment risk for RBI purposes. Thank you very  
20 much.

21           MR. TYNAN: Thank you, Don, very much.  
22 Before we go to the breakout sessions, we're just a

1 little bit ahead of time. So what I thought we might  
2 do is take just a couple of questions, specifically on  
3 the two approaches that you just heard from Dr. Harris  
4 and from Mr. Anderson, and maybe they can respond if  
5 there's any issues that we need to perhaps clarify at  
6 this particular point. I would ask you that if you  
7 have a question that you want to have clarified, if  
8 you could come to a microphone please. State your  
9 name and your affiliation and then you can ask your  
10 question from there. And we'll start over here on my  
11 left, Mr. Painter.

12 MR. PAINTER: Yes. Stan Painter with the  
13 National Joint Council. My question involves  
14 regarding the volume. Are we referring to product  
15 going out the door or product being produced?

16 MR. TYNAN: Mr. Anderson I think wants to  
17 take that one, and we'll get a microphone for him.

18 MR. ANDERSON: We are referring to volume  
19 that's being produced and shipped out the door. The  
20 extension that Dan talked about earlier, it's very  
21 explicit in that the extension questions that we're  
22 talking about, the amount of product that is produced

1 is shipped out the door, not is produced and then used  
2 in further processing.

3 MR. TYNAN: Does that respond to your  
4 question, Stan?

5 MR. PAINTER: No, because you can produce a  
6 product and you can hold it in a freezer. Many plants  
7 have huge freezers and they put it in freezers. And  
8 you take, for instance, whatever, it's whole legs and  
9 the Russians all of a sudden want whole legs, and they  
10 empty out the freezer, and you're going to have a  
11 humongous amount of volume that has gone out during  
12 one period of time versus others. So is it the amount  
13 produced during the day or the amount that's going out  
14 the door?

15 MR. ANDERSON: Well, again, the extensions  
16 has the amount of product that's produced and shipped  
17 in a day. That's what the extension says. Your point  
18 I think is well taken. I'm not sure what else to say  
19 about that. I mean eventually the product will be  
20 shipped. It may be shipped a day later or a week  
21 later or your example, even a month later, but the  
22 product will be shipped.

1           MR. PAINTER:    But it's going to move you  
2 from one level to the other -- has the potential to  
3 move you from one level to the other.  If I have a  
4 freezer full and all of a sudden I unload it, I could  
5 have the potential to move from one level to the  
6 other.

7           MR. TYNAN:    That's a point we'll try and  
8 maybe deal with when we get into the breakout  
9 sessions, but I appreciate that.  Excuse me, Chris,  
10 just before we come to you, Dr. Vetter, I noticed you  
11 were --

12          DR. VETTER:   I was just going to say, it can  
13 be held in the freezer, I mean sometimes for a year.  
14 It kind of depends on the product and where the market  
15 is.  So it's not necessarily just a short period of  
16 time --

17          MR. TYNAN:    Okay.

18          DR. VETTER:   -- before it's actually shipped  
19 somewhere.

20          MR. TYNAN:    Okay.  Thank you.  Chris.

21          MR. WALDROP:   Chris Waldrop, Consumer  
22 Federation.  I had a question that's just a little bit

1 wider than just those two presentations. I think it's  
2 probably common sense to most of us that we need to  
3 include volume somehow in this determination of risk.  
4 And I'm trying to figure out how, beyond common sense,  
5 how we actually know volume should be incorporated,  
6 and Dan in his presentation at the end had mentioned  
7 that there were risk assessment methodology that could  
8 provide predictions about how public health -- the  
9 public health impacts associated with volume.

10           And my question is, has the Agency done  
11 those risk assessments or were you just saying that  
12 it's possible to do that and maybe if the industry  
13 done these kind of risk assessments, I'm just trying  
14 to get an idea of how we know that volume and, and  
15 public health impacts are connected.

16           DR. KAUSE: Thank you, Chris. This is  
17 Janell Kause. I'm the Director for the Risk  
18 Assessment Division. And, yes, for risk-based  
19 sampling and other algorithms we have developed, we do  
20 use formal risk assessments and volume is incorporated  
21 into them to do just what you're saying, to do the  
22 prediction from making certain decisions to how that

1 would actually correlate to public health impact.

2 MR. WALDROP: So you have or are including  
3 them in your risk analysis of various --

4 DR. KAUSE: We have included them and, you  
5 know, when we talk about these decision models, one of  
6 the most well known by the public is the 2003 FDA FSIS  
7 *Listeria* risk assessment where in that case are  
8 ranking products. But we've also done it for ranking  
9 the establishments for sampling.

10 MR. TYNAN: Okay. Thank you, Chris. I'm  
11 going to ask the Operator. Operator, are you still  
12 with us?

13 OPERATOR: Yes. If anyone has a question,  
14 please press \*1 on your touchtone phone. Once again,  
15 \*1 if anyone has a question at this time.

16 Carol Tucker-Foreman, your line is open.  
17 Carol, your line is open. Please touch your mute  
18 button please.

19 MS. TUCKER-FOREMAN: I did not hear the  
20 response to Chris' question. Could the responder  
21 please get closer to a microphone and say it again?

22 MR. TYNAN: Okay. Mrs. Foreman, we have

1 someone coming up to the microphone here.

2 MS. TUCKER-FOREMAN: Thank you.

3 DR. KAUSE: Hi, Carol. This is Janell  
4 Kause. I'm the Director for the Risk Assessment  
5 Division here at Food Safety Inspection Service. And  
6 in response to Chris' question which is have we used  
7 volume data in a risk assessment that links decisions  
8 to public health outcomes and the answer is yes, we  
9 have. The most well known one is where we're ranking  
10 foods for the FDA FSIS *Listeria* risk assessment but  
11 that same type of methodology is also being used in  
12 developing our risk-based sampling frames for  
13 *Listeria monocytogenes*.

14 MS. TUCKER-FOREMAN: Have you done it for  
15 -- in this particular case or will you do it to  
16 determine how your volume of assessment of risk, how  
17 it ties into risk will affect inspection?

18 DR. KAUSE: We will be looking today. Part  
19 of the process is to get the public input today to  
20 think about how we're going to use it in this  
21 particular algorithm. So that is part of the  
22 weighting decision that's being weighted out, too.

1 One of the discussions that did occur is not whether  
2 or not we should use production volume because we  
3 absolutely need to in total risk assessment, in  
4 assessing risk, to use that data but the question is  
5 how do you weight the data and incorporate it in. So  
6 this is sort of an evolving part of this process as  
7 we get the stakeholder input.

8 MS. TUCKER-FOREMAN: But do you have a  
9 formal risk assessment underway to determine, for  
10 example, if whichever system plant control would, in  
11 fact, reduce the risk?

12 DR. KAUSE: We do have that for allocating  
13 sampling resources which could be applied for others  
14 but we also have a variety of other decision support  
15 tools that are predictive models. And I guess the  
16 answer to your question is, yes, we can do that. I  
17 think part of the process right now is just getting a  
18 little bit of feedback from the public on how exactly  
19 we're going to take that next step.

20 MS. TUCKER-FOREMAN: But will you do the  
21 formal risk assessment before you make a decision  
22 that, in fact, better controls do, in fact, reduce

1 the risk of a product depending where there's a  
2 larger volume of product?

3 DR. KAUSE: I think part of that's going to  
4 be gauged, Carol, on just some of our peer review  
5 input that we've had. And with that said, as a person  
6 in the field of risk assessment, people have to  
7 understand that assessing risk doesn't always mean a  
8 quantitative Bayesian process model. That's a wide  
9 variety of models that range from qualitative,  
10 quantitative or semi-quantitative and so on. So, you  
11 know, in this discipline we do have to look at each  
12 issue and what the question is we're trying to answer.

13 So that's why you're not hearing from me saying what  
14 we're absolutely going to do, but I think you're  
15 thinking of it as a quantitative Bayesian model. That  
16 may not be the appropriate model based on our peer  
17 review inputs.

18 MS. TUCKER-FOREMAN: At the end, I  
19 appreciate that. Thank you, and I'll yield the phone  
20 but in the end, we will want to know very specifically  
21 because our concern all along has been that FSIS has  
22 not stated clear public health goals for this project,

1 and we will want to know if you have specific  
2 information that shows that if you treat volume of the  
3 excellence of risk control in a plant, in a manner  
4 that reduces the risk of inspection in that plant,  
5 whether you can demonstrate that that does impact  
6 reduced risk and justifies reducing the inspection in  
7 that plant. We will really have to have some  
8 quantifiable information on that subject rather than  
9 just opinion. Thank you.

10 MR. TYNAN: Thank you, Mrs. Foreman.  
11 Operator, I'll take one more question from the audio.

12 OPERATOR: I'm showing no further.

13 MR. TYNAN: Okay. Thank you. I have one  
14 more here, and then we're going to talk about our  
15 breakout sessions. Ms. Scott.

16 MS. SCOTT: Jenny Scott from GMA/FPA.  
17 Janell made some very interesting, very telling  
18 comments about volume and exposure, and she's exactly  
19 right in saying that, you know, hazard in food and  
20 volume impacts the public health risk when you have  
21 the hazard present, but not when it's not present.  
22 And Janell pointed out that the risk control measure

1 is the only thing that the establishment has control  
2 over, and the only factor that's going to be  
3 influenced by the increased intensity of inspection.

4           So when I look at your Nona Matrix, or even  
5 when I look at our Decatria Matrix which is for 13.  
6 In both instances, we have to figure out where volume  
7 is going to figure in on this. As you've described  
8 your matrix, there is no description of where volume  
9 fits in other than if you go back to your original RBI  
10 algorithm where the volume was part of the inherent  
11 risk. And what we have been saying all along is the  
12 volume calculation more appropriately goes on the risk  
13 control measure side because that's where you can  
14 impact the exposure of -- for the consumer to the  
15 hazard. Thank you.

16           MR. TYNAN: Thank you, Ms. Scott.

17           Okay. In the interest of time, we are ahead  
18 of schedule, which is good. We are going to do  
19 breakouts, and as I mentioned earlier, the folks that  
20 are on the phone, Operator, we're going to try and do  
21 a breakout session with all the folks that are on the  
22 phone. So if you could keep everyone on the line for

1 us a little bit longer, I would appreciate it and  
2 welcome back to talk with your group.

3           The other groups as I mentioned earlier, to  
4 keep everybody to a manageable size, we've envisioned  
5 that we're going to have about three breakout groups,  
6 and with a very sophisticated system of red, green and  
7 blue. So you have your sticker that says, hello, my  
8 name is -- you should have a color on that sticker.  
9 And we're going to have the red group is going to be  
10 in Room 246, and we'll have some of the folks outside  
11 guide you to Room 246, but Dr. Rybolt has offered to  
12 sort of be the Chairperson/Reporter for that group,  
13 and so I'm hoping he was still willing to do that even  
14 after all the conversation. Michael, where are you?

15           DR. RYBOLT: I'm right here. Mine is green.

16           MR. TYNAN: You have green on yours?

17 Well --

18           DR. RYBOLT: I can --

19           MR. TYNAN: One second. No, no. We'll do  
20 you as green. It's just one more glitch that I'm  
21 going to have to fix.

22           DR. RYBOLT: Bryce Quick is color blind, you

1 know.

2 MR. TYNAN: It's Bryce's fault. Okay. So  
3 Michael, you're going to do the Green Group. Okay.  
4 And then the -- so your group is in Room 253. Red  
5 group is in 246 and the Blue Group is in Room 269.  
6 All of the rooms are on this floor. What I'm going to  
7 ask the two groups that don't already have a person  
8 designated for them is when you get to that group, if  
9 you could among yourselves sort of designate a person  
10 to be the Reporter for that group, your person to move  
11 things along.

12 We will, in fact, have a person from our  
13 Office of Public Affairs in the room to help with note  
14 taking, to facilitate time keep, and make sure  
15 everybody gets back here in a timely way.

16 With that, I'm going to give you the charge  
17 for each of the groups. Mr. Painter, I'll come back  
18 to you in just a moment.

19 The focus of the breakout sessions are going  
20 to be related to the two discussions you head from  
21 Dr. Harris and Mr. Anderson. So we're going to ask  
22 you, and this is listed on the Agenda. We're going to

1 ask you to review and discuss the alternative  
2 approaches for using volume as a proxy for exposure  
3 when performing a relative risk ranking. So we  
4 specifically want you to address the following  
5 questions: What are the advantages and disadvantages  
6 of each approach? Are there changes that you would  
7 make to each approach to make it more effective? What  
8 specific records should inspectors use to approximate  
9 production volume for the various product categories  
10 in these approaches? And do you have other  
11 suggestions for how to factor in exposure into  
12 assessing the risk presented by an establishment?

13 So each of the groups has the same four  
14 questions. Time is going to be of the essence, so  
15 that when we get back here for the report outs,  
16 everybody is going to report on question one and they  
17 have spent all their time on that. So you really do  
18 have to time manage. But those are the four questions  
19 that we would like each group to address.

20 Now the two persons that I didn't mention  
21 having a Chairperson, if you could in some democratic  
22 way select a person to be the Chairperson or Reporter,

1 I would appreciate it very much.

2 Are there questions on the charge to the  
3 group? Is there anything I overlooked to mention?

4 (No response.)

5 MR. TYNAN: Okay. With that, I'm going to  
6 let Mr. Painter have the very last word, and we're  
7 only going to give him a minute to do that.

8 MR. PAINTER: Thank you, Robert. Stan  
9 Painter, National Joint Council. Robert, I have a  
10 number of questions regarding inspectors and the  
11 collection of the volume and what have you, that there  
12 seems to be no time. There seems to be no time for  
13 the group to be able to do anything. I mean we're  
14 going into breakout sessions, and it seems to me that  
15 the question that I have and maybe some of the other  
16 people had would have been valuable before we actually  
17 went into the breakout session, you know, because I'm  
18 seeing that there's no other time for questions,  
19 comments or whatever from the group, other than this  
20 miniscule amount of time. So --

21 MR. TYNAN: There are two places, Stanley,  
22 I'd correct you on that. One, we certainly in the

1 question, if there are other suggestions or other  
2 comments that you want to make regarding inspection  
3 resources, how they're utilized or how they capture  
4 volume data, you can do that as part of the breakout  
5 session. So I would expect you to do that. And we  
6 then have, if the breakout sessions end early, then we  
7 will allow a little additional time for comments and  
8 suggestions, and you can see at 12:30 to 12:45, we've  
9 allowed about 15 minutes there as well. So the idea  
10 wasn't to close off conversation, but we thought the  
11 preponderance of the information that we would have  
12 would come out during the breakout sessions, in a  
13 dialogue with all the stakeholders.

14 MR. PAINTER: Okay. But in the breakout  
15 session, everybody's going to be involved in the  
16 breakout session. My understanding is you're going to  
17 put us in different rooms. So everybody's not going  
18 to be privileged to the same information, same  
19 questions and same comments. So I'm just concerned  
20 about, you know, being here and we've got a total of  
21 about 30 minutes for comments from the group and  
22 comments from the telephone people. Thank you.

1           MR. TYNAN:    Okay.    Normally what we do,  
2 we'll have the breakout sessions.    They will talk  
3 about the four questions, and there will be an  
4 expectation that when we come back to this room, at  
5 11:45, that we will have a report out from each of the  
6 breakout sessions.    So the Chairperson that's  
7 designated will be reporting out on what the different  
8 groups came up with.    If there are some questions for  
9 each of the report outs, we'll allow some time for  
10 that, for questions to the Chairperson, and again, we  
11 will have more questions and comments towards the end  
12 of the meeting.

13                        So that's the way we structured the meeting,  
14 and again, Stanley, as always, there's an opportunity  
15 for you to e-mail comments into us that you can't make  
16 during these sessions.    So I admit, we're putting a  
17 lot of information and a lot of effort into a short  
18 period of time, but we think it's better to focus and  
19 do the work in a shorter period of time.    And as I  
20 say, if anybody has any comments, not only the  
21 National Joint Council, but any of our stakeholders  
22 have comments, you're welcome at anytime to send them

1 into our e-mail site or send them directly to me if  
2 you'd like, and we'll get them to the e-mail site so  
3 that they get to the people that make decisions on  
4 that information.

5 So I hope that satisfies you a little bit,  
6 but I know you have some other issues but hopefully  
7 they'll come out during the breakout sessions or  
8 during the comment period before we close.

9 Anything else we need to talk about?

10 (No response.)

11 MR. TYNAN: Okay. So again, we have the red  
12 group in 246, the green group with Dr. Rybolt in 253  
13 and the blue group in 269, and I'm going to ask Sally,  
14 if she's out there and LaVonne, to try and make sure  
15 that everybody gets where they need to be.

16 And Janell, could I ask you and Dan to stay  
17 for just a moment for the people that are on the  
18 phone.

19 (Off the record.)

20 (On the record.)

21 MR. TYNAN: Okay. What I'd like to do is  
22 start off with the Red Group. The second group will

1 be the Blue, and I think that's Dr. Vetter?

2 DR. VETTER: Yes. So Dr. Vetter is going to  
3 start out with group one, the Red Group. Blue Group  
4 will be number two, and that's Skip, and then the  
5 Green Group, and last but not least, we're going to  
6 allow the folks on the audio, Mark, to report out. So  
7 we have a microphone right here for you, Dr. Vetter,  
8 if you'd like. And with that, if you would again  
9 introduce yourself and your association, and then  
10 we'll go from there.

11 DR. VETTER: Yes, my name is Danah Vetter,  
12 and I'm here representing NAFV. I'm a veterinarian  
13 with FSIS in the plant, and I'm also trained as an  
14 EIAO.

15 So our group had quite a bit of discussion  
16 and I have quite a few notes, and I'm going to try and  
17 bring out the main things that we talked about in our  
18 discussion, and I told my group members that if I left  
19 anything out, don't hesitate to let me know so that I  
20 give a voice to everybody's perspective.

21 The first question was the disadvantages and  
22 advantages of the approaches that were presented. And

1 what we decided, we kind of had a consensus in our  
2 group that we agreed with the Nona Compromise being  
3 the best approach because that way or a more  
4 applicable way of using the Nona Matrix because  
5 everyone has an opportunity to be in Category 1 or  
6 Category 3.

7           The disadvantage is the one that was  
8 proposed. There's still a gap, in that if you're the  
9 largest plant with 100, that you have a really good  
10 risk control measure, you still can only be a Category  
11 2. You're locked into Category 2. And theoretically  
12 the same would apply to a very small establishment  
13 that has a very bad risk control measure. They would  
14 still only be a Category 2 versus a 3. So those were  
15 the biggest points that were brought out with the  
16 advantages and disadvantages, and like I said, there  
17 was a consensus that we liked what we're referring to  
18 as the Nona Compromise, and that we thought it was more  
19 applicable.

20           Also during this discussion, there was sort  
21 of an overall question about the impact of risk-based  
22 inspection. I know this is not applying to volume,

1 but I just want to bring it out and say whether it was  
2 to improve public health or whether it was a  
3 management decision, there a little bit of discussion  
4 about that, and that that was upon the Agency to  
5 really clarify that.

6 The second question was -- did I miss  
7 anything from my group members?

8 (No response.)

9 DR. VETTER: Okay. The second question was,  
10 "Are there change that you would make to each approach  
11 to make it more effective?" And number one, since we  
12 all kind of agree with the Nona Compromise, that there  
13 would be an algorithm to support that outcome. So --  
14 or something that, some change to the current  
15 algorithm that would support that outcome.

16 One suggestion also was that you look at  
17 volume in sort of a geometric way I guess so that the  
18 worse that you are, the greater the weight of volume.

19 So if you've got a very large risk control number,  
20 then your volume we count more versus if you have a  
21 really good risk control measure, then your volume  
22 would not count quite as much. Let me go back to my

1 notes, which are like all over the place. That's as  
2 much as I got to organize.

3           Again, there is also a lot of difference in  
4 opinion about whether volume should be part of  
5 inherent risk or whether it should be part of the risk  
6 control measure, and there are opinions on both sides  
7 of that. For it being part of the risk control  
8 measure, the argument was that you're kind of making  
9 the assumption that the product is adulterated by  
10 making it part of inherent risk, and that the public  
11 will be affected by it. And you really can't make  
12 that assumption. That's not an assumption that we can  
13 make. And so they thought that volume should be  
14 placed as part of the risk control measure, and if  
15 you're doing really well, you know, your volume's in  
16 and it plays a part of that number as a whole.

17           The other side -- and if I didn't give that  
18 opinion justice, let me know. The other side is that  
19 volume truly what we're discussing here is a proxy for  
20 exposure and so even in the perfect plant, if they're  
21 producing 100,000 hot dogs a day, if something goes  
22 down and it doesn't work that great, the more people

1 could be exposed. And so that was the other side of  
2 that opinion of why it should be still part of  
3 inherent risk.

4 But I think there was a consensus that  
5 everyone agreed that the volume was overshadowing.  
6 The way that the algorithm is weighted now, we have 1  
7 to 5 for the volume. It is overshadowing the other  
8 risk measures and weighing in too much at this point.  
9 And I believe that within our group there is a  
10 consensus about that.

11 The third question was, "What specific  
12 records should the inspectors use to approximate  
13 production volume for the various product categories?"  
14 And I had a lot of opinions myself about this, but I  
15 believe that the instrument that's been used, the  
16 survey, probably needs to be adjusted to be a more  
17 accurate representation of what's out there because I  
18 think it's low balling for a lack of a better word.  
19 In the explanation, they asked how we got this in-  
20 plant, how we filled these out and got these numbers  
21 and I explained that in a large producing plant, it  
22 was very easy because the amount of volume was so much

1 over the highest choice that it was very easy to  
2 select that, in the survey. So I felt that through  
3 the survey it needed to be -- there needed to be more  
4 breadth to that. It needed to be spread out so we  
5 would have a better range that's more representative  
6 of what plants are actually doing out there.

7           The other thing that was suggested and there  
8 seemed to be a consensus with the group is that the  
9 approach that was taken with the RTE form, that that  
10 same approach be followed to collect more accurate  
11 data about the volume that the plants are putting out  
12 there, and then the suggestion that I made was that  
13 that then be put into sort of a distribution curve,  
14 using statistical analysis, and that could be used to  
15 give a -- to plant volume. And I know that that's a  
16 lengthy process but similar to the way it was done  
17 with ready-to-eat, where the form was produced, it was  
18 given to inspectors. They first got that information  
19 and provided it to FSIS and then later on, once there  
20 was approval for it being used under the Paper  
21 Reduction Act, then the industry did it themselves,  
22 you know, and it could be done annually. It could be

1 done every six months because there's been talk about  
2 looking at a moving window of about every six months.  
3 And then the other benefit that I see is that if a new  
4 plant comes in, they again would have to fill that out  
5 and provide that information, and they would just fall  
6 in wherever they fall in. It would be a more accurate  
7 representation.

8           There was also discussion about whether it  
9 should be product produced versus product shipped and  
10 we had two different opinions on that. One was that  
11 it should be product produced because that  
12 equilibrates to what is potentially out there for  
13 exposure to the consumers, and that particularly when  
14 we were talking about frozen product that could be  
15 held for a long period of time, it was brought up  
16 about that there's a recall on hamburger product. I  
17 think that that's about a year old. So that was one  
18 opinion. The other opinion is that it should be  
19 product shipped because, for example, if it's  
20 *Listeria*, if it's an RTE plant, and FSIS has taken a  
21 test, and they're holding that product, the same goes  
22 for *E. coli*, that product's not going out to commerce

1 if that test comes back positive. Then they are able  
2 to keep that risk from getting out to consumers. So  
3 there was two different sides to that.

4 So I guess that goes back to you guys. Then  
5 that really needs to be defined, shipped versus  
6 produced or both combined or how that's going to  
7 figure into volume, because there's a different --  
8 it's kind of split on that as well.

9 Other suggestions, again we really liked the  
10 Nona Compromise. So sort of adapting the algorithm to  
11 that so that -- because that was where the main focus  
12 was, was the outcome. Everybody talked about the  
13 outcome and that we felt like the Nona Compromise  
14 would be a good outcome, and that the outcomes are  
15 reasonable and do improve public health because that  
16 would be the overall goal.

17 There was a suggestion that an algorithm be  
18 comprised that actually has three components to it,  
19 not two, that you have inherent risk of product and  
20 then you have the risk control number and then you  
21 have volume, and they're three different factors that  
22 could potentially be looked at as three different

1 factors and that would allow you to fall into a  
2 certain group, or they could be combined to ultimately  
3 come up with one number that would allow you to fall  
4 into one group. And then that the volume again would  
5 be weighted. It would be dependent upon how well  
6 you're doing with your risk control measure as well.  
7 And again, just to reiterate, the actual goal is to  
8 improve public health outcomes and that that related  
9 to risk and that all of this comes back to that.

10 If I left anything out, please let me know.

11 MR. TYNAN: Thank you very much, Dr. Vetter.

12 Any questions?

13 (No response.)

14 MR. TYNAN: Okay. I'm going to let group  
15 two come down and Mr. Seward, when you get down, if  
16 you could introduce yourself and your affiliation, I  
17 would appreciate it.

18 MR. SEWARD: Skip Seward, American Meat  
19 Institute, representing the Blue Group, and we'll just  
20 go over this relatively quickly and try not to repeat  
21 too much of what you've already heard.

22 But in the original document, that was

1 issued on April 2nd, the advantages which extends all  
2 the way across all three groups is that we believe  
3 it's appropriate to weight the different products by  
4 their inherent risk, the product mix and how much of  
5 them are produced. So from a certain extent, you get  
6 a little volume entered into it there because of the  
7 proportion of your production, and we think that's  
8 appropriate for all three models if you will.

9           The disadvantage was as you've already heard  
10 several times, was that the volume impact is really  
11 not equitable in the initial model, and we saw that  
12 today.

13           In the second, what's called the Nona model,  
14 all we really had to work with was one page, a sketch  
15 of a box with some -- we didn't have any algorithm  
16 associated with that, but we learned that, in fact,  
17 it's the same algorithm that's being used in the April  
18 2nd. So all of the same concerns are expressed there  
19 as well.

20           There might be some potential benefit to  
21 splitting out the RC, the risk measure and the product  
22 inherent risk measure, and treating those as two

1 separate entities versus adding them together although  
2 that's -- this may be more of an exercise on than  
3 anything else. Again, it doesn't allow all plants to  
4 reach all levels as you heard, and volume is still  
5 part of the PIR which we think is disadvantage.

6 In the compromise model, of course, the  
7 advantages are that it allows all plants to achieve  
8 all levels which you've heard, and the volume  
9 component is either going to be part of the  
10 establishment risk measure or an independent variable  
11 which we think is advantageous, gives you a lot more  
12 flexibility. Of course, the limitation more than a  
13 disadvantage is that there's no final algorithm at  
14 this point to share with everyone to show how all  
15 those work together.

16 What changes need to occur? Well, I think  
17 we can just disregard the April 2nd one, but we think  
18 the volume factor overrides a good establishment risk  
19 measure, and that's true for both the Nona model and  
20 the April 2nd model, and that's pretty straightforward  
21 and you've heard that more than once. For changes for  
22 this, we need a better description of how the data is

1 going to actually going to be used, and that's what we  
2 talked about before is that I know an industry group  
3 has been working on how to make that work for all  
4 types of establishments. So that's the work to be  
5 done either by FSIS or by the industry group or by a  
6 cooperative effort there.

7           What type of records need to be produced or  
8 need to be available, and these are the HACCP records  
9 that FSIS has access to now. We think that that's  
10 appropriate and accurate and, you know, but we thought  
11 that there was some opportunity here and it could be a  
12 component of the upcoming data sharing exercise where  
13 we, you know, industry may be willing to take a form  
14 and voluntarily supply that information to help the  
15 inspection staff out, say this is what we're planning  
16 to do in the next 30 days. This is what we did the  
17 last 30 days and just keep going on and on since it's  
18 in their best interest to make sure that the  
19 inspection staff has a good idea of what they're going  
20 to be manufacturing in the plant. So this is  
21 something that could be discussed later, but we don't  
22 see any reason why that might not be an option.

1           And lastly, how do you make the exposure  
2 evaluation a little bit more meaningful than strictly  
3 volume, and we again talked about this voluntary  
4 production schedule giving a perspective approach on  
5 what we're going to be making, and in the sense that,  
6 you know, it's a little bit helpful I'm sure to FSIS  
7 to know what that establishment's going to be doing,  
8 but certainly when it comes to exposure and tagging  
9 onto what a couple of people have said already,  
10 obviously you want to know if there's a potential  
11 pathogen in the finished product. So here's where  
12 verification and testing data on finished product,  
13 even though it's captured in the risk control measure,  
14 what we're really talking about is if product has been  
15 shipped from an establishment and there's a potential  
16 pathogen there, that certainly suggests that the  
17 exposure from products coming out of that facility, at  
18 least on that day, on that lot of product is higher  
19 than it would be otherwise. So we think that might be  
20 a way to capture a little bit more accurate exposure  
21 information. And the last thing, of course, is we've  
22 already had a meeting on attribution but the sooner we

1 get there, and we have a link between an illness and a  
2 specific product from a specific establishment, that  
3 those data would also obviously helpful in trying to  
4 better gauge the exposure.

5           Anyone else from the group want to add  
6 anything else?

7           (No response.)

8           MR. SEWARD: Okay. That's it from us.

9           MR. TYNAN: Thank you very much, Skip. I  
10 appreciate that.

11           Dr. Rybolt, you're on, and you're the Green  
12 Group.

13           DR. RYBOLT: I'm the Green Group. We had a  
14 lot of good discussion. I'm sorry. I'm Michael  
15 Rybolt with the National Turkey Federation.

16           We had a lot of good discussion in our  
17 group. We started out trying to address the questions  
18 and the discussion led to, we really can't answer  
19 questions 1 and 2 because we didn't have enough  
20 information about how you would move a plant within  
21 those boxes there. So the outcome of questions 1 and  
22 2 is we need more details of the approach.

1           And some of the I guess items that came out  
2 during that discussion, one was that there needs to be  
3 more matching of product type with some of the  
4 interventions that are in place. Some of that is  
5 incorporated into the expert elicitation, but it may  
6 need to go a little bit further. Maybe that can be  
7 calculated into the equation as well. One suggest was  
8 that volume, and these are all suggestions, we didn't  
9 have any consensus on any of these points, that the  
10 volume should not be a direct multiplier because it  
11 negates the ability to control or the establishment's  
12 controls and I think that was articulated by some of  
13 the other groups.

14           Question 3, we talked about, you know, what  
15 are some processes or means to actually capture this  
16 information. We had a lot of good suggestions here.  
17 One was that the circuit supervisor should update the  
18 volume data regularly, and that could be done through,  
19 I think it was mentioned by Dr. Vetter earlier, you  
20 know, that can be done through similar processes that  
21 we have in place now with 10240.1 and that can be  
22 done, more of an onus on the plant to make sure that

1 that is updated. Suggested timeframes would be maybe  
2 monthly. Daily obviously would become a little bit  
3 too burdensome on everybody involved. Weekly might be  
4 possible but then again, you would have to assess how  
5 burdensome that may be and some of the information  
6 that's on here is already actually articulated and  
7 it's just some thoughts that we put. So I'm not going  
8 to ready through everything.

9           One thing that was mentioned was that  
10 interventions should be incorporated into the RBI. I  
11 know Dr. Raymond has articulated this before by  
12 incentives to establishments to move. Another  
13 suggestion that was made was that when the levels of  
14 inspection are identified for an establishment, that  
15 not only are inspectors identified, but the plant  
16 should be made aware of that at the same time. We  
17 talked about how often the plant profile should be  
18 updated to incorporate, you know, product changes,  
19 product type and interventions and things like that.  
20 So how often would that be incorporated. Maybe that  
21 could be incorporated with the volume updates. We had  
22 an example of or suggested equation for factoring in

1 volume. Again, we didn't come to any consensus here.  
2 I don't know if it's going to work itself. So -- but  
3 that was an example that was put up on the board. We  
4 also did talk about volume, strictly moving volume  
5 over to the risk control measure side of the equation  
6 because that's where the plant has control of the risk  
7 of a product.

8           We did talk about the Nona and Jenny's  
9 Decatria. We talked about the two different matrixes.  
10 We talked about how those worked. I explained how the  
11 Decatria would work, and again, we didn't come to any  
12 consensus there, but there was also no objection to  
13 one or the other. It was back to the first point  
14 there is how do we know how a plant moves within this  
15 or setting some sort of examples of how plants would  
16 move, would probably help us determine which matrixes  
17 would work best.

18           So I think some similar comments were made  
19 by the others.

20           Dr. Engeljohn was just making sure I said  
21 something about the circuit supervisors, and that was  
22 a suggestion for updating the volume production.

1           Do you have any other comments, Stan or  
2 Chris? Something I left out or forgot?

3           (No response.)

4           MR. TYNAN:     Dr. Vetter, did you have a  
5 question?

6           DR. VETTER:   I was going to comment on the  
7 circuit supervisors' suggestion.     I mean they're  
8 already overburdened and you --

9           MR. TYNAN:    If I could just ask you to --  
10 wait just a second. Let's get you a microphone so the  
11 folks on the phone can hear as well.

12           DR. VETTER:   I was just going to comment on  
13 the circuit supervisors' suggestion, is they, you  
14 know, some of them have 20 plants. Some of them have  
15 15. Some of them have 30, and so for them to enter  
16 that data in would probably just increase their  
17 already overburdened expectations.

18           MR. TYNAN:    Okay. Thank you. Stanley?

19           MR. PAINTER:   Stan Painter with the National  
20 Joint Council. I'm going to disagree with the last  
21 comment that was made. When an inspector is assigned  
22 in certain situations to cover 21 facilities, you

1 know, in a daytime which that has happened, you know,  
2 I don't need to hear overburdened from a circuit  
3 supervisor because they have 30 something  
4 establishments period. I know the circuit supervisor  
5 of the plant where I'm located has come into that  
6 facility twice in about the past seven days. So, you  
7 know, and I don't want to be put into the position as  
8 a representative that the, you know, plants are  
9 needing updated and because of staffing and computer  
10 issues and what have you, if it's meant to be  
11 distributed by the computer because, you know,  
12 although we have a satellite system, you know, dial up  
13 is in a lot of cases faster than the system. You  
14 can't get on. You can't stay on, you know, and that's  
15 further going to complicate the issue of, you know,  
16 our relationship with plants and circuit supervisors  
17 outside the plants, they can come in, they can do  
18 that. They have assessments they have to fill out.  
19 If they do what they're supposed to do, they're  
20 supposed to be coming to the plants anyway.

21 MR. TYNAN: Okay. I don't think there was  
22 any question that it was a heavy workload for the

1 inspectors in the field. I don't think that was the  
2 implication at all. The last group -- and then you  
3 for your comment.

4 The last group is on the phone, and Mark  
5 Schad is the Chairperson and going to be the reporter.  
6 So if the operator can open his mike, and I'm going to  
7 turn it over to Mr. Schad.

8 MR. SCHAD: Yes, I'm here, Robert. First of  
9 all, I want to thank the Operator for her time and  
10 thank the people in the group for their input.

11 As far as question number 1, some advantages  
12 here of the Nona Approach, there was a comment made  
13 that one advantage is it's more descriptive of these  
14 plants having nine categories as opposed to the three  
15 levels as we talked about on April 2nd, eliminate some  
16 subjectivity for consistent and uniform. There was a  
17 comment from one person on the phone that he liked  
18 Dr. Harris' approach to the algorithms.

19 Some of the disadvantages and I think this  
20 was just some concerns overall about not using proper  
21 collection tools as far as the collection of the  
22 volume data, not having an OMB form to use. There was

1 concern about not apparent there was a linkage between  
2 volume and testing and data driven -- another comment  
3 about data driven, not convinced inspection collection  
4 of volume data is good.

5           As far as question number 2, about changes,  
6 there was at least three or four comments about volume  
7 should be a third axis or the Z axis. Another  
8 comment, need to insure specific records are used to  
9 assess volume. Another comment, volume needs to be  
10 clearly defined so the data is consistent. Need to be  
11 sure the matrix will address the volume if a plant is  
12 having difficulties. Another comment, volume is risk  
13 of exposure to the consumers and OMB needs to be used  
14 to get good collection data.

15           As far as putting those comments together  
16 for question 2, I think that was one -- I'm talking  
17 about -- let me get through the axis first. That was  
18 not a consensus as far as the axis, but there was  
19 enough people that made that comment about the third  
20 axis. I think it's more warranted to make as far as a  
21 strong comment. And the other thing I think we got  
22 together on is the consistence was we need to use

1 shipping records because that is where it gets down to  
2 the actual exposure to the consumer. We talked about  
3 the one on weight of incoming product and the one  
4 about yield loss during the production process, but I  
5 think the bottom line is we agreed upon you have to be  
6 concerned with what is the actual volume exposure to  
7 the consumer, and that is best defined by the amount  
8 of product that is shipped out.

9           As far as question 3, regarding records for  
10 the inspectors to use, several comments here. Using  
11 inspectors to collect data under the best  
12 circumstances may not be accurate. If inspection  
13 personnel are used, plants need to verify or  
14 challenge, needs to be inspector/plant combination to  
15 insure quality control. There was one comment about  
16 the MP404 form from years past. Maybe that could be  
17 brought back because that was used to report on plant  
18 volume.

19           Question 3, I think that's one area where as  
20 a group we came to a consensus on. That would be the  
21 inspector doing what access he had, as far as putting  
22 together a production report, and then going to plant

1 management and asking them to verify or validate that  
2 data as far as its accuracy. The plant manager could  
3 say, yeah, that's correct or, no, I don't believe  
4 that's correct and then show information to the  
5 contrary. And I think we could go across the board  
6 there as far as industry. The people in the industry  
7 from the group felt like that industry would be  
8 willing to share that data, and -- groups felt like  
9 that would be an acceptable way of doing things.

10           As far as question 4, several comments  
11 there, incorporate what is known from other agencies.  
12 The comment again about using volume as a third axis  
13 in the matrix, that was again brought up. There was a  
14 comment and I thought it was an interesting one about  
15 you've got two plants making the same volume of  
16 product, one is a single product plant and the other  
17 one is a multiple product plant over different  
18 inherent risk categories, maybe they should not be  
19 considered the same from strictly a volume standpoint.  
20 The question is, how are we going to address this?  
21 And the last comment on question 4 was plant's  
22 history, compliance, testing, these changes should all

1 affect volume. And that's what I have, Robert.

2 MR. TYNAN: Okay. Thank you, Mark. Any  
3 comments from the group or questions?

4 UNIDENTIFIED SPEAKER: Could you ask him to  
5 repeat his last point?

6 MR. TYNAN: Mark, could you repeat the last  
7 point you made? Mark, are you still there?

8 MR. SCHAD: I'm sorry, Robert. I forgot to  
9 push my --

10 MR. TYNAN: I thought you were going back on  
11 your vacation.

12 MR. SCHAD: Might ask somebody from the  
13 group if that's a possibility to come in to make the  
14 comment because this is one of those things that I  
15 just wrote down in my notes, and just in fairness, I  
16 wanted to report on it because in looking back, I'm  
17 not sure I understood the comment, but the comment was  
18 plant history, compliance, testing and changes should  
19 affect volume. So I'm going to ask for some help from  
20 the group so we can get somebody to call in and  
21 comment on that.

22 MR. TYNAN: Okay. Thanks again, Mark. I

1 appreciate it very much.

2           We're a little bit ahead of time, and I  
3 wanted to mention that after the meeting, we're going  
4 to put up the Greek numbering system so that it will  
5 be available for everybody prior to these meetings, so  
6 we all know or are speaking the same language.

7           But I also wanted to take just a second, I  
8 know we had a little glitch this morning with the  
9 audio, but I want to thank the folks that helped put  
10 these meetings together. We have Sheila Johnson at  
11 the back who has worked tirelessly along with Sally  
12 Fernandez, Kathleen Barrett up front, despite the  
13 little glitches. It's not thing that they were able  
14 to control. So I want to thank them for all the hard  
15 work and they'll be doing it again in about an hour  
16 for next Monday. So I want to thank both of them.

17           Now we're at the point in our agenda where  
18 we are going to solicit general comments and concerns  
19 regarding the entire meeting, anything that came up.  
20 So again, I would invite you to come to one of the  
21 microphones that are in the aisle. If you have any  
22 questions or comments on anything that's been

1 discussed here today, whether it's the breakout  
2 sessions or if it's the presentations that occurred  
3 earlier this morning. And I'll take a question from  
4 here, and then I'll go back to the folks on the phone.

5 MR. SEWARD: Skip Seward, American Meat  
6 Institute. One thing that I guess I sort of expected  
7 to see today that didn't come forth that would be nice  
8 to have is a little bit further analysis or conveyance  
9 of the Food Safety and Inspection Service data itself.  
10 When I, you know, looked at the volume issue and  
11 exposure issue, I think all of us, you know,  
12 understand that if you have a high volume producer  
13 that ships product that's adulterated and there's a  
14 high risk and a high exposure to the public with that.  
15 But when you look -- so my question is, I'm going to  
16 share a little data with you, and then I'd like to  
17 hear from some folks at the Food Safety and Inspection  
18 Service about, you know, their take on these data.

19 For example, if you look at the suspension  
20 data, and I think this is in your quarterly  
21 enforcement report, but if you look at the suspension  
22 data, and I suppose there's a lot of reasons for

1 suspension, not all related to food safety issues and  
2 so forth but, you know, and I looked at the last 8  
3 quarters from the second quarter 2005 to the first  
4 quarter 2007, and 58 percent of the suspensions were  
5 very small establishments, 38 percent were small and 4  
6 percent were in large. And I looked at the 2006  
7 ready-to-eat testing data for *Listeria monocytogenes*,  
8 and 42 percent or 25 of 60 samples were from very  
9 small establishments, 57 percent or 34 of 60 were from  
10 small and 2 percent, 1 out of 60, was from a large  
11 establishment and you can also look at it by volume  
12 and it pretty much parallels that. But that's a  
13 pretty telling story in terms of potential exposure  
14 and where those samples are coming from, at least  
15 according to that data for *Listeria monocytogenes*.  
16 When you look at the *Salmonella* data for 2006, it's  
17 not clear at all.

18           It's very product dependent in terms of  
19 relative to the distribution across plant sizes for  
20 the different product categories but I wondered if  
21 the Food Safety and Inspection Service could comment  
22 about, you know, whether they look at these data and,

1 you know, use those in their analysis of the volume  
2 issue as it pertains to risk-based inspection. Thank  
3 you.

4 MR. TYNAN: Okay. Don, were you going to  
5 respond to that?

6 MR. ANDERSON: I'll maybe try to facilitate  
7 it as much as respond to it. I mean one comment you  
8 made, you talked about the distribution of  
9 suspensions in plants of the three different -- I  
10 think you were referring to HACCP sizes. You're  
11 nodding yes.

12 MR. SEWARD: Yes.

13 MR. ANDERSON: The suspensions, proportion  
14 suspensions. I didn't write down the numbers. You  
15 went through them pretty quickly, but I think the  
16 distribution of suspensions by HACCP size was not  
17 much different than the distribution of  
18 establishments out there by HACCP size or it wasn't  
19 clear to me, and I don't know what you were trying to  
20 say exactly except that I think we would expect to  
21 see, you know, we would expect to see more  
22 suspensions in very small plants if we have an

1 equitable if you will, for lack of a better term, if  
2 we have an evenhanded suspension system that we would  
3 expect to see that very phenomenon.

4 MR. SEWARD: That could be. I guess my  
5 point was the analysis of what was the cause of those  
6 suspensions and were they related to food safety  
7 issues. That was my take on that but thank you.

8 MR. ANDERSON: Well, it is true that in the  
9 -- remember that in the, and I know this goes back to  
10 a specific presentation on April 2nd, but remember  
11 that one of the seven factors in the risk control  
12 measure are what we call enforcement states, and a  
13 plant that's suspended or operating pending, you  
14 know, further action and there are six or seven  
15 different suspension states and more are enforcement  
16 states, and establishments that are under some type  
17 of enforcement action do get points for that in their  
18 risk control measure and they would be subjected to a  
19 higher level of inspection. And is that, is that  
20 some how connected with volume, no. It's treated in  
21 the risk control measure but, yes, to establishments  
22 with equal volume and equal hazardous products,

1 establishments that have suspensions as you put it or  
2 any kind of enforcement action would -- all else  
3 equal would be receiving a higher level of  
4 inspection.

5 DR. KAUSE: Okay, Skip. This is Janell  
6 with the Risk Assessment Division. I want to just  
7 recap real quick the *Listeria* testing. I think the  
8 numbers that you went through were basically there's  
9 a higher percentage of testing among the small plants  
10 versus the large?

11 MR. SEWARD: A higher percentage of  
12 positives for *Listeria monocytogenes*.

13 DR. KAUSE: Right. I'm going to walk  
14 through real quickly about risk-based *Lm* sampling  
15 that we have here at FSIS. The way that we allocate  
16 our samples is really based on risk, and when I say  
17 that, the major factors that are driving that  
18 particular algorithm is the interventions that are in  
19 place in each of those establishments that are  
20 producing post-lethality exposed ready-to-eat meat  
21 and poultry products and the produce, whether or not  
22 it can support the survival and growth of the hazard.

1 And the way that we get the ratings for both of those  
2 factors is two process Bayesian models. One is the  
3 2003 FSIS *Listeria* risk assessment, which helps us  
4 with the interventions. That's how we get  
5 alternative 1, 2, 3, and then with the product, we  
6 get that from the risk ranking which is a set of 23  
7 quantitative risk assessments that we did with FDA  
8 back in 2003.

9           The volume factors in as after fact, in  
10 that particular model because it's adjusting it.  
11 Volume is another factor that gets weighed in but  
12 it's not weighed in heavily because as my discussion  
13 was this morning, it's about the likelihood of a  
14 contaminated serving, and then after you know that,  
15 how many servings are going out the door. So the  
16 sampling is directed in that way, in a way to  
17 hopefully find those positives. We want our  
18 inspection -- our verification resources going to  
19 where we expect to find them. So hopefully that is  
20 what we are seeing.

21           MR. TYNAN: Okay. I'm going to ask the  
22 Operator if she could open the lines for whoever has

1 a question on the phone.

2 OPERATOR: Once again, \*1, if anyone has a  
3 question.

4 (No response.)

5 OPERATOR: No one has queued up at this  
6 time.

7 MR. TYNAN: Okay. Thank you, Operator.  
8 Any other questions from the group here?  
9 Mr. Painter.

10 MR. PAINTER: Stan Painter with the  
11 National Joint Counsel. Robert, I basically have a  
12 comment. I do appreciate the opportunity to be a  
13 part of the process and hear what we have to say. I  
14 was under the impression that this was going to be a  
15 little bit different than it was. It seems to me  
16 that the -- instead of the Agency saying this is the  
17 process and we'd like your comments on it to refine  
18 it, you're asking us to develop it, and I have a  
19 concern with that. It's, to use some southern  
20 terminology, it's like developing the process in  
21 which for us to whip you with, you know. Do you want  
22 us to whip you with a belt or do you want us to whip

1 you with a hickory, you know, and we're charged with  
2 developing the whipping tool? And I'm really not  
3 comfortable with that process. I certainly am  
4 comfortable with making comments on something the  
5 Agency has developed but not, you know, and refining  
6 and doing not what needs to be done but, you know,  
7 developing the process is something I'm not  
8 comfortable with.

9 MR. TYNAN: Okay. I would disagree with  
10 you a little, Stan, and I know that that's not the  
11 Moderator's role but I do think Dr. Raymond pointed  
12 out earlier that FSIS doesn't take the position that  
13 we have all the answers for everything. So we think  
14 our intent was to try and open up the discussion. We  
15 heard some comments at our April 2nd meeting and  
16 tried to make some adjustments. So our purpose today  
17 was to present those adjustments, the ones that we  
18 developed and also give some of our other  
19 stakeholders an opportunity to do the same, to  
20 present alternative views, and based on that, we'll  
21 make some decisions on how we want to proceed.

22 So I understand it's a little bit fluid,

1 perhaps was not the way you viewed it happening, but  
2 I don't think we're asking anybody to develop  
3 anything for us. We're asking for everybody to  
4 provide the best ideas that they can come forth with.

5 So unless somebody else has some other  
6 comments, I'm going to introduce our Deputy  
7 Administrator, Mr. Bryce Quick, for some closing  
8 remarks, and I want to point out again, he was kind  
9 enough to give up his time this morning so that we  
10 could have a little extra time for our breakouts and  
11 so on. So I'm going to turn it over to him.

12 MR. QUICK: Thank you, Robert. As usual,  
13 Robert's done a fantastic job of moderating. We're  
14 very lucky to have him on board with us.

15 I want to thank every body in this room and  
16 those on the phone for once again taking time out of  
17 your schedule and demonstrating your commitment to  
18 risk-based inspection and building the most effective  
19 and robust system that we possibly can. I couldn't  
20 help but notice that Mark Schad is on vacation right  
21 now and earlier we had Carol Tucker-Foreman calling  
22 in from the beach. So I don't know if that's crazy

1 or not, but it's notable.

2           The only real disappointment that I have is  
3 that Tony Corbo sent his shy twin brother today and  
4 that's a real loss. What have you done with him?  
5 Did you want at least one word?

6           MR. CORBO: Dr. Vetter can testify that I  
7 participated quite vigorously in the workshop.

8           MR. QUICK: That's what we wanted to hear.

9           MR. CORBO: And I don't want Dr. Raymond to  
10 get his blood pressure to go up. I gave him a pill  
11 right before this so --

12           MR. QUICK: Thank you, Tony. Well, as I  
13 said before, our efforts are improved every time we  
14 meet, and we are improving our system as we go along,  
15 and your ideas and thoughts have been incorporated at  
16 every step of the process as much as possible, and  
17 we're going to continue to try to incorporate some of  
18 your thoughts and ideas to make this the strongest  
19 and most effective public health driven system  
20 possible. And so we will continue to have these  
21 meetings and we're going to make adjustments on an  
22 appropriate needs basis and hopefully you all

1 continue to participate in these sessions.

2 I need to point out that as we move through  
3 this process, we've talked about this before, but the  
4 component of evaluation is the most important in my  
5 mind and in the Agency's mind and there will be a lot  
6 of folks evaluating and auditing and analyzing the  
7 data and other components of this system throughout  
8 the process.

9 Through this process, we're going to be  
10 asking two questions. Is RBI being implemented as  
11 designed? We'll be asking other questions. But are  
12 inspection resources being effectively allocated under  
13 RBI thus improving public health? We will be mindful  
14 of these things as we move through this process.

15 The evaluation component will be made up of  
16 quantitative and qualitative components. Our  
17 evaluators will conduct qualitative analysis through  
18 interviews with field and Headquarters personnel and  
19 site visits to RIB establishments. FSIS evaluators  
20 will conduct quantitative analysis of inspections,  
21 sampling and other data related to RBI. Through  
22 quantitative data analysis, once RBI begins,

1 evaluators will be able to begin to determine whether  
2 inspection program personnel are performing their  
3 duties at the required intensities. How RBI  
4 establishments are performing in comparison to their  
5 past performance and to control establishments and  
6 what changes in data trends show about the  
7 effectiveness of RBI, and we're hoping that by  
8 examining the data trends of both RBI and control  
9 establishments for statistically significant changes,  
10 our evaluators will be able to assess whether a change  
11 was related to or caused by RBI.

12           It's important to point out that if you're  
13 watching some of the Congressional activities, the  
14 Office of the Inspector General will be taking a very,  
15 very strong look at what we are doing, and that was  
16 directed by Congress. And quite frankly, we are very  
17 -- we welcome this -- because it will I believe help  
18 us build a very strong system. Having a third party  
19 and we were talking and joking about this between the  
20 sessions, third, fourth, fifth, sixth party, look at  
21 what we're doing, I think it's helpful, and it goes to  
22 what Dr. Raymond has said over and over and over. We

1 want to be fully open and transparent in this process,  
2 and the OIG has informed us and they are looking at  
3 our initial rollout, but also they will be out in the  
4 field and there will be some overlap in our plants, in  
5 these establishments. They will be looking at our  
6 data, and they will be looking at the algorithm, every  
7 aspect of that algorithm to make sure that it's sound  
8 and that we have the data underlying a system that is  
9 actually making improvements to public health.

10           On that note, we want to make sure that we  
11 invite you, Skip referred to our next meeting, on  
12 industry data. It's a subject that we have discussed  
13 quite a lot over the last four years. We haven't made  
14 a lot of progress but we're hopeful that building on  
15 the, I think the basis of knowledge that we've created  
16 so far, we can actually come up with something from  
17 that, recognizing how important that data is and how  
18 helpful it would be to this cause.

19           So we would invite you all to join us here  
20 again Monday. So we're holding these as often as  
21 possible and we're not giving you a lot of rest, but  
22 we hope that you will take advantage of that

1 opportunity to come here and join in that discussion  
2 as well.

3           Also, on July 10th, we will hold a Fifth  
4 Summit on the current expert elicitation on inherent  
5 product risk, and we'll continue to keep you informed  
6 about the meetings through our website. You can also  
7 go to the website to FSIS Constituent Update and FSIS  
8 News and Notes. You can also -- we need to remind you  
9 that you can submit further comments at anytime in  
10 this process to our website, and that's  
11 riskbasedinspection@fsis.usda.gov.

12           And I think in closing I'd like to say that  
13 regardless of where you're coming from, government,  
14 industry, consumer groups, I think that we all share  
15 the one common goal, and that is improving public  
16 health. So I want to thank you again for coming and  
17 hope to see you all on Monday.

18           (Whereupon, at 12:35 p.m., the meeting was  
19 concluded.)

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C E R T I F I C A T E

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

PRODUCTION VOLUME AND ITS ROLE

IN RISK-BASED INSPECTION

Arlington, Virginia

April 25, 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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