

UNITED STATES DEPARTMENT OF AGRICULTURE  
FOOD SAFETY AND INSPECTION SERVICE

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USING DATA FROM OTHER SOURCES

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April 30, 2007  
9:00 a.m.

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

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

2 (9:00 a.m.)

3 MR. TYNAN: Hi. Good morning. My name is  
4 Robert Tynan. I'm the Deputy Assistant Administrator  
5 in the Office of Public Affairs, Education and  
6 Outreach. So we have my introduction out of the way.

7 In addition to the folks that we have here  
8 in the room, we do have folks that are participating  
9 by phone, and hopefully they can hear us. I'll check  
10 with my sound guy here who has a wonderful job. He  
11 has us all set up today, as opposed to last Wednesday  
12 when the University couldn't get their connection  
13 done.

14 For those on the phone, I want to mention to  
15 everyone that we have all of our PowerPoint  
16 presentations and materials for the meeting today, the  
17 agenda, on our website, and you'll see on the front  
18 page there that says FSIS to hold a series of meetings  
19 on risk-based inspection. Click on for more  
20 information, and they'll take you to the April 30th  
21 meeting, and you can get the PowerPoints that we'll be  
22 using for today's meeting.

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1           We're going to continue the same format that  
2 we had for the meeting last week, and we want to make  
3 the sessions a little bit more interactive and allow  
4 more contributions from everybody that is here.

5           I'm going to take just a moment and walk  
6 through the agenda, and you should all have a copy  
7 from the front table. Well, and introductions for  
8 Dr. Goldman, and you'll see Dr. Raymond is there.  
9 He's not going to be here with us this morning. I'll  
10 let Dr. Goldman explain that.

11           We're going to have three parts to the  
12 meeting. The first part is going to be Data  
13 Integration, and we'll have presentations regarding  
14 The Role of FSIS' Data Analysis and Integration Group,  
15 and Ms. Maczka is going to do that for us. And we'll  
16 have another presentation on Guidelines for Protecting  
17 and Using Data from Industry and Other Third Parties,  
18 and we'll have Michelle Catlin who is presenting that.

19           And the second part of our meeting is going  
20 to be -- we're going to shift to Current Thinking on  
21 Industry Data, and we're going to have a little bit of  
22 a review of materials that were presented at the

1 National Advisory Committee for Meat and Poultry  
2 Inspection. I think all of you are probably aware  
3 that over the last couple of years, data has been the  
4 subject of that gathering. So we're going to give you  
5 sort of a review to get everybody up to speed on  
6 comments and questions that we have gotten from that  
7 group.

8           And then at 10:15, we're going to have  
9 Current Thinking on How FSIS Can Best Use Third Party  
10 Data in the Development of RBI, and that's going to be  
11 Dan Engeljohn, and he will be making a presentation on  
12 that.

13           Once all the presentations are done, we're  
14 going to have some breakout sessions, the third part  
15 of our meeting, as we did last Wednesday, and that  
16 seemed to work out very well. So I think we --  
17 hopefully it will work out as well today. So we'll  
18 have a series of questions for you to engage in the  
19 discussion at the breakout sessions. I won't go into  
20 those right now.

21           At 11:45, we'll have reports on the  
22 breakouts and again we'll be doing sort of the same

1 format as before. We'll have a period of comments and  
2 questions and then we'll have some closing remarks and  
3 we'll be done hopefully at 1:00.

4 I should mention also that as we go through  
5 the agenda today, if we gain a little bit of time, if  
6 the presentations are a little bit shorter, we may  
7 open it up for some questions during the session  
8 itself. So we may have some other question and answer  
9 periods. It just depends on how the time runs. So  
10 most of the general comments are going to be held  
11 until the end. We're going to be using the breakout  
12 rooms similar to the way we did the other day, and  
13 again, probably you notice on your "Hello, my name is"  
14 there should be some colored dots on that, and we're  
15 going to assign you breakout rooms based on what color  
16 you are.

17 I should also point out as we have in past  
18 meetings, there's obviously the touch on issues that  
19 have come up at previous meetings or may come up in  
20 future meetings. The purpose of our meeting today is  
21 to focus specifically on data. So we're going to try  
22 and focus on that as opposed to talking about the

1 elicitation which we'll have another public meeting at  
2 the end of June or July.

3 I think Mr. Quick mentioned at our last  
4 meeting that we tentatively have that set up for July  
5 10th. I know for some of you that's a concern because  
6 it conflicts with other meetings that are coming up in  
7 July, and we are working to change that date to one  
8 that's more acceptable for everybody's schedule. So  
9 right now it's July 10th, but we are working to fix  
10 that and we'll post any changes on our website and try  
11 to get information out through our constituent update  
12 the usual way.

13 And again, before I start, I also want to  
14 remind everybody that if you can't get all of your  
15 comments in during the session today, we do, in fact,  
16 have an e-mail address that you can use to send in  
17 short comments or long comments. It doesn't matter.  
18 And we are working and assisting to get those to the  
19 appropriate people so the comments and questions or  
20 issues that you raise get addressed and some response  
21 goes back to the person that sends it in. And that  
22 address, the e-mail address is

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1 riskbasedinspection@fsis.usda.gov. And probably  
2 that's old hat. Everybody should have that memorized  
3 by now for all the meetings we've been to.

4 Last but not least, we don't have any  
5 specific break times built into the agenda, and as  
6 always, we're going to leave it to you to get up, take  
7 a stretch, get some coffee, whenever the spirit moves  
8 you. I was just told that the coffee shop is not open  
9 or at least it wasn't a few minutes ago, and hopefully  
10 by the time you're ready for your second cup, it will  
11 be, but there's a coffee shop downstairs. You take  
12 the escalator downstairs, hang a U turn, and there's a  
13 bookstore on the left that has coffee, and then  
14 there's a little shop around the corner that also has  
15 coffee. And the restrooms, just in case, they're to  
16 my left, to your right around the corner toward the  
17 back of the room.

18 And I think with that, if there are no  
19 questions regarding the agenda, or how we plan on  
20 proceeding, then I'm going to introduce Dr. Goldman.  
21 Are there any questions?

22 UNIDENTIFIED SPEAKER: Do you want to check

1 with the Operator?

2 MR. TYNAN: I'm sorry.

3 UNIDENTIFIED SPEAKER: Check with the  
4 Operator?

5 MR. TYNAN: Yes. Operator, are you there?  
6 Please be there. Operator?

7 OPERATOR: Yes, sir.

8 MR. TYNAN: You can hear us okay?

9 OPERATOR: Yes, we can. Thank you.

10 MR. TYNAN: Okay. So you caught all my  
11 introduction?

12 OPERATOR: Yes, we did.

13 MR. TYNAN: Great. And with that, I'm going  
14 to turn it over to Dr. Goldman, our Acting  
15 Administrator.

16 DR. GOLDMAN: Thank you. Good morning to  
17 everyone. I want to thank you all again for being  
18 here for another -- of meetings that we're hosting as  
19 we continue to improve risk-based inspection systems  
20 in processing plants. And again, as we always say,  
21 your feedback is very important to us as we move  
22 forward.

1           We realize that it is important to say each  
2 time that your opinion is important, that we need to  
3 listen to you as we move forward, and as Robert just  
4 said, I think maybe we've had some questions about our  
5 response to questions and comments. We are working on  
6 that as well, and we appreciate in this particular  
7 issue of the use of third party data or other data,  
8 that there are some strong opinions on both sides of  
9 the issue, that we've dealt with this issue as you'll  
10 hear from some of the panelists in just a few minutes  
11 for some number of years. So I think it will be  
12 important for you to hear that this is an issue that  
13 we've been dealing with even pre-dating risk-based  
14 inspection. So I hope that will become evident to you  
15 as well.

16           Today represents the fourth in the series of  
17 technical meetings that we've been holding as we  
18 continue moving toward implementation of a risk-based  
19 inspection system.

20           Some of the topics that we've been dealing  
21 with at these technical meetings have immediate  
22 application. Last week's meeting is, of course, a

1 good example of that. We already had volume  
2 production in our equation. So there's certainly some  
3 things we needed to deal with rather immediately in  
4 order to make that work for all of us.

5 This week's meeting or today's meeting is a  
6 little bit different, and I would liken it more to the  
7 attribution meeting that we had a few weeks ago in  
8 that what you'll hear today is kind of our current  
9 thinking. We are not ready to implement third party  
10 data into the formula right at the moment. So the  
11 effects of the use of such data will not be  
12 immediately apparent to those of our stakeholders as  
13 we move forward with risk-based inspection, but rather  
14 the benefits and the full benefits are to be realized  
15 as we move forward with probably on the longer term.

16 The issues about how to use large amounts of  
17 data that the industry possesses and uses on a daily  
18 basis are not new. As I just mentioned, we've been  
19 dealing with this and the specific issue of the use of  
20 industry data for several years. You heard already  
21 about the National Advisory Committee on Meat and  
22 Poultry Inspection. We'll hear a little bit more

1 detail about the recommendations that came out of that  
2 meeting.

3 I also want to acknowledge that many of you  
4 probably have been involved already in a separate  
5 effort that's been going in the private sector. The  
6 University of Maryland has been sponsoring a series of  
7 meetings under the rubric of the Food Safety  
8 Information Infrastructure Project. It started at the  
9 Resources for the Future and then moved to the  
10 University of Maryland, and if you're not familiar  
11 with that, we do have a representative from that group  
12 who may be willing to contribute some of the  
13 information if we don't cover it here in today's  
14 meeting, so that you are aware of that effort as well.

15 It is important that we try to find some  
16 agreement on the issues that we're going to lay out  
17 today, but as I just mentioned, I don't think we'll  
18 come to any definitive solutions. I think rather  
19 we'll be talking about the possibilities for use of  
20 data that doesn't already reside in our systems, and  
21 hopefully move us forward to counter some of the  
22 criticism that we've received that we don't have the

1 science-based data that we need to implement risk-  
2 based inspection systems. We do know that the  
3 industry, the industry that we regulate, has lots of  
4 data that they use for their purposes for both  
5 decisions and for public health decisions, and we're  
6 all interested I think and have an interest in how to  
7 use that data so that we can together improve our food  
8 safety systems.

9           This is yet another chance to I think  
10 improve public health protections in this country with  
11 respect to food safety, and I think that we should  
12 never allow any opportunity to pass us by to improve  
13 the things that we're doing. So I will look forward  
14 to the ideas that you will express in response to the  
15 presentations you heard, and certainly in the breakout  
16 groups because I think the breakout groups have proven  
17 to be a useful vehicle, in a smaller setting, for  
18 expressing candid ideas about the issues that you've  
19 heard about.

20           And with that, I will welcome you again.  
21 I'll pass along apologies from Dr. Raymond who can't  
22 be here at the very beginning. He will be joining us

1 a little bit later. He had a rearrangement of his  
2 schedule this morning. So he will be joining us  
3 probably between 10:00 and 10:30 or so.

4 But again, welcome from FSIS and we look  
5 forward to another productive meeting, and I will turn  
6 it back over to Robert. Thank you.

7 MR. TYNAN: Thank you, Dr. Goldman. The  
8 first presenter we have this morning is Carol Maczka  
9 who is our Assistant Administrator in the Office of  
10 Food Defense and Emergency Response, and I'm going to  
11 let her tell you about her topic. What I'm going to  
12 do is figure out how to get your PowerPoints up  
13 without losing them.

14 DR. MACZKA: Okay. I'd like to start by  
15 talking about an important initiative at FSIS which is  
16 the creation of a Data Analysis and Integration Group.  
17 And what I'm going to do is talk about the role that  
18 this group will play with the rest of the Agency and  
19 with stakeholders in improving the Agency's data and  
20 data analyses.

21 This next slide is things that I think we  
22 can all agree to with respect to data and FSIS

1 decision making. And that's that risk management  
2 decisions that are aimed at protecting the food supply  
3 should be based on sound science, and that valid and  
4 high quality data are the underpinnings of sound  
5 science. And finally, that the use of data to inform  
6 FSIS actions needs to be transparent, consistent and  
7 appropriate.

8           With those principles in mind, the Agency  
9 has met internally on a number of occasions in what  
10 we've called status summit meetings where we've  
11 actually discussed how we can improve the data  
12 infrastructure of the Agency.

13           We've also received a number of external  
14 comments from our external groups about the  
15 deficiencies in FSIS' data. Some of these comments  
16 have come from NACMPI, some through OIG reports and  
17 some through this process here where we've involved  
18 stakeholders at these meetings.

19           I think it's safe to say that all these  
20 groups emphasize that FSIS needs a stronger focus on  
21 identifying data needs and on analyzing and  
22 integrating its data.

1           In response to these comments and our own  
2 internal efforts through our data summits, the Agency  
3 has formed the Data Analysis and Integration Group.  
4 And this is going to be a dedicated group. It is a  
5 dedicated group that's focused on data analysis and  
6 data. It's comprised of senior scientists within the  
7 Agency with expertise in data analysis and statistics.  
8 And we've also set up a standing committee, the Data  
9 Coordination Committee, which I'll get to in a minute.

10           What I'd like to talk about right this  
11 minute are some of the responsibilities of the Data  
12 Analysis and Integration Group, and I'm just going to  
13 say DAIG, so I don't have to keep saying all those  
14 words. So some of the responsibilities of the DAIG  
15 will be to evaluate individual data streams and  
16 integrate data analyses across program offices. The  
17 DAIG will also ensure that data analyses are relevant  
18 to the business processes and practices of the program  
19 offices and to the Agency's mission. It will ensure  
20 that the data analyses are consistent and of high  
21 quality. And it will actually conduct analyses to  
22 inform the Agency's decisions. It will identify data

1 gaps and needs across program offices, and it will  
2 ensure that data analyses are consistent with FSIS  
3 policies including enterprise architecture and the OMB  
4 guidelines.

5           The next question is who will the DAIG  
6 interact with? Well, the DAIG will interact with the  
7 one group that I've already mentioned, the Data  
8 Coordination Committee, which is a standing internal  
9 committee comprised of senior representatives from  
10 each program office within FSIS. These individuals  
11 will serve as liaisons between the DAIG and the  
12 program offices, and we're hoping that they will help  
13 us identify data that is needed as well as analyses  
14 that need to be conducted. They will provide a  
15 resource to us and also advice.

16           The DAIG will also interact with external  
17 experts. We hope to augment our expertise with renown  
18 scientists and statisticians through contracting  
19 mechanisms. And I think most importantly the DAIG  
20 will interact with stakeholders, and by that I mean  
21 consumer groups, trade associations and industry. And  
22 we're hoping that these groups will provide feedback

1 on the Agency's data in terms of collection,  
2 validation, analysis and application.

3 Also we're hoping that these groups will  
4 help identify external data that we can use to augment  
5 the Agency's data. And that is the focus of today's  
6 meeting, and you'll be hearing more presentations  
7 about that from Drs. Catlin and Burgess and  
8 Dr. Engeljohn.

9 It's envisioned that the DAIG will also work  
10 very closely with the Office of Policy, Program and  
11 Employee Development and that DAIG will work with  
12 OPPEd to help prioritize its work with respect to data  
13 needs and data analysis. And we also recognize that  
14 we have to work very closely with our Chief  
15 Information Office to create the IT structure to  
16 facilitate data analysis, integration and reporting,  
17 and to secure information that will be entered into  
18 electronic databases.

19 So in summary, and before I hand this over  
20 to the next presenter, we acknowledge that the actions  
21 of the Agency need to be transparent, consistent and  
22 appropriate, and most of all, data driven. And we're

1 hoping that with the creation of the DAIG and the  
2 standing committee, the data coordination committee,  
3 that we'll strengthen the Agency's focus on data and  
4 data analysis and thereby strengthen the Agency's  
5 foundations for their decisions.

6           So I'll hand it over to -- do you want me to  
7 -- okay. So let me introduce Dr. Catlin, and I'll  
8 play moderator, Dr. Catlin will be discussing  
9 guidelines for protecting and using industry and third  
10 party data.

11           DR. CATLIN: Hello. As Dr. Maczka said,  
12 I'll be here talking about some of the guidelines and  
13 regulations that we have to consider when thinking  
14 about using not only third party data but our own data  
15 as well.

16           Now you've heard this before and it will be  
17 a common theme that you will hear at all the  
18 presentations this morning, and that's because it is  
19 so important. As an Agency, it's essential that sound  
20 data is present to support the decisions and the  
21 actions that the Agency conducts in carrying out its  
22 mission to protect the food supply and protect public

1 health.

2           Now when we're looking at how we can best  
3 use data, we've come to the realization that the use  
4 of data from other parties, be it industry, academia,  
5 state, local folks, consumers or foreign countries,  
6 could play a valuable role in supporting our  
7 scientific decisions. And they could play a role in  
8 filling important data gaps that the Agency has  
9 identified and needs to augment as well as making sure  
10 that the Agency has the best available data to inform  
11 its decision making process adding robustness, quality  
12 and validity to the data and any subsequent decisions.

13           Now, however, when we go to use data, we  
14 have to make sure that we are working within a number  
15 of different federal and USDA information quality  
16 guidelines and regulations. And those guidelines and  
17 regulations apply to the creation, collection,  
18 maintenance, dissemination and protection of the data  
19 that we use.

20           Those guidelines are put in place to make  
21 sure that all the data we use in decision making,  
22 regardless of the source, meet certain criteria. And

1 those criteria including objectivity, utility and  
2 integrity with integrity including security and  
3 confidentiality of the data.

4           When looking at objectivity, we need to  
5 ensure that the data is substantial, that there's  
6 enough of it, that it is accurate, that it's reliable,  
7 that it is complete. So we're not just getting part  
8 of the picture, we're actually getting the whole  
9 picture when we receive the data and when we look at  
10 our own data, and that it is unbiased.

11           We also have to make sure that the source of  
12 the information is identified to allow those people  
13 who are looking at the data to know what the source is  
14 and know whether or not that data would be considered  
15 objective and how we got it.

16           Looking at utility, we have to make sure  
17 that the data is useful, that the data is such that  
18 it's the right information to answer the questions  
19 that we need answered. We also have to make sure that  
20 it's clear or if someone who's looking at the data  
21 that's coming in, will know what those data are and  
22 how we're using them. It also has to be accessible as

1 per the Rehabilitation Act. And that is specifically  
2 dealing with special needs for people with hearing and  
3 sight impairments.

4 We also have to ensure the integrity of the  
5 data. That involves preventing the corruption or  
6 falsification of the information by protecting  
7 unauthorized access or revision of the data. And as  
8 Dr. Maczka mentioned, one of the reasons we need to  
9 work closely with the Office of the Chief Information  
10 Officer to make sure that the secure mechanisms are in  
11 place in any computer systems to ensure that that  
12 cannot be corrupted. And one of the regulations that  
13 we have to follow as an Agency when looking at those  
14 security mechanisms is the security of information as  
15 per the Federal Information System Managers Act or  
16 FISMA.

17 There's a number, and I'm going to bore you  
18 with a number of different regulations, but I'm not  
19 going to tell you much about them. But just so you're  
20 aware, when looking at our own data, or data coming in  
21 from others, there's a lot of information that we need  
22 to look to, to ensure that we are having proper

1 confidentiality on that information. And that  
2 includes the Privacy Act of 1974, the Paperwork  
3 Reduction Act of 1995, the Computer Security Act of  
4 1987, as well as the Freedom of Information Act. Now  
5 we do have to be concerned about the Freedom of  
6 Information Act, one, to make sure that we are in  
7 compliance with it and, two, to make sure we have  
8 mechanisms in place if we are receiving proprietary  
9 information, make sure that we can protect that  
10 information from being released under the Freedom of  
11 Information Act. As well, there's a number of OMB  
12 Circulars we have to be concerned, A-123 which deals  
13 with some internal controls, A-127 which deals with  
14 financial management systems, and A-130 which deals  
15 with management of federal information resources.

16 So when looking at how to use our own data  
17 and data coming in from others, there are a number of  
18 different regulations and guidelines that we have to  
19 look towards. And not only do we have to make sure  
20 we're compliant, but they also provide assurance to  
21 those who are providing us with the information that  
22 there are some guidelines for handling that data.

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1           Now as the Agency has been looking towards  
2 the use of third party data, they have been looking at  
3 various options for how to handle the data, how to  
4 receive it, and how to protect it once we have it, and  
5 how to evaluate it.

6           We've had a number of different people make  
7 suggestions on how do this, and we've been looking at  
8 those carefully. One is NACMPI, and you will be  
9 hearing more about that from Dr. Burgess in a moment.  
10 So I'll just briefly point out that NACMPI has made  
11 some comments that we should establish ground rules  
12 for the submission and acceptance and use of  
13 voluntarily submitted data and that some of those  
14 involve the possibility of a third party repository, a  
15 third party to review the data coming in, and the use  
16 of aggregate data versus individual plant data and how  
17 those could be differentiated.

18           We are lucky as an agency that we are not  
19 the first agency that has had to tackle some of these  
20 issues. So we can take some of the lessons learned  
21 from other agencies and how they've been handling data  
22 and look towards those as possible models.

1           I'm going to tell you a couple of different  
2 things that have been done more as points to think  
3 about as you go off into your breakout groups to be  
4 able to ponder, give you some food for thought as to  
5 how the Agency might be able to handle third party  
6 data.

7           One is a model that the Environmental  
8 Protection Agency uses, the EPA, and they use a  
9 taskforce for look at data coming in from outside  
10 sources. The taskforce is comprised of industry and  
11 Agency representatives and I think possibly consumer  
12 groups, but if not, that's something we would want to  
13 consider. And they set the criteria for submitting,  
14 reviewing, accepting and protecting data. And that  
15 organization, the taskforce, is organized in order to  
16 gain consent from the owners of the data and consent  
17 to share that information as needed within the Agency  
18 for the Agency to make decisions.

19           FDA has also looked at some different data  
20 mechanisms for sharing. I won't go into too much  
21 detail of those but some involve JIFSAN and NCI and  
22 using NCI as a third party.

1           Another thought we've had internally is the  
2 possibility of having regular data meetings with  
3 stakeholders to be able to discuss some of the data  
4 needs and mechanisms for sharing the data. So that's  
5 something else we would like you to consider in the  
6 breakout groups today.

7           Our next step is that we are currently  
8 examining these various options, and we're hoping to  
9 be able to get further suggestions and ideas from  
10 yourselves of the type of data that could be shared  
11 and the best mechanism for sharing those data, making  
12 sure that we can accept and protect the data as  
13 submitted. And therefore, we are inviting you at this  
14 meeting and in the future to provide us with input on  
15 ideas as to how we can receive information from  
16 stakeholders, use that information and protect that  
17 information.

18           And I just want to finally remind you that  
19 any process that is developed by FSIS with stakeholder  
20 input needs to ensure that we have checks and balances  
21 in place for the data, needs to be transparent so  
22 someone looking and evaluating how the Agency is

1 conducting itself can see how we're using data, and,  
2 we need to make sure that mechanisms and processes are  
3 coordinated with Agency policies and IT security  
4 requirements.

5 And with that I can play moderator and turn  
6 it over to Dr. Michelle Burgess.

7 MR. TYNAN: I'm sorry. I'm taking the  
8 Moderator role back again. I'm almost out of a job, I  
9 can see. We are ahead of where we planned on being at  
10 this particular point. So I thought before we go onto  
11 the next segment and introduce Dr. Burgess, that we  
12 might take a few questions at this particular point if  
13 there are any. But I would suggest if you have some  
14 questions, if you would please come to the microphones  
15 and introduce yourself and your affiliation, and we'll  
16 go from there.

17 MR. WALDROP: Hi. Chris Waldrop, Consumer  
18 Federation of America. I have a question for Carol.  
19 When was the DAIG formed? When did you guys first  
20 form that?

21 DR. MACZKA: It's very recent. I'd say as  
22 of about a month ago, that we formed the DAIG.

1           MR. WALDROP:       Okay.       And why wasn't  
2 something like this formed at the beginning of this  
3 whole risk-based inspection process? Why is it being  
4 so late in this process?

5           DR. MACZKA:   Well, I think, and I tried to  
6 mention this, we have been meeting through various  
7 what we call data summits and discussing how we could  
8 best organize ourselves, what is the data we're trying  
9 to get our hands around, and it's just all coming  
10 together now. But it's not like this wasn't, you  
11 know, over the course of about a year and a half,  
12 we've been deciding where should this body reside, who  
13 should it be comprised of. So it's all just coming  
14 together now.

15          MR. WALDROP:   Okay.   Considering the fact  
16 that you guys want to start this up in July, I think  
17 you guys have a lot of work to do. So I hope you're  
18 ready for some long hours.

19          DR. MACZKA:   We're very energized about it.

20          MR. WALDROP:   Good.    I had one other  
21 question. Are there any statisticians in the DAIG?  
22 You said you were going to contract out for somebody.

1 Are there any that are on your team?

2 DR. MACZKA: Yes, there are.

3 MR. WALDROP: There are. Okay. Thank you.

4 MR. TYNAN: Carol is not adverse to long  
5 hours. I've been late myself a couple of nights and  
6 she always seems to be there after me. So I know.

7 DR. BERNARD: Dave Bernard with Keystone  
8 Foods. Thank you both for your presentations.

9 Michelle, it may be a bit early to get so  
10 deep into the process, but you've thrown a lot of  
11 references at us here, and for those of us who are  
12 uninitiated, could you give us a little bit more  
13 detail as to the data security requirements that we  
14 may have to face if, for example, we wanted to  
15 contribute data from our establishments that would be  
16 used in some way in the risk-based inspection process?  
17 Thanks.

18 DR. CATLIN: Okay. I'll start with a huge  
19 disclaimer that I am not one of the IT folks. So  
20 that's why I say we work carefully with our OCIO shop,  
21 the computer folks who know all the details about the  
22 computer security. We do have in place as an Agency

1 and within the department a lot of the mechanisms so  
2 that we're making sure that our computer systems  
3 aren't hacked into, that type of security issues,  
4 those types of security issues.

5           Along with that, we have to have those in  
6 place so that anything that you submit to us would be  
7 protected from that secure perspective.

8           And if we are moving down and I believe we  
9 are and I'll speak more to this, moving down to have  
10 data directly submitted into us through the computer  
11 systems themselves, there is something called e-  
12 Authentication which is a secure password protected  
13 way to have things submitted. Unfortunately, I can't  
14 go into the details of IT as to how all that works,  
15 other than tell you that it is in place and it is a  
16 mechanism that we can use to have data submitted  
17 electronically yet still protected. Does that help at  
18 all? I'm not a computer person. So I'm not going to  
19 be able to go into the IT details.

20           DR. ENGELJOHN: While Dane is going back up  
21 to the microphone, this is Dan Engeljohn. I'll just  
22 add a few points of information about the process that

1 we use for the current 10240 form, which is a web-  
2 based form. It's one in which industry is required to  
3 submit to us by regulations and for which we have OMB  
4 approval for and it also is one for which there was a  
5 level of security for which each establishment that  
6 wanted to submit the information could go through to  
7 submit it. So there are varying levels of security  
8 that we can ask, level 1, level 2, as an example,  
9 depending on whether or not the establishment chooses  
10 to register with a source providing information that  
11 would provide some security with a password protected  
12 process, and then the information can be directly  
13 uploaded into the Agency's databases. So those are  
14 the processes that we're beginning to use now with  
15 some of our data retrieval from industry.

16 MR. TYNAN: Dane, you had a follow up?

17 DR. BERNARD: Yeah, I do. Dan's comments  
18 clarify a good deal. And why do we set these  
19 microphones up like this? Excuse me, Tony.

20 I was actually as much interested in what  
21 it's going to take from our end as from your end, I'm  
22 very gratified to know that you're thinking in terms

1 of your own security, et cetera. But obviously there  
2 will be some restrictions or some expectations on our  
3 end not only in terms of the security of the system,  
4 but the integrity of the data, and I was curious as to  
5 whether you might remark on those.

6 MR. TYNAN: I did a public meeting with  
7 Dr. Wotecki, one of our previous Under Secretaries,  
8 and Donna Shalala, who was Secretary at HHS, and my  
9 job was to be sure that there was a little platform  
10 behind the thing so that she could get up to the -- so  
11 I'll have to remember that for another meeting, Dane.  
12 Mr. Corbo.

13 MR. CORBO: Tony Corbo, Food and Water  
14 Watch. I know that the Agency has been grappling with  
15 this issue for a long time, and I happened to sit in  
16 the subcommittee three and a half years ago that the  
17 Meat and Poultry Inspection Advisory Committee held on  
18 this issue. And I thought the process was very  
19 thoughtful. The subcommittee spent a lot of time  
20 grappling with, you know, legal issues and  
21 confidentiality of the data. I'm wondering why it's  
22 taken the Agency this long to implement those

1 recommendations. It just seems that, you know, since  
2 this is an issue, the whole RBI process has been  
3 something on the Agency's platter for a long time.  
4 Why are we still fooling around with the details in  
5 terms of access to industry data?

6 MR. TYNAN: Is that a question or sort of a  
7 rhetorical question because I'm not sure we have the  
8 answer.

9 MR. CORBO: No, it's a legitimate question.  
10 You know, I think, you know, this has been -- like I  
11 said, it's been three and a half years, and maybe, you  
12 know, the next presentation will shed some light, but  
13 it seems to me that the NACMPI did present some  
14 recommendations that were -- there were industry  
15 representatives as part of that process. Why are we  
16 still dealing with this? And why are we, you know,  
17 talking about alternative proposals to deal with  
18 access to industry data?

19 DR. MACZKA: Well, I don't want to pay for  
20 the -- of others in the past, but all I can say is  
21 that I do believe that with setting up the DCC and the  
22 DAIG, that these things will get bedded, and I really

1 believe that we will come to some conclusion as to how  
2 and if this can be done. So --

3 DR. ENGELJOHN: This is Dan Engeljohn. If I  
4 could perhaps touch on a bit of what Tony asked, and I  
5 think Michelle Burgess will talk a bit about the  
6 NACMPI summary just to give an overview of the  
7 information from there, but part of the issue has been  
8 for the Agency, and there's two issues here. And I  
9 think you bring up one issue, which we really haven't  
10 touched on. And that is the Agency's use of the data  
11 that we have access to, meaning the in-plant data  
12 that's there, and then how we use that, and so our  
13 process up to this point has been that our inspection  
14 program personnel do have access to industry data that  
15 serves as part of the food safety system. They're  
16 required to have access to that data and any decisions  
17 that the plant makes with regards to that data should  
18 be incorporated into the decision making process of  
19 the HACCP system.

20 So the data is available. The question is  
21 how do we as an inspection agency use that data that  
22 we don't collect and accumulate, but have the ability

1 to observe. And part of that is what our inspectors  
2 are capable of doing, with the training that we have  
3 provided to them at this time, and then what our  
4 trained individuals, our enforcement and investigation  
5 analysis officers, our EIAO officers who do the food  
6 safety assessments, what they are capable of doing  
7 with more advanced training and capability of  
8 assessing that data from the perspective of how it  
9 influences the validity of the food safety system.

10           So the issue in part is for the Agency that  
11 we think about is how can we access more of the data  
12 and use it to our advantage in terms of making  
13 decisions whereby we would have a means to collect  
14 that information but the issue that we focused on  
15 mostly at this point has been industry supplying us  
16 data voluntarily, and that's been the issue that has  
17 been most contentious and the one for which we haven't  
18 to date really had much success in, in the sense that  
19 we have some data submitted by industry in aggregate  
20 form, but not specific in-plant data. The individual  
21 in-plant data has mostly been used by the Agency when  
22 we're following up on a failure of that system. So

1 that's really how we've used the industry data to this  
2 point. The issue becomes one of how we can better use  
3 it to be able to predict trends and things like that  
4 in the future.

5           So I don't think it's so much that we've not  
6 had mechanisms in place. We do every day try to find  
7 ways to use the data that is available to us, that for  
8 which don't collect but can observe and then that  
9 which we'd like industry to submit to us. So there  
10 are a number of compounding issues all of which I  
11 think we're at the point now where we really are  
12 looking for a way to go forward. But in part, that's  
13 a desire by the industry who house significant amounts  
14 of data of sharing that with us, which hasn't  
15 generally happened to this point.

16           MR. TYNAN: Okay. Before we move onto the  
17 next presentation, I'm going to ask the Operator.  
18 Operator, if you could poll your folks on the phone  
19 and see if anyone has any questions.

20           OPERATOR: If there are any questions from  
21 the folks, press \*1. You will be announced prior to  
22 asking your question. To withdraw your question,

1 press \*2. Once again, it's \*1 to ask a question.  
2 Please stand by for the first question. There's a  
3 question from Barbara Kowalcyk.

4 MR. TYNAN: Okay. Thank you.

5 MS. KOWALCYK: Hi. This is Barb Kowalcyk.  
6 I had a couple of questions. One is a follow up on I  
7 believe what Chris Waldrop brought up. Is it possible  
8 to make public the members of DAIG -- data committee?  
9 Is it possible to make that public?

10 MR. TYNAN: I'm sorry, Ms. Kowalcyk. I'm  
11 having trouble hearing you. You seem to be breaking  
12 up a little bit.

13 MS. KOWALCYK: Okay. Is it possible to make  
14 the members of the DAIG public?

15 MR. TYNAN: To make the names of the folks  
16 on the DAIG public?

17 MS. KOWALCYK: Who is serving on the DAIG,  
18 and the question I had about that was have you  
19 involved the Office of Chief Economist at all? They  
20 have a lot of expertise in data and statistics and --  
21 resource to do it --

22 MR. TYNAN: Okay. I'm not quite sure I

1 heard the second part, but I'm going to leave it to  
2 Dr. Maczka maybe to try and respond.

3 DR. MACZKA: We'd be happy to let you know  
4 the names of the present members of the DAIG. We are  
5 looking, as I said, to increase the staff also in the  
6 DAIG. So, yes, we can provide that. And we have not  
7 yet involved the Office of the Chief Economist Office  
8 yet, but thank you for the suggestion and we will move  
9 on that.

10 MS. KOWALCYK: The other question that I had  
11 was is -- subject to the Data Quality Act. Is that  
12 correct?

13 DR. CATLIN: Yes.

14 MS. KOWALCYK: Okay. And I know a very  
15 little about that Act but it certainly, I could see  
16 where it would impact RBI and all the data -- if I  
17 recall correctly, one of the main requirements of Data  
18 Quality Act is objectivity of the data and its  
19 usability. And, of course, this is certainly going to  
20 be an issue if my recollection is correct, that would  
21 be an issue when we talk about industry data, is one,  
22 is it truly objective and, two, is the analysis that

1 results from using that data --

2 MR. TYNAN: Ms. Kowalcyk, I had a hard time  
3 hearing you. I don't know if Michelle caught  
4 everything.

5 DR. CATLIN: Yeah, I believe that you are  
6 asking about the concerns with industry data and the  
7 objectivity of it and the validity of the analysis.  
8 Is that correct?

9 MS. KOWALCYK: Right.

10 DR. CATLIN: That's one of the things I was  
11 -- one of the reasons I was sort of drilling a hole in  
12 my topic that we have to meet all the data guidelines  
13 and data regulations is because of those very issues.  
14 And we're looking at different options as to how best  
15 to ensure the objectivity and the quality of the  
16 analysis that are being conducted and that's why I put  
17 forth various suggestions such as the taskforce that  
18 would be able to evaluate that. We would also have to  
19 look at how we could validate that the data that was  
20 being given is actually what was out there.

21 One way that this could be done that EPA  
22 does, with the toxic release inventory, when they

1 receive sample results from industry on toxic  
2 releases, they actually will spot check by going out  
3 and taking duplicate samples or have -- samples with  
4 industry in doing their own internal analyses to  
5 ensure that industry's data does match up with what  
6 they have been doing.

7           So these are just different options that  
8 we're looking into and exploring as to how we could  
9 best do this, and this could also speak partially to  
10 why we haven't moved forward with this because we are  
11 trying to -- one thing that does have to be done is we  
12 have to come up with the best way to be able to ensure  
13 the objectivity and validity of the data that we are  
14 receiving.

15           MS. KOWALCYK:     And my third and final  
16 question has to do with something that Dan Engeljohn  
17 said, is that the FSIS inspectors are actually looking  
18 at industry data and using it as part of their  
19 assessment, but they don't necessarily collect data.  
20 I think that the Agency ought to look at in what  
21 situations is that occurring and why isn't the Agency  
22 actually collecting data that the inspectors are using

1 to make their assessments.

2 DR. ENGELJOHN: I'm sorry. This is Dan  
3 Engeljohn, Barbara. We really are having difficulty  
4 understanding you because you're breaking up. You  
5 asked something to the effect that the FSIS inspectors  
6 have access to data and I think you're asking why we  
7 don't have the inspectors collect it. Is that what  
8 you asked?

9 MS. KOWALCYK: Yes.

10 DR. ENGELJOHN: Well, part of the issue of  
11 -- I'll just give a general response in that when the  
12 Agency collects the data from an establishment, it in  
13 part becomes part of the public record. And so the  
14 issues becomes one of which data should we collect and  
15 how should we do so, in the sense of do we collect it  
16 for just individual observations or do we summarize it  
17 and get summary information over a period of time  
18 which is in part what our EIAO investigators do when  
19 they look at a food safety assessment. They may look  
20 at an extended period of time and summarize the  
21 information to try to make sense out of it in terms of  
22 their analysis.

1           But the real issue becomes one of, for the  
2 most part, there is -- each individual establishment  
3 has a rationale for why they collect the data the way  
4 they do, and why it is, in fact, serving as a  
5 rational, justified basis for that food safety system.  
6 And so part of the issue becomes one of, in part,  
7 identifying what is the value of an inspector  
8 collecting individual observations. The inspectors  
9 presently are tasked with making sure that the  
10 establishments are properly responding to the data  
11 that the establishments are collecting, and that that  
12 data is being used in a proper manner which there have  
13 been examples in the past where that didn't occur, and  
14 we'll be talking about that a bit later.

15           But I think it really boils down to as to  
16 what data would be of value to collect and how we  
17 would interpret that. But presently, inspectors are  
18 trained in tasks with making sure that the  
19 establishment is properly responding to the data that  
20 they're collecting.

21           MR. TYNAN: Ms. Kowalcyk, I'm going to move  
22 on and see if there's somebody else on the phone, if

1 we could, with some questions. Operator, is there  
2 someone else?

3 OPERATOR: Yes. Thank you. Rick Prins,  
4 your line is open.

5 MR. PRINS: I'm Rick Prins with Maple Leaf  
6 Farms. My question is on DAIG and DCC also, and how  
7 well the industry and the public will be able to  
8 monitor the direction that they're taking and  
9 recommendations that they're making?

10 DR. MACZKA: Well, we will be working  
11 closely with our Office of Policy to actually  
12 prioritize the work we undertake, and I'm not sure to  
13 what extent that information can be released about the  
14 kind of analyses and what not that we'll be doing.

15 DR. ENGELJOHN: This is Dan Engeljohn.  
16 Well, part of the goal of the Agency, as Carol said  
17 for at least the last year and a half to two years,  
18 there's been an extensive evaluation of the Agency's  
19 databases and use of that data so that we can get it  
20 all into the business case, make sure that we properly  
21 documented the business case for the data that we  
22 have.

1           One of the activities I think was to itemize  
2 an inventory of the type of data that we're  
3 undertaking, so that Agency-wide individuals would  
4 know what analyses are underway, what data are  
5 available, but more importantly a means to identify  
6 what data are needed, and I think that's part of a  
7 larger Agency issue. And I do think we're looking  
8 into means by which we can make available perhaps on  
9 the Agency's web pages, what data would, in fact, best  
10 help the Agency or we think would best help us in some  
11 of our decision making and then find a mechanism to  
12 make that available.

13           So I think we are looking into things that  
14 we can do about data needs that also fits in with  
15 research needs that we need, but data needs would be  
16 one thing that we could easily add to that.

17           But I got a sense from your question that  
18 you're also wanting to know how stakeholders can  
19 monitor the progress of the Agency, and I think that  
20 because data is such an important issue for the  
21 Agency, that we'll find ways to be able to identify  
22 progress reports and perhaps make that more publicly

1 available. We have not done so thus far but I think  
2 that we're certainly open to the idea of making sure  
3 that others who know how important data are to the  
4 Agency can track what we're doing. So we will pursue  
5 avenues to make it more available.

6 DR. MACZKA: And I do think that one of the  
7 things I said in my presentation is that we do want  
8 the stakeholders to provide feedback on the data that  
9 we're collecting as well as how we're analyzing it.  
10 We would really like to create an open dialogue. And,  
11 in fact, recently we did meet with consumer groups and  
12 we did meet with industry on some of the data that we  
13 are looking at analyzing. We hope to continue those  
14 kinds of dialogue.

15 MR. PRINS: Thank you.

16 MR. TYNAN: Operator, I'll take one more  
17 question from the phone.

18 OPERATOR: Thank you. Carol Tucker-Foreman,  
19 your line is open.

20 MS. TUCKER-FOREMAN: Hello. Can you hear  
21 me?

22 MR. TYNAN: Yes, Ms. Foreman.

1 MS. TUCKER-FOREMAN: I want to go back to  
2 the same issue that Chris said and Barbara Kowalcyk  
3 raised. The problem is that the Agency has gone  
4 forward with specific conclusions and based a risk-  
5 based inspection program on those and is getting ready  
6 to roll out a pilot project for risk-based inspection  
7 and there is no -- based on your presentation today,  
8 you do not have any of these things in place now, they  
9 weren't in place, they're in place now, but they  
10 certainly weren't in place when the Agency began to  
11 develop risk-based inspection.

12 Transparency is fine but you cannot begin to  
13 build the program starting at the second floor and  
14 then go back down and fill in the basement and the  
15 first floor. Right now the risk-based inspection  
16 program is based on what Agency officials think is  
17 important, what the Agency officials define as a  
18 typical plant, which they still haven't been able to  
19 give a definition for, and the best guess of an Agency  
20 working group in some cases. This is -- everything  
21 that's -- to date is prospective. None of it can be  
22 cited as a basis for -- and to create a risk-based

1 inspection program.

2 I don't know really anybody who assesses the  
3 quality of regulatory programs who would suggest that  
4 this is an appropriate way to go forward.

5 MR. TYNAN: Okay. Ms. Foreman, I'm going to  
6 let Dr. Maczka respond.

7 DR. MACZKA: And then Dr. Engeljohn might  
8 also like to give a response but I do want to say that  
9 the DAIG that we have set up is bigger than risk-based  
10 inspection. It's not just going to be dealing with  
11 RBI, but that the data analyses were conducted for  
12 RBI, and I think there is a basis for a lot of the  
13 ways in which they have moved forward, and they did,  
14 the Agency's way of operating was to have stakeholder  
15 meetings to get input on their thinking with regards  
16 to RBI and the analysis they did do.

17 MS. TUCKER-FOREMAN: Well, with all due  
18 respect, we have at each one of these meetings raised  
19 exactly the same problems. You do not ask us for the  
20 data that are basic to building your program. That's  
21 not how it's supposed to work. You're supposed to  
22 have gone out and developed that data and then ask us

1 to review it. And again I raise that I have been  
2 unable at each one of these meetings to get  
3 definitions that I have sought. So if there's nothing  
4 -- if it's there, you've not been able to convey it.

5 MR. TYNAN: Okay. Ms. Foreman, thank you  
6 for your comments.

7 It's 10:00, and we're going to begin the  
8 next segment of our agenda which relates to current  
9 thinking on industry data, and we have Michelle  
10 Burgess here that's going to talk a little bit about  
11 some of the conversations we had with our National  
12 Advisory Committee on Meat and Poultry Inspection.

13 DR. BURGESS: Good morning. And I apologize  
14 for my voice. I was single handedly trying to coach  
15 the nationals yesterday from Section 304. So I hope I  
16 still have it. And, yeah, I should keep my day job.

17 So I'm here to talk to you today about just  
18 briefly some of the recommendations that the National  
19 Advisory Committee on Meat and Poultry Inspection have  
20 given to FSIS when we consulted them on the topic  
21 today, and that is the use of other data in our  
22 decisions.

1           As you may know, the National Advisory  
2 Committee on Meat and Poultry Inspection, which from  
3 here on out I'm just going to call NACMPI, advises the  
4 Secretary of Agriculture on food safety matters. And  
5 actually the way that process works is that these  
6 recommendations are actually brought up through the  
7 Under Secretary of Food Safety when he consults the  
8 Secretary of Agriculture.

9           The members have been broadened to represent  
10 broader based consumer or more like the stakeholders  
11 and that is consumers, industry, academia, and such,  
12 and constituents are distinguished individuals drawn  
13 from all walks of life you could say, academia,  
14 consumers, and state communities as well.

15           FSIS consults NACMPI on several technical as  
16 well as science policy issues with regards to food  
17 safety matters.

18           Since 2003, as many of you already know,  
19 NACMPI has consulted NACMCF on improving data quality  
20 used for Agency actions. And there's been three main  
21 focus groups or topics regarding data quality, the  
22 first being again what we've been touching on today,

1 the best use of data in RBI, but also how can we  
2 associate food safety activities with public health  
3 surveillance data and the third is data acquisition to  
4 improve anticipation of foodborne hazards before they  
5 actually become a public health problem.

6 In any of the transcripts or any of the  
7 summary papers, if you've read those, they all seem to  
8 have a common theme, that they recognize there's a  
9 wealth of information from reliable sources that are  
10 responsible for ensuring the safety of the food  
11 supply.

12 So one of the recommendations has been to  
13 supplement the Agency data with third party data, and  
14 that has been as a result of these discussions and  
15 like Dr. Maczka, I want to echo her sentiments. This  
16 group is looking farther than just RBI. It's all data  
17 or information that the Agency would use to enforce an  
18 action or just not even under regulatory purposes, but  
19 how we would use that information to go about our  
20 daily business.

21 One of the things that came out of the  
22 recommendations is that we should expand our sources

1 of data. We would look beyond ourselves and find out  
2 what other information could be out there that we  
3 could use for Agency actions. Another thing would be  
4 providing the Agency with the best data that's out  
5 there and to inform our decision making, but more  
6 importantly adding the validity, the robustness,  
7 quality and again that transparency that I think we  
8 all here want to have in our decisions.

9           Well, as you look at this recommendation, it  
10 also -- that you have to look at these other  
11 considerations such as quality which we've already  
12 touched upon here, that what are the characteristics  
13 of that information, how reliable is it, and also is  
14 it reproducible. The second thing would be data  
15 transfer. Again, this goes into the confidentiality  
16 portion. We would like to have this information. We  
17 feel like it's important. However, we want to protect  
18 those that would like to provide that information but  
19 yet want to move our mission forward.

20           Data sharing, whether it be aggregate or  
21 like we were talking about, individual establishments.  
22 How do we want to use that information. And then last

1 of all I guess is the use of the information. How  
2 appropriate is its application for Agency actions?  
3 These are the considerations that we have to take into  
4 account before we could ever move forward with this  
5 activity.

6 I think one of the strongest recommendations  
7 that came out of these proceedings is that there  
8 should be a data repository. And the things that  
9 we're wrestling with is what are the incentives for  
10 stakeholders to submit information to whether it be a  
11 third party repository or a gathering of this  
12 information.

13 Administration again, should it be an  
14 aggregation of data so that it would be information  
15 that's shared across the board but again knowing the  
16 limitations for its intended use, and also access  
17 rights. Who should have this information and at to  
18 what level should people be able to gain information.

19 Also responsiveness to our needs. As we go  
20 forward, as Dr. Maczka talked about with the DAIG,  
21 then we're going to start seeing that there's going to  
22 be specific information that the data would need to

1 move forward in its mission, and we could use this  
2 repository in such a fashion. And also again, the  
3 assurance of data quality, what checks and balances do  
4 we have in place to ensure that the data that we're  
5 relying on is of quality, robustness and validity.

6 Another activity that was borne out of that  
7 was pilot sharing. Maybe we should just test the  
8 waters a little bit before we go gung-ho in this and  
9 do a pilot sharing program. And one way to achieve  
10 that goal in a very short order would be to do so, and  
11 therefore one recommendation was made that it should  
12 be non-threatening and also maybe use an indicator  
13 bacteria to assess process control and also another  
14 one would be maybe the effectiveness of equipment  
15 disinfection protocols and efficacy of eliminating or  
16 abating foodborne hazards. We thought this would be a  
17 great idea because what we could do is really see how  
18 this would work and therefore optimize it in future  
19 programs and, of course, it would be a great resource  
20 for allocating our resources to focus on what is  
21 really needed.

22 So what do we do to move forward? Well,

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1 the Agency is really making a concerted effort toward  
2 addressing the issues of data and more importantly,  
3 data sharing. And so as we've already touched on,  
4 we're increasing our focus and we're increasing our  
5 awareness on the data quality by forming these cross-  
6 agency work groups, revisiting the NACMPI  
7 recommendations as well as other reports from other  
8 stakeholders, seeking further input. We've been  
9 meeting the last couple of weeks with consumer,  
10 industry and professional/trade groups. We'd like to  
11 go on and talk to some of our sister agencies as well  
12 as other academicians. And we also feel that by  
13 supplementing this information and by getting the  
14 stakeholder input, it would really support the  
15 scientific basis for which we are making our decisions  
16 as well as feeling like we're all a part of this  
17 community that is responsible for ensuring food  
18 safety. And so I want to thank you so much for taking  
19 the time to be here today, I know you're all busy, and  
20 I hope you enjoy the rest of the meeting. Thank you.

21 MR. TYNAN: Michelle was the only one in the  
22 group that didn't want to be the Moderator. I'm going

1 to introduce Dan Engeljohn. How many FSISOs does it  
2 take to get a PowerPoint presentation up? That's a  
3 joke.

4 DR. ENGELJOHN: Good morning. I'm Dan  
5 Engeljohn, with the Policy Office, and I'm going to  
6 give you a perspective on the Current Thinking for Use  
7 of Third Party Data in Risk-based Inspection.

8 The goals for the use of the data have been  
9 identified in many of the previous meetings but  
10 specifically today I wanted to highlight that we want  
11 to appropriately inform risk management. This would  
12 be through the data directly collected and analyzed by  
13 FSIS in a number of different ways in which we collect  
14 data, either through inspection procedures or through  
15 observations by the inspectors in the plants or by  
16 investigations and looking at the food safety system  
17 as well as through the microbiological testing  
18 results, as well as by the data collected and acquired  
19 by FSIS from known FSIS sources.

20 We want to ensure that any of the data we  
21 collect help us to demonstrate a desired, measurable  
22 impact on public health protection through safe food.

1 And so obviously the purpose would be able to have  
2 this data that, in fact, ties what we do with its  
3 impact on the food that's consumed and on consumers.

4 To give you a big of perspective on prior  
5 use of non-FSIS data, that the Agency has been using  
6 for quite a long while, one example would be through  
7 our risk assessments where we ask for data from  
8 industry or from academia or from any source that  
9 would help fill a research or data gap. And an  
10 example of one for which the Agency recently used was  
11 in our *Listeria monocytogenes* risk assessment in which  
12 we looked at the impact of interventions on our  
13 regulatory process. In that particular data  
14 submittal, industry did provide to us the ratio of  
15 *Listeria* species to *Listeria monocytogenes*. This was  
16 through blinded industry data that was submitted to  
17 Cornell University. The Agency referenced it in the  
18 risk assessment and then we had a public process in  
19 which we made the risk assessment available for public  
20 input, accepted comments on that. We had that risk  
21 assessment peer reviewed for the design of the risk  
22 assessment as well as any interpretations, and then

1 used the final results in making rulemaking decisions.

2           On a regular basis, the Agency uses the  
3 economic impact data that it receives from a variety  
4 of sources, mostly from data that may be, in fact,  
5 submitted by industry through a number of ways. An  
6 example, in our recent specified risk material interim  
7 final rule, the Agency published a preliminary impact  
8 analysis. In that analysis, submitted as part of the  
9 public record, the American Meat Institute provided a  
10 report that was done by Sparks Companies, and this  
11 related specifically to the regulatory options that  
12 the Agency was looking at or possibly looking at for  
13 rulemaking.

14           In any case, the Agency makes available the  
15 information that we rely upon for our decision making.  
16 That information would be part of our administrative  
17 record that's available in the docket room. Anyone  
18 could have access to that information because much of  
19 the information that we cite has copyrighted material  
20 in it. You're able, as part of the public, to come in  
21 and look at the information. You can copy it when you  
22 come into the docket room, but unless we receive

1 permission from the publishers of copyrighted  
2 material, oftentimes we do not post that information  
3 to our web page. So there are some limitations as to  
4 the type of information we make available but for the  
5 most part, information submitted as part of the public  
6 rulemaking is made available to the public, either by  
7 coming in person to the docket room or by us posting  
8 it on the web page.

9           And then for pathogen testing results, the  
10 Agency does routinely rely upon third-party laboratory  
11 analyses in terms of making decisions about whether or  
12 not we will act on adulterated product. Now in many  
13 cases, these would be data that are submitted to us by  
14 State Department of Health laboratories or, in fact,  
15 may, in fact, be the industry's own data in which they  
16 have a piece of information that they share with us.  
17 But in any case, the Agency does insure that we have  
18 information about the type of analysis that was done  
19 so that we can be sure that the lab results, at least  
20 by the methodology, would result in identification to  
21 the particular pathogen or markers that we're looking  
22 for. And that the chain of custody for that sample

1 is, in fact, maintained so that there aren't questions  
2 raised about whether or not there was potential cross-  
3 contamination. So there are a number of criteria that  
4 we've identified in the past that we rely upon  
5 whenever we're looking for third party laboratory  
6 results. In any case, the Agency -- can identify  
7 those criteria so the public is aware of it.

8 In terms of current thinking for using risk-  
9 based inspection, I think what we're really talking  
10 about is how do we credit the data that we would like  
11 to use. This would be supplementing the FSIS findings  
12 with establishment-specific data, and for most of you  
13 who are aware of our risk-based inspection process,  
14 although we look at national impact of what it is that  
15 we intend to do, we have to be aware of what the  
16 individual establishment is doing in terms of the  
17 information that we are relying upon. And so the  
18 issue becomes one really of how do we credit and  
19 obtain information on an individual plant basis.

20 I mentioned a bit earlier about our *Listeria*  
21 testing program in which the industry is required to  
22 submit to the Agency information about their

1 particular production practices, and we've identified  
2 on a OMB approved form the information that has to be  
3 submitted to the Agency at least on an annual basis or  
4 when there are substantive changes made to the  
5 process, and within the last month or so, the Agency  
6 was finally able to convert a manual process in which  
7 that form was filled out and then faxed into the  
8 Agency and mailed into the Agency, and then we rekeyed  
9 the information into our system. Industry is now able  
10 to submit that information in a web-based form where  
11 it's automatically inputted into a database that  
12 downloads into our system.

13           For those of you who were here for the  
14 attribution meeting, I had a slide on how we actually  
15 used this information in terms of determining how we  
16 schedule the 800 samples that we collect each month  
17 for *Listeria monocytogenes*. So the information on  
18 that form directly impacts how we schedule on a  
19 monthly basis are risk-based verification testing for  
20 *Listeria*.

21           And then the ultimate goal with how we use  
22 this information in risk-based inspection would be to

1 adjust inspection activity as a consequence of the  
2 information, the totality of the information that we  
3 have, and inspection here being that we do by  
4 observation, that we would do by a records review and  
5 that we would do by testing, both by FSIS and possibly  
6 by the establishment, and this could either increase  
7 or decrease the amount of inspection activity that  
8 would occur in that establishment.

9           To give you an example of the reliability  
10 issues that we as an Agency needs to attend to in  
11 terms of how we look at this information, I use the  
12 example of the ConAgra recall which many of you are  
13 familiar with, and it is a public document. It is an  
14 OIG report, number 24601-2-KC from September of 2003.  
15 And in that report, specifically it identifies that at  
16 the time and the Agency has changed its process since  
17 then, as a consequence of this audit in which  
18 identified a number of vulnerabilities, but in any  
19 case, at that time, the Agency had in place what we  
20 called incentive programs where if the industry did  
21 certain things, the Agency would adjust its  
22 verification testing program such that we would

1 significantly reduce our testing in establishments.

2           In this particular case, as an example, the  
3 establishment had a number of intermicrobial  
4 interventions, those which we would have assumed, just  
5 by the mere fact that they were implementing those  
6 interventions would be effective in controlling for  
7 O157:H7, that we had assumed that they had a degree of  
8 validation of that food safety system such that those  
9 interventions worked as intended. They identified  
10 that they tested for the pathogen and that they, in  
11 fact, presented outside source material from coming  
12 into the establishment. All of those things together  
13 would lead one to believe that the establishment would  
14 have in place the types of interventions and controls  
15 that should be credited in terms of having the right  
16 type of things present.

17           The reality is, and this was simply not a  
18 situation where the establishment was at fault. There  
19 were Agency weaknesses here as well, but the issue was  
20 the establishment had these issues but weren't  
21 necessarily validating them to the degree to which  
22 they need to be validated, and were not necessarily

1 responding to the data that they were collecting, nor  
2 was the Agency responding to the data that the  
3 establishment had. And so that identified  
4 specifically for the 0157.H7 testing program  
5 weaknesses that need to be dealt with in terms of  
6 designing a future system whereby we would want to  
7 credit activities that would occur in the  
8 establishments, not just give them credit if they have  
9 things, but have in place mechanisms that could  
10 discern degrees of confidence that what they're doing  
11 is, in fact, going to be effective.

12 And so a couple of solutions that we've  
13 identified that could possibly work and what we have  
14 been using now for sometime, particularly since the  
15 ConAgra recall and since the Wonka recall, which was a  
16 similar situation as ConAgra, the Agency has put in  
17 place what we call our food safety assessment in which  
18 we have skilled and trained individuals who are  
19 capable of going in and making in depth analyses of  
20 the food safety system as to whether or not its  
21 effective in terms of doing what the establishment  
22 believes it's supposed to be doing, whether or not

1 there is data available to demonstrate that.

2           In any case, I use the example of *Listeria*  
3 *monocytogenes* again in that the Agency has created a  
4 checklist which we did make available for comment by  
5 the industry, in particular, and it's for use by our  
6 EIAO officers when they do a food safety assessment on  
7 *Listeria*, but it's designed to ask a series of  
8 questions about alternative 1, 2 and 3 processes. And  
9 it's specifically geared at discerning whether or not  
10 there are compelling data available and on file for  
11 which the establishment is relying upon to make  
12 decisions about the food safety system, whether or not  
13 there is not compelling in the sense that there isn't  
14 a challenge study that it was actually done to  
15 demonstrate that the shelf life of the product would,  
16 in fact, be maintained as the establishment believes  
17 it would be by the design of its system, but they  
18 actually have other documentation such as published  
19 research which their process mimics that process, or  
20 computer modeling which would demonstrate that the  
21 important factors that affect that system are, in  
22 fact, accounted for and result in a predicted or

1 estimated degree of control.

2           And then the third level of control is  
3 simply that the establishment has on file validation  
4 documents but not ongoing in depth data that actually  
5 demonstrate that the establishment is actually  
6 controlling the process in the manner that it is  
7 intended to. Oftentimes, what's on file is the  
8 ongoing verification data which is just simply the end  
9 product testing that is there to demonstrate that they  
10 either have or haven't found adulterated product, but  
11 it doesn't actually get at the issue of whether or not  
12 the system is actually controlling the hazard as  
13 intended.

14           In any case, using the food safety  
15 assessments is one way that the Agency believes that  
16 it can make some discernment about the degree of  
17 validity and rigor of the validation for the food  
18 safety system, and this would account for the  
19 interventions that are in place and the data that is  
20 relied upon by the establishment. And then it would  
21 also mean that the Agency needs to better identify the  
22 criteria that need to be in place in order to make

1 some discernment and there I would use the example of  
2 *E. coli* O157:H7 in which it matters to a great extent  
3 whether or not when you're testing manufacturing trim,  
4 if you're testing excised surface tissue or if you're  
5 grinding whole muscle whereby you might be diluting  
6 the effect of the exterior where the contamination  
7 would be.

8           And so there are some questions that the  
9 Agency has identified for various processes that we  
10 could articulate in the form of giving guidance to our  
11 employees to make some discernment about the degree or  
12 rigor the validation is based upon. That information  
13 we certainly would make available to the industry  
14 since that would be information that we would be  
15 making decisions about but the bottom line is that  
16 there really do need to be criteria identified that  
17 would help discern whether or not the sampling program  
18 is designed to actually find the problem, at what  
19 frequency that sampling program is designed to find  
20 it, and then at what confidence, specificity and  
21 sensitivity the lab methodology is being used to find  
22 the problem.

1           So there are a number of things that the  
2 Agency has developed in the form of compliance  
3 guidelines that we make available but we believe that  
4 as we go forward with the decision about how we credit  
5 information, there would need to be more information  
6 developed by the Agency in its decision making as to  
7 when it gives various types of credit.

8           And then the Agency is interested in more  
9 information related to standardized third-party  
10 audits. We know that almost all of industry undergoes  
11 a variety, a number of audits that they use amongst  
12 themselves. A larger purchaser of product may, in  
13 fact, require annual or quarterly audits, that we know  
14 addresses quality and safety. So there is the issue  
15 that we have to make some discernment about with  
16 regards to safety and quality issues but there are  
17 information contained within those audits that perhaps  
18 could serve as the Agency in part of its decision  
19 making, and we've not used third party audit before.  
20 We also have a sister agency at the Department that  
21 conducts audits in the form of paying for those  
22 through purchase specifications and certifications.

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1 But the Agency is open to helping it identify degrees  
2 of validation and support for food safety systems as a  
3 means to give credit in risk-based inspection as we go  
4 forward.

5 So these are some of the issues that we've  
6 identified that we think are important and would lead  
7 you and your breakout groups today to perhaps touch in  
8 and come back with some advice to us as to how we can  
9 better address these. Thank you.

10 MR. TYNAN: We have about five minutes I  
11 think on our schedule where we could entertain a  
12 couple of questions either from the audience here or  
13 from the folks on the phone. Do we have any comments  
14 or questions at this point on the agenda from the  
15 folks that are here in the room regarding Michelle's  
16 presentation or Dan's?

17 (No response.)

18 MR. TYNAN: Okay. Operator.

19 OPERATOR: Yes, thank you. We have Patricia  
20 Buck. Your line is open. Patricia Buck, do you have  
21 your line muted?

22 MS. BUCK: Yes, I did.

1 OPERATOR: Your line is open.

2 MS. BUCK: I'm just wondering we talked  
3 about all of this data, what is the -- I know that  
4 Dr. Engeljohn just, you know, -- over that but have we  
5 thoroughly looked at all of the data that FSIS  
6 currently has to determine whether or not it's  
7 necessary for us have more data -- Agency does not  
8 have enough data to certainly put in place a risk-  
9 based inspection system. Some of the other  
10 presentations, it was also clear that this data  
11 repository -- so are we trying to tackle too much is  
12 my question, than what we're trying to do is put place  
13 a risk-based inspection. Does this make sense to  
14 anybody out there?

15 MS. MACZKA: In terms of what data do we  
16 presently have, we are right now in the process of  
17 looking through all the data that the Agency collects,  
18 and we are analyzing that data to see if, you know,  
19 the limitations in the data, the lacks in the data,  
20 what the fallout is of the data. So we are doing that  
21 data stream by data stream. Now your question about  
22 RBI, I'm going to pass that over to Dan here.

1 DR. ENGELJOHN: This is Dan Engeljohn and,  
2 Pat, I apologize. I wasn't able to pick up everything  
3 that you had asked but I got the sense that you were  
4 asking should the Agency be asking for more data when,  
5 in fact, we should be better utilizing the data that  
6 we have. Perhaps that's not what you asked but that's  
7 what I got out of that. I'm sorry. Were you  
8 following up?

9 MS. BUCK: No, I think that's part of it. I  
10 mean have we thoroughly investigated the data that  
11 FSIS currently has and how efficiently we are using  
12 that?

13 DR. ENGELJOHN: Okay. And this is Dan  
14 Engeljohn. The data that the Agency currently has, it  
15 is the data that we have been relying upon now for  
16 years in terms of making the day-to-day inspection  
17 decisions that we have, and conducting our inspections  
18 as we do from year to year. That data has served  
19 useful purposes but it has not been utilized fully in  
20 part because the Agency had data systems that were not  
21 talking to each other and they were all individually  
22 housed data systems for which -- I'll just give you

1 the example of the efforts that have been underway now  
2 for a number of years, not just as a consequence of  
3 RBI, but for the last several years, the Agency has  
4 been working to ensure that we have a single data  
5 warehouse where all the data gets put into and that  
6 there is no need to rekey information. And the  
7 example that I would give is that for those of you  
8 familiar with the establishment numbering system that  
9 we have, it matters whether or not you put a 0 in  
10 front of the M or a 0 in front of the P or if you  
11 forget to put the P or the M at the end of the number  
12 or you start the number out without the 0 at the front  
13 or you put the M or the M or the P at the front of the  
14 establishment name.

15           And there was no software program that the  
16 Agency had in place that checked for these things. So  
17 that if the information got put into each individual  
18 system in a number of different ways and then manually  
19 we would do data quality checks to try to match up the  
20 data and find out why we didn't have any information  
21 on certain establishments that we knew would have the  
22 information. So it was more of a manual review.

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1 Well, that process has been underway for years in  
2 terms of getting modifications made to standardize the  
3 data sets that we have, and that alone would be one  
4 way to better utilize the data that we have coming in  
5 from individual establishments, as opposed to having  
6 individuals capable of extracting data from each data  
7 system, and then running the analysis on that data  
8 system after they invested time in doing data quality  
9 checks.

10           So my response would be that the data has a  
11 wealth -- I mean the Agency has a wealth of data that  
12 has not been fully or in many cases properly utilized.  
13 That effort has been underway for sometime now to  
14 correct that. But what we're looking at in terms as  
15 we go forward, and again I would just use what  
16 Dr. Maczka said is that the efforts underway aren't  
17 just for RBI as a narrowly defined entity, but it's to  
18 make sure that we are best using the information that  
19 we have. We're no longer collecting the information  
20 that we don't need or don't have a purpose to use or  
21 that isn't fully informing us or might not be properly  
22 informing us, and making sure that all the data that

1 we have is, in fact, being used to its fullest. And  
2 there are data that we know that we should be  
3 collecting that we aren't yet collecting, and those  
4 kinds of things are, I think that we've identified are  
5 the process of looking at how do we best look at our  
6 inspection system, trying to figure out what data  
7 would best inform the Agency in terms of going  
8 forward.

9           And just the one example would be that the  
10 Agency has traditionally collected a microbiological  
11 sample from an establishment, not collecting a great  
12 deal of information about what that sample represents  
13 when we pull it, and then analyzing it for just one  
14 pathogen. Whereas the Agency could, and it certainly  
15 has the resources to collect some information about  
16 what that sample represents in terms of production  
17 size, whether or not interventions are used and  
18 whether or not that particular production was tested  
19 by the establishment before we sent it. And then  
20 looking at that sample for a host of pathogens or  
21 markers as opposed to just one particular pathogen.

22           So there are things that we can do as we go

1 forward, now that science has caught up with us in  
2 terms of us moving forward, or at least we've caught  
3 up with science in some places, we can better utilize  
4 the information we have with the resources we have.  
5 And so I think right now is what we're trying to do is  
6 to put all that to bear by getting the system to do  
7 more than what it has in the past. But I think we  
8 have collected an enormous amount of information.  
9 We're just now in the process of identifying all the  
10 weaknesses to that data and then correcting those  
11 weaknesses.

12 DR. MACZKA: And if I could just add, in  
13 addition to creating the data warehouse, we are also  
14 developing systems that will quickly pull and analyze  
15 the information and display it. So we're working on  
16 that right now.

17 MS. BUCK: Well, thank you. That was a very  
18 complete response but again I'm just a little  
19 concerned. This is a major undertaking that you've  
20 just outlined and I think for the purposes of putting  
21 a risk-based inspection program in place, I think --  
22 of this year. I don't see how you could do that

1 before that happens, number one, and number two, I  
2 think the very first part of that step would be to  
3 look at the data that FSIS currently has to do that  
4 analysis, see how it works, whether or not we do it  
5 efficiently because the efficient use of what we  
6 already have is our first step. You're talking about  
7 major monetary efforts here I would think, since the  
8 first step would have to be that you use efficiently  
9 that information that you already have. So I mean I'm  
10 all for everything that you've said in your response,  
11 Dr. Engeljohn. It's just that I don't see how we can  
12 put that in place. It doesn't mean that this meeting  
13 isn't important, but I think we're -- a significant --  
14 away from getting industry data worked into the  
15 equation.

16 MR. TYNAN: Ms. Buck, not to cut you off or  
17 not because your comments are worthwhile or to be  
18 rude, but we are past our time. So I'd like to, if I  
19 could, go to discussion of the breakouts and I'm going  
20 to ask the folks that are on the telephone to remain  
21 on the telephone and not leave. We're going to use  
22 you on the telephone as your own breakout group. So

1 some of these instructions will be important for you  
2 as well.

3           For here at George Mason, we have three  
4 breakout groups. We are using a very sophisticated  
5 system to put you in different breakout groups. You  
6 have a color code on your nametag that will indicate  
7 which group you're to be in. We have a Red Group, a  
8 Green Group and a Blue Group. So that's very complex,  
9 and what we're going to do is ask each room, when you  
10 get to your room, to designate a person to be the  
11 chairperson/reporter for that room. So the  
12 expectation is that individual when we have our report  
13 outs around 11:45, that you'll be coming back to this  
14 room, and you'll be providing a synopsis, a short  
15 summary of what the group discussed. So that's the  
16 chairperson's role. In each of the rooms, we will  
17 have an FSIS person that will be helping you take  
18 notes. I think we have flipcharts in each of the  
19 rooms. So I think we'll be geared up so that anything  
20 that's said, the highlights can be captured there and  
21 you'll have that information when you come back to the  
22 room for the report out.

1           The Red Group is going to be in Room 257.  
2 The Green Group is in 253. And the Blue Group is in  
3 Room 245. And all of those rooms are here on this  
4 floor. I would ask to help the person that is leading  
5 the group, if you could keep your comments short,  
6 concise, so that we can stay within the timeframe.  
7 You have about an hour that's going to be allowed. So  
8 the report outs need to start at about 11:45. So  
9 you'll have to wrap up probably just about an hour.  
10 And we'll ask you to report out in that order. So it  
11 will be Red, Green and Blue and then we'll let the  
12 Audio go last. I'm going to ask our panelists if they  
13 would not object, maybe to disperse themselves to the  
14 various breakout rooms to perhaps lend clarity to some  
15 of the issues but not to be the sole discussers. I  
16 think they have made their presentations. So if you  
17 have questions for them to clarify issues, that will  
18 be fine, but don't put them on the spot to do too much  
19 talking.

20           We have four questions that you need to  
21 address. They're on the agenda, and let's just talk  
22 about them real quick. So the questions you will be

1 responding to is, "What data could third parties  
2 provide to FSIS to further enhance protection of  
3 public health?" That's question number 1.

4           Question number 2 is "How can stakeholders  
5 assist the Agency in improving collection, validation,  
6 analysis and application of data?"

7           The third question is, "What mechanism or  
8 mechanisms can be developed to bring different  
9 stakeholders together and share quality data?" So  
10 could that be the taskforce that Michelle mentioned  
11 earlier, some type of third party repository,  
12 regularly scheduled stakeholder meetings, perhaps some  
13 other mechanism that we didn't discuss today but comes  
14 for mind for all of you.

15           And the last question is, "What are the  
16 barriers to creating such a mechanism?" So in one  
17 part it's "What are the barriers to creating such a  
18 mechanism?" And then the other side of the point is,  
19 "What incentives could be used to encourage sharing of  
20 data?"

21           So those are the four questions. Each of  
22 the groups will respond to those questions and be back

1 here at 11:45. And with that, are there any questions  
2 regarding the breakout sessions? Dr. Bernard.

3 DR. BERNARD: Thank you. Dane Bernard,  
4 Keystone. Just a question or clarification and Jenny  
5 and I were just discussing what do you refer to as  
6 third party? Would that include a plant which I would  
7 look at as second party but, you know, as far as data  
8 submission, I think it's an important point.

9 MR. TYNAN: We had a discussion about third  
10 party, and I think it would be second party or third  
11 party, and I'll let Dan maybe talk about that.

12 DR. ENGELJOHN: We realize the issue that  
13 third party has some technical term associated with  
14 it. And I would say it's non-FSIS data. Does that  
15 help you so that we're getting it from any source in  
16 some fashion.

17 MR. TYNAN: Okay. With that, if you want to  
18 take a fast break and be at your breakout sessions as  
19 soon as you can. And don't forget to designate a  
20 reporter right off the bat.

21 (Off the record.)

22 (On the record.)

1           MR. TYNAN: We're going to start with the  
2 Red Group and Michael Batz, who is going to give the  
3 report out for his group, and then we'll go to Green,  
4 and I think that's Steve Pretanik and then the Blue  
5 Group is -- I'm sorry --

6           UNIDENTIFIED SPEAKER: The Blue Group is  
7 Steve.

8           MR. TYNAN: I'm sorry. Okay. And the Green  
9 Group is Danah. Thank you very much. And on the  
10 phone, we'll have Mark Schad and he'll finish us out  
11 with the folks that were on the phone. Mike, take it  
12 away.

13           DR. BATZ: All right. Well, David, before I  
14 get started on this, I just wanted to note that David  
15 mentioned our Food Safety Information Infrastructure  
16 Project, and I came here sort of because as part of  
17 that project we've discussed information flow  
18 throughout the food safety system and ways to improve  
19 that, whether it's private data, public data, the  
20 whole system-wide thing. The scoping project was  
21 really aimed at sort of facilitating the community to  
22 identify what those opportunities for improvement

1 might be.

2           We had four workshops one of which was  
3 focused on industry data, and there was quite a few  
4 people here that were at that, and I just wanted to,  
5 you know, we have some materials online that may be  
6 interesting to you, probably not, but they may be  
7 interesting and include some summaries from our  
8 workshops and so on. But we'll be having our final  
9 conference in September if you're interested in sort  
10 of the broader issues of information for the system.

11           But to get to this group, I will say up  
12 front, I think it's pretty obvious that -- I'm going  
13 to try to read from this so that people on the phone  
14 can hear and, you know, obviously these are not my  
15 viewpoints nor were they consensus viewpoints, but  
16 more in a brainstorming kind of way, and these  
17 obviously don't capture all of the intricacies of the  
18 discussion but just to summary them. I'm sure we've  
19 got four presentations that probably cover a lot of  
20 the same ground.

21           When we talked about -- can I see the agenda  
22 and the actual question? Okay. So the first question

1 was what data could third parties meaning non-FSIS  
2 parties provide FSIS to further enhance protection of  
3 public health?

4 I think we started with, you know, some  
5 obvious ones, in-plant pathogen testing, plant  
6 processing control data which might include indicator  
7 organisms for process control and other data  
8 associated with the food safety management systems.  
9 We've got intervention validation data, other  
10 information related to volume production. There may  
11 be testing on raw materials. There may be lot  
12 descriptions, or other sort of traceability kind of  
13 information. A lot of information, you know, there  
14 may be -- the data is limitless is the next one here  
15 which I actually might have said myself but I think  
16 the point was just that there may be a lot of data and  
17 it may be purpose driven by the specific need of  
18 whatever the process is.

19 There was also talk about going beyond  
20 industry data, let's say, there might be a lot of data  
21 collected by state, whether it's for inspection  
22 programs, agriculture offices, public health

1 departments, maybe even local data. There may be --  
2 CDC certainly has surveillance data that's useful  
3 through its activities, as well as, you know, true  
4 third party data through academic research or from the  
5 literature and so forth. So that's a pretty broad set  
6 of data but -- I don't know if there's any questions  
7 or should I just keep going here.

8           These are color coded. So one is purple.  
9 Okay. Number 2, the question was how can stakeholders  
10 assist the Agency in collection, validation, analysis  
11 and application of data? And the way we framed this,  
12 with some guidance from some FSIS folks in the room,  
13 was that this is really about how stakeholders can  
14 help FSIS in its own data collection efforts, in its  
15 own analysis. So rather than talking about just third  
16 party data or third party involvement, in FSIS data  
17 collection.

18           So then to read this off it says we, as in  
19 FSIS, need to show how the Agency is using data and  
20 collecting it now. There is the idea of some support  
21 through the room, discussed about a data warehouse or  
22 data repository for industry data in which the public

1 and which would be open for viewing and analysis of  
2 it. There was talk about a more regular release of  
3 data, perhaps quarterly where the data would actually  
4 be disseminated on a regular basis, maybe through  
5 summary documents or whether through actually the data  
6 itself. There was some discussion about how --

7 I guess the analysis of data for trends, and  
8 comparability of data, might prevent FSIS to change  
9 reporting as it is now. So that FSIS may be reluctant  
10 to change reporting and should actively try to improve  
11 the current method of these systems and overcome some  
12 of the issues that are there for trend analysis.

13 FSIS should follow risk analysis approach,  
14 that is to engage the stakeholders in the whole  
15 process, to move towards the stakeholder involvement  
16 throughout from the beginning to the end. Similarly,  
17 there was discussion about the use of a taskforce to  
18 include all the stakeholder issues as another way to  
19 bring stakeholders into the discussion of data quality  
20 and data use. There were discussions about creation  
21 of guidance documents to guide the collection of data.  
22 And there was some -- in a similar, well, you know,

1 thing here we see stakeholder involvement as actually  
2 getting stakeholders to either belong to DAIG or to  
3 interact with perhaps with the taskforce.

4 Anybody that was in the Red Group, please  
5 feel free to either take over or correct me.

6 Number 3 here was where we were actually  
7 getting into the mechanisms for using third party data  
8 and the question explicitly is what mechanisms can be  
9 developed to bring different stakeholders together and  
10 share quality data, taskforce, third party repository,  
11 regularly scheduled stakeholder meetings or other  
12 mechanisms.

13 I think there was a lot of support in the  
14 room for the idea of using a taskforce to bring people  
15 together to discuss the issues that may be purpose  
16 driven or specific to a given context. There was a  
17 lot of support and appreciation for FSIS looking at  
18 the EPA and other agencies that have grappled with  
19 similar issues in the past to see what kind of  
20 protocols and approaches they have used.

21 The next one here is to find a way to look  
22 at the current simple process of looking at, okay,

1 I'll read this one and maybe I'll try to interpret it.  
2 Look at current simple process and guidance material,  
3 looking at data and enter into database and  
4 incorporate into model. I think the discussion here  
5 is talking about, you know, the data that's already  
6 collected in the plant, just coming up with a simple  
7 process of, you know, stuff that should already be  
8 fairly standardized that is done following guidance  
9 documents and just looking at a way of, you know, how  
10 can that data be aggregated up to be used in this sort  
11 of risk-based inspection model. Does anyone want to  
12 clarify that? No. That means I either got it right  
13 or everybody's asleep.

14           Okay. The other thing is just to formalize  
15 a process for how the data is incorporated and how  
16 stakeholders are involved so that there is this sort  
17 of standard procedure for how the parties are brought  
18 together and how this data is looked at in the  
19 process.

20           The other thing here was there needs to be  
21 buy in from everyone so that everyone is following the  
22 same exact procedures so that, you know, even though

1 it's volunteer, everybody is doing the same thing.  
2 And the subset there is to use information based on  
3 FSIS guidelines.

4           And the fourth part here is where we're  
5 getting into incentives and barriers. I think these  
6 may be separated into two pages here. So first I  
7 guess what are the barriers to creating such a  
8 mechanism, and the first thing that came up very  
9 quickly was that the information needs to be  
10 protected, and that it can't be subject to FOIA. So  
11 that, you know, there may be barriers there of how  
12 data can be used when it's confidential, you know, you  
13 have an open system with confidential data.

14           There was a need that everybody needs to  
15 know how the data will be used. So the barrier there  
16 is I guess one of communication and openness and  
17 transparency. I don't know what improved public  
18 health means, I mean it's a good thing, but I don't  
19 remember -- that might have been an incentive. I  
20 don't know.

21           One of the resource issues in the plant,  
22 especially with respect to small processors, and also

1 any party, state, government, academia, there are  
2 resource limitations everywhere that may make sort of  
3 providing data or cleaning it or whatever, kind of  
4 difficult. Would there be a regulatory or punitive  
5 action? How will the data be standardized and an  
6 explicit need for some compliance guidelines on that.

7 The data needs to be objective and include  
8 all the data. That was a response to say, well, you  
9 know, the data can't be cherry picked. The system  
10 needs to be voluntary. There was some discussion  
11 about that, that it can't be a mandatory program.  
12 Don't want to discourage people from doing pathogen  
13 testing because of the fear of regulatory action. So  
14 you don't want to have a system in place that actually  
15 presents incentives not to test.

16 And there was some discussion about breaking  
17 down this barrier by setting up a pilot program, so  
18 therefore it could be set up, a pilot program, on a  
19 small number of plants, and then there was some  
20 concern there mentioned about identifying the  
21 establishments with the data, I guess which is similar  
22 to some of the confidentiality issues.

1           There was some discussion of what incentives  
2 could be put in place and this was sort of -- this  
3 went back and forth a little bit but there was some  
4 discussion about adding credit so that you would get  
5 credit for sharing the data in your RBI score, but  
6 then there was some concern that that -- from others  
7 that that would not be fair. It wouldn't make sense.  
8 Would there be an incentive for plants asking on  
9 validation in FSIS -- okay. Would there be an  
10 incentive for plants asking questions on the  
11 validation and FSIS have a mechanism to respond to  
12 those questions. Then the plant might share data.

13           The plant or, you know, they shouldn't be --  
14 there was some discussion I think related to this RBI  
15 level of inspection that there shouldn't be a benefit  
16 to sharing bad data. So therefore -- by bad data, I  
17 think there was sort of poor levels or showing failure  
18 in the system, that you shouldn't be rewarded for that  
19 even though you're sharing it, the difficulty between  
20 wanting to provide an incentive to share without  
21 providing a, you know, a benefit when it showed  
22 something negative.

1           Some discussion of sharing data from  
2 academics, and then lastly, a public health angle  
3 might be an incentive to show how the data being  
4 collected is affecting public health. So that's the  
5 long laundry list of things that have to be done  
6 today. That's it. I mean I guess now we're going to  
7 have three more that have covered these points and  
8 hopefully some others.

9           MR. TYNAN: Any questions for Michael?

10           (No response.)

11           MR. TYNAN: Okay. Thank you, Michael, very  
12 much. Okay. We've got the second group with is --  
13 what did we decide, would be the Green Group and that  
14 would be Dr. Vetter.

15           I should point out at this juncture I don't  
16 think we acknowledged at the very beginning that we do  
17 have some of our employee organizations represented  
18 here today, one of them being Dr. Vetter. Danah  
19 Vetter is a representative of our National Association  
20 of Federal Veterinarians. And we have Ms. Olga  
21 Morales, who is representing the Association of  
22 Technical and Supervisory Professionals. And

1 Mr. Painter who is our NJC President, who has some  
2 back problems, expected to be here and was not able to  
3 attend today. So with that, Dr. Vetter.

4 DR. VETTER: Okay. I think you'll hear me  
5 echo a lot of what Michael referred to. I think we  
6 even referenced him in some of our discussions.

7 So question number 1, where did his cheat  
8 sheet go? What data can third parties provide to FSIS  
9 to further enhance protection of public health?

10 And pretty quickly we focused in on some of  
11 the current testing that's going on in plant which is  
12 part of the operational verification on a daily basis  
13 like microbial testing and allergen testing, and how  
14 that's currently being used and if that could possibly  
15 provide some benefit to FSIS.

16 Some examples of that, we started discussing  
17 inbound load on raw product, which led to some other  
18 discussion as well about barriers. That's probably  
19 one of the main examples that we talked about, was  
20 inbound levels on raw product as well as *Salmonella*  
21 testing. So you'll hear me reference both in there.  
22 They were saying that this could be looked at

1 basically outside the regulatory standards, sort of as  
2 a research project, to provide useful information to  
3 FSIS that could help them make certain decisions. And  
4 also what is the means to the end, what is going to be  
5 the reason for collecting this type of data was  
6 discussed.

7           Some people suggested state data which I  
8 heard you reference as well as other agencies. APHIS  
9 has the National Poultry Improvement Program that does  
10 quite a bit of *Salmonella* testing and microbial  
11 testing as well. And also there was a suggestion that  
12 you could look at the hazard analysis or third parties  
13 could provide information from their hazard analysis  
14 in order to help FSIS focus on food safety hazards at  
15 the highest priority within certain processes. And I  
16 think I've covered just about everything with question  
17 1.

18           Question number 2, how can stakeholders  
19 assist the Agency in improving collection, validation,  
20 analysis and application of data?

21           Somebody said this would be a better example  
22 or look at microbial and allergen testing because it's

1 real more time and you have an increased frequency of  
2 this testing being done. It could help the Agency  
3 form an opinion about everyone of these aspects, and  
4 when we talk about everyone of these aspects, talking  
5 about improving collection, improving validation,  
6 analysis and application.

7           And again, we kind of got back to that  
8 barrier. We kept kind of going around back to that  
9 but if we don't know the end stage and how the data  
10 will be applied, it's very hard to answer these types  
11 of questions. So that other agencies could help the  
12 Agency formulate what that data is and how it could be  
13 collected and how it would be used. That is should be  
14 an orchestrated well throughout process and one of the  
15 points we thought out is that this question number 2  
16 pretty much formulates what would be required of a  
17 research project, those types of improving collection,  
18 validation, analysis and application of data.

19           Let's see. There was a big emphasis on that  
20 FSIS needs to articulate the public health goals of  
21 risk-based inspection as well as collecting this data,  
22 how is it going to be used, is it going to be

1 attribution data, how will the Agency look at this?

2           Okay. There was a comment that stakeholders  
3 could help point out with all their certification  
4 programs for the data, and again we got back around to  
5 what is the outcome, why are we collecting all of this  
6 data. Why would we need a place to put the data and  
7 look at it? What is going to be the end result. So  
8 therefore, we must agree on a path to achieve the  
9 goals, the Agency, the industry and the consumers.  
10 And that goes back to the stakeholders can help, you  
11 know, point out what all we have available and how it  
12 can be used.

13           And I have to say, if you think I'm going  
14 all over the place, so did our conversations. That's  
15 why my notes are like this.

16           Okay. And again, the number one challenge  
17 is what is the goal of this and what do we know at  
18 this point.

19           All right. Anybody want to add to that  
20 within my group? Did I miss anything?

21           (No response.)

22           DR. VETTER:       Okay.       Number 3, what

1 mechanisms can be developed to bring different  
2 stakeholders together and share quality data?  
3 Taskforce, third party repository, regularly scheduled  
4 stakeholder meetings or other mechanisms.

5           They thought that the current DAIG could be  
6 enhanced by bringing in other stakeholders.  
7 Basically, those participants might vary, depending on  
8 what project was ongoing at the time and those project  
9 goals, different people with different areas of  
10 expertise that it might apply to be part of DAIG,  
11 depending on the current project.

12           A lot of people were in support of a third  
13 party repository. There was an interest that they  
14 thought it should be independent and also that the  
15 standards need to be set of what data will be  
16 acceptable and how it will be analyzed. Will right or  
17 wrong conclusions be drawn from this data?

18           We were kind of looking at, there were two  
19 ways that a repository could be looked at. It could  
20 be a data dump, which again does this make sense? Why  
21 would we have this data dump? What would we use it  
22 for? And again back to would you draw the right

1 conclusions from it? Would you draw the wrong  
2 conclusions from it? Or could it be used for research  
3 purposes within FSIS, within the industry, and then  
4 that sort of led to a comment that was brought up at  
5 by Dr. Denton at the meeting in 2003, that there could  
6 be a board that would screen a request for information  
7 within the repository so that it wouldn't just be out  
8 there for everybody but it would need to be a valid  
9 request for using that information.

10           And again, why would we have a repository  
11 that we know what we're going to use it for, but we  
12 just don't put stuff in there that's going to be  
13 useless information.

14           There was a suggestion that they work with  
15 Mike Taylor, so that they don't duplicate work and  
16 they learn from his experiences. There was a belief  
17 that taskforces and stakeholder meetings would be  
18 useful both now to develop the process and know where  
19 we're going and get that infrastructure that we need  
20 and also later to evaluate how are we doing? Is this  
21 accomplishing what we intended it to. And that those  
22 types of taskforce and stakeholder meetings would be

1 very useful within that process.

2           And also that FSIS already has an advisory  
3 committee such as the National Advisory Committee on  
4 Meat and Poultry Inspection, that currently advises  
5 FSIS and we could use what's in place to look at this  
6 as a taskforce or stakeholder. And that we have  
7 quality data, not just quantity. That was really,  
8 really a prevalent theme.

9           Barriers, one of the biggest barriers is  
10 that we don't know the current or desired outcome or  
11 goals for this. Again, is it for better attribution  
12 data or for better allocation of our FSIS resources?  
13 Another point that was brought out is the scope is  
14 very, very large right now. We're talking about data  
15 on a lot of different things with different  
16 perspectives and different ways of collecting it. And  
17 so it may be more appropriate to focus on a much  
18 smaller scope and use that as a starting point and  
19 then branch out from there. For example, what's been  
20 done with *Lm*. Again, the infrastructure, we don't  
21 have the infrastructure that we need currently to  
22 obtain this or make this work.

1           There's also proprietary issues, legal  
2 ramifications and then also there was a concern with  
3 the length of time that it's taken to get to this  
4 point, and will it take another three years to move  
5 forward again? So that was another concern.

6           Also small establishments don't typically  
7 have the same resources that large establishments do  
8 to obtain data, microbial.

9           Incentives, we also kind of touched on the  
10 public relations issue, that this would be a good  
11 aspect for industry as well as FSIS about what we are  
12 doing to improve public health, and that it is  
13 effective, and that there's an effort out there.

14           Sharing data results could result in a lower  
15 RBI score and where this is coming from is something  
16 we're not talking about right now but will be talking  
17 about in the future, risk-based inspection in  
18 slaughter establishments and how industry data will  
19 probably be a large part of that.

20           And also there was something, Yancy brought  
21 this up, that it will drive the discussion of real  
22 meaningful conversations about data validity, and I

1 think one of the best examples he gave was *Salmonella*  
2 whereas right now we just look at positives and  
3 negatives versus serotypes. I know we are serotyping  
4 some, but as far as overall, that's probably a smaller  
5 portion of plants that are doing that, and if this  
6 moves us forward in looking at quantitative data of  
7 say *Salmonella* and serotypes, then those people that  
8 are kind of looking at it from the standpoint of why  
9 would I do that, because FSIS doesn't currently look  
10 at quantity in that type of thing, it's all going to  
11 be a positive, and it's all going to count the same,  
12 then this would move that forward to give those people  
13 with that attitude an incentive to do that, and do  
14 that type of testing.

15 MR. TYNAN: Questions for Danah?

16 (No response.)

17 MR. TYNAN: Okay. There being none, I'm  
18 going to ask Steve to come on down. He'll be the Blue  
19 Group.

20 MR. PRETANIK: Some of this others have  
21 covered but briefly we'll go through some of the  
22 concerns and suggestions that we had. We had on

1 question 1, considerable discussion on type of data  
2 and basically what we ended up with really centered on  
3 data that could be used for risk assessment, and here  
4 we're talking about validation data, the data on  
5 interventions, how well they work, in process steps,  
6 throughout the process, food processing, post-  
7 distribution, looking at things such as the number of  
8 microbe tests, results of microbe tests, audit scores,  
9 internal, external, production volume, statistical  
10 process control analyses, all of these things which  
11 could factor into establishing a risk assessment both  
12 from a product end within an individual plant.

13 I'm going to flip to the next one. On  
14 question 2, we felt that the stakeholders at best be  
15 involved in defining the criteria, that would be used  
16 basically to define the processes really for  
17 collecting these other things addressed in question 2  
18 such as validation analysis, classification of data.  
19 We thought the scope should be pretty much limited to  
20 that, and with relation to that, we felt that they  
21 could perhaps be involved in coming up with a  
22 standardized data format.

1           We thought this was absolutely critical, in  
2 that any data collected, going forward with risk-based  
3 inspection, at this point forward, it's going to be  
4 very difficult to take data previously collected, try  
5 to fit it all together if you will. People report  
6 things differently. Even when they're given a  
7 standard format, they don't always report things the  
8 same way. So there really needs to be some effort to  
9 develop a uniform standardized way of collecting data,  
10 how you want it to be reported and it has to be based  
11 on the type of data you're looking for, too.

12           So we think that this is a very critical  
13 step that may or may not be in place already but  
14 certainly needs to be placed before we move forward.

15           With regard to question 3, we did have some  
16 comment on what was meant by quality and we assume  
17 that you meant quality of data, not quality control  
18 data from a plant. What role should the group play?  
19 Basically, we kind of bounced around, and I'm sure  
20 that others did, too, on 3 and 4, with this question.  
21 Where we essentially ended up, if you'll flip over for  
22 me, is that we do have, depending on how and the type

1 of data you're going to be addressing, we felt that  
2 you do have some committees in place that should be  
3 used and perhaps depending on what you expect them to  
4 do, you may have to use them. And those would be  
5 National Advisory Committee both for inspection and  
6 microbiological criteria. And they can be used to  
7 define such things as, you know, what constitutes good  
8 data and what are the expectations of the  
9 stakeholders.

10           There was also some discussion as to using  
11 these groups and public meetings to help or perhaps  
12 discuss the needs and flush out the Agency's need with  
13 respect to data. The only job drawback with using the  
14 Advisory Committees is that it could take time, more  
15 time than you like, although I understand that it can  
16 move very quickly if given a task and the opportunity.  
17 So there was a suggestion that perhaps we might want  
18 to look to finding some other type of group, getting  
19 volunteers perhaps from the various stakeholders, to  
20 initially address this and then perhaps pieces of that  
21 could be passed onto the Advisory Committee.

22           With respect to barriers and incentives,

1 there was a lot of discussion and concern about  
2 whether we're talking about aggregate data or industry  
3 specific data. There's a concern about data being  
4 released under to FOIAs, industry data by inspectors  
5 for NRs, and there was some discussion about possible  
6 antitrust in sharing this data, but I think those  
7 things may be worked out.

8           And the big concern was perhaps misuse of  
9 data, due to lack of understanding of the data or  
10 misinterpretation. It could be used in an  
11 inappropriate manner.

12           Incentives, it can be used, sharing data  
13 certainly could be used we feel to make adjustments in  
14 inspection. Certain inspection tasks could be done by  
15 industry. This would provide more efficiencies for  
16 that particular plant. It would also provide for more  
17 emphasis on consumer expectations with respect to  
18 product and spend time with some activities that may  
19 not be as important. So we felt that that's a  
20 possible incentive to get industry to share data.

21           And I believe that pretty well wraps up  
22 without going into what everybody else has already

1 suggested.

2           One of the things we did suggest is using  
3 the DAIG possibly to work on third party data,  
4 assessing it, putting it together, just as they would  
5 with their in-house data, take on that task with the  
6 third party data.

7           MR. TYNAN:     Mr. Schad, did you want to  
8 report out for your group? Operator?

9           MR. SCHAD:    Can you hear me, Robert?

10          MR. TYNAN:    I can now. Thank you, Mark. Go  
11 ahead anytime.

12          MR. SCHAD:    Okay. I have notes here from  
13 the group. We did have an open line and it seemed to  
14 work a lot better than last week. I don't really have  
15 comments on each specific question per se but I'd just  
16 like to go through all the comments that was made  
17 during the call. And really, I'm going to kind of  
18 like start at the bottom there. We talked about the  
19 barriers to creating such a mechanism, and a couple of  
20 barriers we come up with, and that was with the  
21 confidentiality issue. I know in the presentations  
22 earlier this morning, there was some talk there of how

1 to ensure confidentiality, but industry kind of feels  
2 like we need a strong assurance that if we shared that  
3 data with the Agency, that it would be confidential  
4 and not open to the public.

5 Another concern there as far as a barrier  
6 was FSIS needs to clarify collection criteria, so that  
7 all data can be considered the same or all data can be  
8 sound data, science-based data. There was a concern  
9 from representatives of very small plants such that we  
10 need statistical guidelines as far as we're collecting  
11 this data that is it meeting statistically based data.  
12 So, you know, as far as we're collecting it, we know  
13 that it will be good, sound data.

14 There was concerns of not clear of the value  
15 of benefits of FSIS collecting this data, not clear of  
16 how the data will be used, and also the timeframe with  
17 RBI as far as getting the whole mechanism in place as  
18 far as establishing how we're going to collect this  
19 data, making sure it's statistically sound and good  
20 useable data, setting up the -- if we have a  
21 repository, setting up the repository and getting all  
22 of this done by the time the RBI timeline is currently

1 established.

2           There was concern about the resources, are  
3 there enough necessary resource in place that the  
4 Agency has to be able to collect this data and ensure  
5 the soundness of this data. It was brought up on what  
6 can we use with this data to improve public health and  
7 that was taking this data, making sure it's sound and  
8 sharing it with FoodNet, PulseNet and the CDC. That  
9 was more of a question in response to question number  
10 1.

11           And I think just my overall comment from our  
12 conversation, that a taskforce would be a good thing  
13 to have that would represent all stakeholder groups  
14 because we just have so many diverse different  
15 comments and disagreements over this entire issue. So  
16 that's the notes that I have, Robert.

17           MR. TYNAN: Okay. Thank you very much,  
18 Mark. I appreciate that. And again, as he was last  
19 week, he's still on vacation but willing to dedicate a  
20 little bit of time. It's nice to be able to have two  
21 weeks of vacation. Thank you though, Mark.

22           And with that, we've gotten all the report

1 outs. Are there any questions for Mark's group?

2 (No response.)

3 MR. TYNAN: Okay. There being none, we're  
4 about 12:30 on the agenda. So we're right on time.  
5 We are to a point where we are going to talk a little  
6 bit about comments and questions overall for the day,  
7 not including the -- not necessarily excluding the  
8 discussion we had in the breakouts, and I think I  
9 would invite the panelists to come back up for this  
10 portion of the session, maybe to sit up here and  
11 respond to any questions. Thank you, Dan.

12 It just occurred to me, hopefully there will  
13 be some questions now that we've made them come up.  
14 And it's not a requirement however. I thought this  
15 would be a little bit better. So if there are some  
16 questions, either from the folks here in the audience  
17 or the folks that are on the phone, if you could come  
18 to the microphone, state your name and your  
19 affiliation and ask your question, we'll be good to  
20 go. Are there any questions? Mr. Waldrop?

21 MR. WALDROP: It's not really a question.

22 MR. TYNAN: Is your microphone on?

1           MR. WALDROP:   It's not really a question.  
2   It's more of a comment.   This is Chris Waldrop,  
3   Consumer Federation.   On the presentations, there were  
4   a number of suggestions on incentives, and one of  
5   those was how the industry or how the Agency could  
6   maybe apply or give some incentive in the risk-based  
7   analysis algorithm, the final number, and I would just  
8   encourage the industry to think very or the Agency to  
9   think very carefully about how they do that because  
10   depending on where you add or take off that point, it  
11   could have a much larger or smaller influence on the  
12   entire algorithm.   So I don't have an answer for that,  
13   but I'm just saying that that's something the Agency  
14   needs to consider very, very carefully.

15           MR. TYNAN:    Thank you, Chris.    Other  
16   questions from the group here?

17           (No response.)

18           MR. TYNAN:    Okay.    Operator, are there any  
19   questions from the group on the telephone?

20           OPERATOR:    I'm sorry.    No questions from the  
21   phone lines.

22           MR. TYNAN:    There are none?

1 OPERATOR: No questions on the phone lines.

2 MR. TYNAN: Okay. Thank you. Okay. So  
3 we're a little bit ahead of schedule, and if there are  
4 no other questions or comments from either the phone  
5 or here in the audience, I'm going to introduce again  
6 Dr. David Goldman and he's going to have some closing  
7 remarks for us.

8 DR. GOLDMAN: Thanks, Robert, and thank you  
9 once again to all of you who came to the meeting, who  
10 joined us by phone, who participated in the breakout  
11 sessions. I think we heard a lot of recurring themes  
12 as we often do especially when we have breakouts and  
13 the breakouts are dealing with the same questions, we  
14 tend to get some of the same answers which is good  
15 validation I think of the process and of the questions  
16 that we asked.

17 I do want to thank everyone for coming.  
18 Again, I want to thank our panelists for presenting  
19 today. I'm not going to go into any great detail at  
20 all about what we heard because we all just heard it.

21 I do want to highlight a couple of things,  
22 and I want to address one thing that perhaps caused a

1 little bit of confusion right out of the box, and that  
2 is that even though the focus of the meeting and the  
3 title was Using Data From Other Sources, we started  
4 off by talking about FSIS' use of its own data and the  
5 efforts that you heard Carol describe in particular on  
6 the development of the Data Analysis Integration Group  
7 that she is heading up. And I want to tell you that  
8 the reason for doing that was twofold at least. One  
9 is that this, as she mentioned, is an effort that the  
10 Agency's been involved with for sometime, the first  
11 data summit that we call it on the Management Council  
12 occurred in November 2005. So the idea of enhancing  
13 our data analysis and figuring out where best to put  
14 that function does have quite a long history.

15           The second reason for having that as part of  
16 the leadoff to this discussion is that the efforts of  
17 the DAIG, as we're now accustomed to calling it, will  
18 be very important as we evaluate RBI, both as we  
19 evaluate as we go along, but particularly as we  
20 evaluate its success or lack therefor with the  
21 implementation of the prototype locations. So that's  
22 another very important reason for having Carol leadoff

1 and having that discussed.

2           Just a couple of other themes that I think  
3 emerged that I think are important, is that you also  
4 heard from Carol that there is this Data Coordinating  
5 Committee which is also very important for you to know  
6 about, and the reason is that it involves a  
7 representative from each of the program areas. So  
8 whereas the DAIG is kind of embedded in Carol's  
9 program area, the Data Coordinating Council or  
10 Coordinating Group will be consistent of  
11 representative across the Agency, and I think that's  
12 very important because not every data analyst in the  
13 Agency is in the DAIG. There are programs that still  
14 have their own data analysts and will need to have  
15 them for other purposes. So I did want to clarify  
16 that as well.

17           We talked a little bit about the mechanisms  
18 for both our own analysis as well as for incorporating  
19 other or non-FSIS data, the use of contractors, and  
20 the very important notion of including stakeholder  
21 input into this process. And we heard that come up in  
22 the breakout sessions as well. And so I think you've

1 heard already today a commitment on the part of the  
2 Agency to involve our stakeholders, probably to an  
3 unprecedented level in terms of involvement with our  
4 data, our data analysis and the way we use that data  
5 for policymaking. And certainly one possibility for  
6 seeing that through would be to perhaps use the NACMPI  
7 which was a suggestion from one of the breakout  
8 groups, and establish perhaps a standing subcommittee  
9 who would be intimately involved with the DAIG and the  
10 DCC so that at each NACMPI meeting we have this very  
11 good discussion about the ongoing work of the DAIG as  
12 well as kind of a report out about its progress.

13 I was very happy that we had Mike Batz join  
14 us today to briefly mention the project that as I  
15 said, Resources for the Future began and then the  
16 University of Maryland has taken up which is what they  
17 call the Food Safety Information Infrastructure  
18 Project. He described it as a scoping project, and I  
19 think I heard from Mike Taylor as well, the week  
20 before last, that really they haven't even completed  
21 their analysis of what they've heard yet, but I think  
22 we're all invited to September's meeting that they

1 will sponsor where they will perhaps tell us what  
2 they've learned and their process which is very much  
3 parallel to some of the discussion we had today.

4           We talked about the use of data or non-FSIS  
5 data in our past in the Agency. We heard examples of  
6 *Listeria*, SRMs and third party lab data, just a way of  
7 telling you that this is not something we haven't done  
8 before, and that we do have mechanisms in place for  
9 dealing with non-FSIS data.

10           Just to highlight very briefly some of the  
11 themes from the breakouts, I was very happy to hear  
12 that we were not confined to simply industry data,  
13 which, of course, is one of the goals and reasons for  
14 calling it using data from other source or non-FSIS  
15 data, and the other thing that we heard is it's not  
16 only in-plant testing data which is kind of where we  
17 might naturally focus, but pre-harvest testing for  
18 example, the use of audit scores which I don't think  
19 we've had a lot of discussion about was also a good  
20 suggestion.

21           Also another theme that came out in keeping  
22 with an earlier theme was the interest on

1 stakeholders' part to not only be involved in our  
2 ongoing data analysis, but also to see that data that  
3 we currently have, the analysis that we've done to  
4 date, and to have a chance to look at that and maybe  
5 even see the data warehouse dashboard that we use and  
6 how we manage that data infrastructure that we have.

7           We have heard now for at least three and a  
8 half years, and probably longer, the very significant  
9 concerns of FOIA and the regulatory consequences of  
10 the industry in particular submitting data. Those are  
11 issues we definitely will have to grapple with and  
12 resolve in order to move this forward.

13           The idea of the third party repository is  
14 not new. I think there is already some creative  
15 thinking within Agency certainly and we can have that  
16 discussion about how we might use a third party and  
17 meet some of the concerns on the part of the industry.

18           The issue of using aggregate data versus  
19 plant specific data is a very important discussion.  
20 The Agency has an interest in aggregate data for lots  
21 of reasons apart from RBI but when it comes to RBI and  
22 creating a score, we do have an interest in plant

1 specific data. So we have to work through that as  
2 well.

3           So I think that that is my summary of this  
4 meeting. I did want to answer a little bit Carol  
5 Tucker-Foreman's comment from very early on and  
6 reiterate I think a theme that we've tried to repeat  
7 at every meeting. I do believe we have the data to  
8 begin the prototype implementation, and that we have  
9 been conducting data analysis. We know how to do  
10 that, and therefore we have a basis for moving  
11 forward.

12           As I mentioned earlier, when I was talking  
13 about Carol's piece, the analysis of the early results  
14 in those prototype locations and our evaluation of  
15 those results will be a critical activity for our  
16 Agency in deciding whether to move beyond the  
17 prototype locations. So I just want to reiterate  
18 that.

19           Finally, as was mentioned by Robert early  
20 on, we have a little bit of a hiatus here in terms of  
21 our public meetings. We're still working on the date  
22 for the next summit which will be on the results of

1 the ongoing second expert elicitation which is  
2 underway right now. We will keep you informed through  
3 our usual mechanisms and so you'll know exactly when  
4 we've made that decision about a date for that  
5 meeting.

6 And finally to reiterate again, Robert's  
7 comment earlier, please send us your comments on this  
8 meeting, on any other meeting that we've already  
9 posted in the past so that we can consider your  
10 comments and, as Robert pointed out, we're coming up  
11 with a mechanism for actually having a response to  
12 your comments and getting them to the appropriate  
13 people for response. So please continue to do that.

14 With that, I will end unless there are any  
15 last comments in the room from any of the  
16 participants. Anyone?

17 (No response.)

18 DR. GOLDMAN: And again, I just want to  
19 thank you for coming. Dr. Raymond, do you want to --

20 DR. RAYMOND: I do just want to thank  
21 everybody in the room and on the phone for  
22 participating with us in this marathon of public

1 meetings which I think have been extremely helpful to  
2 the Agency and to each one of you to better understand  
3 what we're doing. I want to thank this panel today  
4 for their expertise, and I apologize for not getting  
5 to hear it. We had a little problem with the Melamine  
6 and the pork feed that we're still working through.

7           So I give you Loren Lange, to get the last  
8 word in today, a famous author once said, ideas are  
9 just like rabbits. If you get a couple of them, and  
10 take good care of them, pretty quick you've got a  
11 dozen. And we got a lot of ideas out of these  
12 meetings, and we'll try to take good care of them and  
13 maybe they'll multiply even further and further, and  
14 we'll continue to get ideas.

15           So once again, thank you for all your  
16 participation today and the previous meetings. We'll  
17 see you in June sometime.

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

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C E R T I F I C A T E

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USING DATA FROM OTHER SOURCES

Arlington, Virginia

April 30, 2007

were held as herein appears, and that this is the  
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ANDY VOGEL, Reporter

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