

UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

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PLENARY SESSION

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February 6, 2008

8:15 a.m.

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

2 (8:15 a.m.)

3 MR. TYNAN: Good morning. We could take
4 our seats so we can start our deliberations for this
5 morning.

6 We're waiting for Dr. Raymond. We checked
7 with his office. He is not going to be able to
8 attend this morning. So he'll probably be with us
9 after lunch for the later deliberations.

10 Yesterday we did the public health risk-
11 based inspection related to processing and other
12 slaughter activities. Today we're going to talk a
13 little bit about poultry, but before we get into the
14 agenda itself, I was going to turn it over to
15 Mr. Almanza, and maybe he can get us started off.

16 MR. ALMANZA: Well, good morning,
17 everybody. I'm sorry I had to leave yesterday. I
18 had to go to a meeting up on the Hill. I'm sure some
19 of you understand what that's like, and I missed part
20 of it, but I understand that you all had a lot of
21 good discussion, a lot of good stuff to talk about,
22 and about the public health inspection system or

1 risk-based inspection system, and I want to continue
2 that.

3 The one thing that I will ask is that we
4 continue this discussion as it relates to poultry
5 slaughter today. And everybody's speaking about the
6 rule, but we're not here today to talk about the
7 rule. We need to continue to focus on this
8 particular concept and how to make it better.

9 I know that we've learned a lot over the
10 years about HIMP and we've tried to build in the
11 positive attributes into our new thinking. So using
12 our resources to verify process control at vulnerable
13 points makes more sense for protecting our public
14 health.

15 So we also have a component to address,
16 performance standards in our system that we'll be
17 discussing this morning, and then we'll just move
18 forward but I do or we did hear a lot of things that
19 we expected to hear. We also heard some things that
20 were a bit surprising but nonetheless we need to
21 continue that. We need to continue the discussion
22 and get everybody's perspective and understanding

1 because this is how we're going to move forward. So
2 we need to continue the dialogue.

3 And so rather than listen to me, again I'm
4 going to have to leave for another meeting, as I've
5 come to learn that in this position, meetings which
6 were always one of my favorite things, I get to enjoy
7 them even more now. So I will get the information
8 that you all are talking about and the discussion,
9 and I'll turn it back over to Robert to go ahead.

10 MR. TYNAN: That's why they're paying you
11 all these big bucks so that you can go to these
12 meetings.

13 With that, I'm going to start into the
14 agenda. I think we have an ambitious agenda as we
15 did yesterday. I anticipate that it will be going
16 pretty much the full day. We again have a closing
17 time of approximately 5:00, and we'll get as much in,
18 in that time as we possibly can.

19 The first speaker for this morning, to give
20 us a little bit of an overview of the concept on risk
21 public health risk-based inspection in poultry
22 slaughter is Dr. Carol Maczka, and I'm going to turn

1 it over to her, and let her begin the presentation.

2 DR. MACZKA: I'd like to, like Mr. Almanza,
3 our Administrator, thank you for the comments we
4 received thus far, and thank you for all your hard
5 work.

6 Today we're going to talk about the public
7 health risk-based inspection for poultry slaughter,
8 and what you're going to see is we're proposing to
9 use the same approach that we spoke about yesterday.
10 So we're going to use the same algorithm to allocate
11 inspection activities across plants. We're going to
12 use the same approach to focus inspection activities
13 at vulnerable points. So it's exactly the same
14 approach.

15 Drs. Dreyling and Arrington will describe
16 how the system will be prompted to focus inspection
17 activities at the vulnerable points. And similar to
18 what Dr. Arnold did yesterday, Dr. Arrington will
19 also describe a case study, and in that case study,
20 she will try to demonstrate how the proposed system
21 would have prevented problems.

22 Dr. Travis is going to apply the algorithm

1 across poultry establishments. He's going to apply
2 it to a set of data, and this was discussed in our
3 reports, but he'll go over that analysis. And if you
4 think about it, Felicia Nestor actually recommended
5 that we do need to test the algorithm. So this is
6 our opportunity to show you how it tested out.

7 Ms. Kause is going to describe how the risk
8 assessment supports our approach, and Dr. Catlin will
9 describe how performance standards will be used in
10 the proposed system.

11 So like yesterday, we're interested in your
12 comments but because we are using the same approach,
13 some of the comments you made yesterday will also
14 apply to what you're hearing today.

15 And we've already begun discussing some of
16 your comments. We heard yesterday about attribution,
17 your comments on attribution and volume. We heard
18 that you wanted us to bring the issue to CDC, to
19 perhaps discuss it with the Advisory Committee for
20 Microbiological Criteria. We're also thinking of
21 bringing certain target questions to the National
22 Academy of Sciences.

1 We heard your comments about volume, to
2 distinguish between product that is further processed
3 versus that which is shipped. And I've begun already
4 speaking to Dr. Engeljohn about trying to collect
5 this type of data.

6 In terms of NRs, we heard you say use the
7 NRs, try 30 days as a starting point. Somebody else
8 threw out 90 days. But apply it against a set of
9 data and we do intend to do that also.

10 We heard test the prompt questions and as
11 Bill Smith said yesterday, we are planning, use a
12 testing for these prompt questions.

13 One of the things we wanted to continue to
14 do is work with the Data Subcommittee as we revise
15 the reports in response to the issues that we'll
16 raise today. And so we hope to continue that
17 dialogue. For example, one of the things we
18 discussed last night was, in terms of attribution,
19 one of the questions we had and would like some
20 further clarification on is whether or not we should
21 use the numbers we've generated so far. The
22 advantages to doing that would allow us to

1 distinguish between products and not treat them all
2 equally. So why should we treat a steak the same way
3 we would treat ground chicken or ground beef? By
4 using the numbers we have so far, we could
5 distinguish between these in terms of a relative risk
6 ranking. So these are some of the things we will
7 take up further with the Data Subcommittee as we move
8 forward.

9 But right now, I'd like to introduce or
10 hand it over to Drs. Dreyling and Arrington, and so.

11 DR. DREYLING: Thank you, Carol, and good
12 morning to everyone. Let's get our slide
13 presentation up.

14 This morning I want to go through a brief
15 overview of the within establishment public health
16 risk-based inspection system, specifically for
17 poultry slaughter, and for those of you who were here
18 yesterday, I did give a similar overview but I want
19 to go through that for anyone that's new in the
20 audience today.

21 And then following this overview,
22 Dr. Arrington will go over how one of the prompt

1 examples would work, specifically for poultry
2 slaughter, and then she will also go through a case
3 study with you of problems we have had for poultry
4 slaughter in the past and how she feels that we feel
5 that the new system would address these problems that
6 we've experienced.

7 So as we spoke yesterday, the new Public
8 Health Inspection System for within establishments is
9 intended to focus inspection activities on the
10 vulnerable points within a poultry slaughter
11 establishment. And when we're talking about a
12 vulnerable point, what we're talking about is a point
13 that is most vulnerable to microbial contamination or
14 growth if process control is not maintained.

15 So how will the system be implemented? The
16 inspector will carry out their existing inspection
17 activities, such as those that relate to HACCP and
18 SSOPs and SPSs, and when they're prompted by the new
19 Public Health Information System, they will answer
20 questions regarding vulnerable points within the
21 poultry slaughter establishment.

22 And I want to point out here that the

1 Public Health Information System will be monitoring
2 the results of infection activities, and the system
3 will carry out the prompts. We have identified
4 specific prompts for poultry slaughter that are
5 related to public health and the system will monitor
6 these. These will be past inspection activities, NRs
7 that are recorded. It could be a series of NRs being
8 recorded. It could be a change of profile
9 information. These are the things that will prompt
10 an inspector through the new Public Health
11 Information System to carry out a directed procedure
12 at which he or she will look at vulnerable points
13 within the poultry slaughter establishment and answer
14 questions that are specific to those vulnerable
15 points.

16 It is intended that the observations that
17 the inspectors make in aggregate at these vulnerable
18 points will help them decide whether or not there is
19 a noncompliance, and therefore issue a NR if it is
20 appropriate. But it is not intended that they will
21 issue a NR for a single observation. It's supposed
22 to be an aggregate of your observations.

1 I also want to point out that we will be
2 developing compliance guidelines for industry that
3 will help them to understand better what inspectors
4 are looking for at these vulnerable points, and we
5 will post these compliance guidelines on the web for
6 comment, and we will revise them accordingly with the
7 input that we get and also as has been pointed out
8 throughout this meeting, the proposed system will
9 require a lot of training for our inspectors and we
10 are working already to develop that training.

11 This diagram just gives you an idea of how
12 the proposed within establishment system will work in
13 the new Public Health Information System. As I just
14 said, the inspector will perform their routine
15 activities within the establishment and if
16 noncompliance is found as part of their routine
17 activities, they will document the NR and verify that
18 corrective actions are taken.

19 The NR will be recorded in the Public
20 Health Information System and the system will be
21 monitoring and will be looking for specific public
22 health prompts, and this is a single NR. It could be

1 a combination of NRs or repetitive NR or profile
2 information. And then if it is applicable, the
3 system will generate a for cause procedure at which
4 the inspector will then look at the vulnerable points
5 and answer questions regarding those vulnerable
6 points. And then when it is applicable and when it
7 is appropriate, they would issue a NR or that they
8 will -- and they will be gaining more information
9 that could be used later for enforcement if
10 necessary.

11 And I want to point out, Dr. Travis will be
12 going into our algorithm in which he'll be talking
13 about the different levels of inspection, and it is
14 intended that if you are in one of the higher levels
15 of inspections, so our Level 2 or our Level 3. These
16 are establishments in which we have reason to believe
17 that process control is not being maintained. We
18 will on some routine frequency have directed
19 procedures in which the inspector will go and look at
20 vulnerable points and answer questions and there will
21 not be a prompt involved. We want to look at the
22 vulnerable points in those establishments on a

1 routine frequency because we believe there are the
2 points that are most vulnerable and most related to
3 public health.

4 I do want to give you an idea that this
5 system, the proposed system was developed based upon
6 the scientific literature and Agency experiences with
7 HACCP and contamination events. We used the
8 literature to identify the vulnerable points within
9 poultry slaughter establishments, and we had a panel
10 of FSIS experts which consisted of people from the
11 field, policy people and also people from our
12 training, and they helped us to determine what the
13 prompts would be that were specific for each of the
14 HACCP categories, specifically today for poultry
15 slaughter, and they also helped us to determine the
16 questions that inspectors should be answering at
17 these vulnerable points to determine if process
18 control is being maintained.

19 I want to go through that we do believe
20 there are many benefits, and I think that
21 Dr. Arrington's presentation is going to help you to
22 understand these benefits specific to poultry

1 slaughter. The proposed system is focusing on the
2 identification of vulnerable points within the
3 overall food safety system, and we believe that this
4 system will help our inspectors to verify the
5 execution of the decisions that have been made by the
6 establishment in their hazard analysis such as their
7 prerequisite programs. They'll not only be looking
8 to see if they have the prerequisite program, but to
9 also make sure that they are carrying out the
10 decisions that they've made.

11 We believe that the new system will help
12 our inspectors to better link and respond to
13 noncompliances and we also believe that the system is
14 improved because it will have automatic monitoring of
15 our inspection results, and will be looking for
16 anomalies. So the system will be looking for
17 specific public health related NRs or combinations of
18 NRs and it will be prompting inspectors to respond to
19 these findings.

20 And with that, I'd like to turn it over to
21 Dr. Arrington, and she's going to walk through one of
22 the poultry slaughter prompt examples so you can

1 understand how this would play out.

2 DR. ARRINGTON: Okay. Thank you very much,
3 Erin. And what I'd like to do is just back it up one
4 slide to remind us what I'm going to be talking about
5 is where it says the box almost at the bottom, that
6 says the inspector will record answers to questions
7 about vulnerable points. So I'm going to be giving
8 an example of where the inspector is getting the
9 prompt, an example of the prompt, gets the prompt,
10 what are the questions, examples of the questions
11 they might be asking themselves, and then something
12 about how we will use that in our in-plant
13 inspection.

14 So first of all is what we're calling the
15 description and the threshold. The description means
16 what is the prompt description, what is it? And, in
17 this example, and this is just one of several
18 prompts, we are using the one where the establishment
19 has exceeded half the standard for their *Salmonella*
20 or other microtesting such as *Campylobacter* and
21 Generic *E. coli*, and we set a threshold that is based
22 on the frequency. In some cases, if it's repetitive

1 NRs, that would happen to occur more than once or it
2 may be that there's a NR for say an SSOP, and that's
3 occurred three different times in a week, that might
4 be the prompt, or it may be one finding such as the
5 *Salmonella* has exceeded half the standard.

6 So, again, with the variety or combination
7 of information that would lead to the prompt for
8 cause, and then as Erin said, if it's in the
9 situation where we're in Level 2 or Level 3 of
10 inspection, then they would be directed and would not
11 necessarily need these prompts in order for that to
12 take place, in order to go to the vulnerable points
13 inspection.

14 So, in this example, in poultry slaughter,
15 from our literature review, we did identify that
16 scalding, evisceration including on line reprocessing
17 and chilling were the vulnerable points. And, as you
18 know, we are taking or we would like to receive any
19 comments about whether those should be the vulnerable
20 points or whether there should be other ones and we
21 would like to receive that, you know, today, not
22 today, we would like to receive that.

1 This also is supporting our OIG Principle 1
2 where we simply use scientific information to help us
3 to develop policies that are based on risk and
4 inspections based on risk.

5 Now we'll move to one of those vulnerable
6 points, and that's scalding. And here is several
7 questions that the inspectors would answer, and the
8 example I'm going to use is the middle one, does the
9 establishment have controls to maintenance water
10 temperature effective to reduce microorganisms?

11 This would be at the CSI and the IIC level,
12 and we will have guidance and training in place for
13 the inspector to know how to answer that question.
14 In other words, what the inspector might see that
15 would make them say, yes, they do, or what might make
16 the inspector observe that the inspector would say,
17 no, they do not have control. And again, as we
18 mentioned, having just one of those where we might
19 say they don't have control, would not necessarily
20 mean a NR. Just as we know plants have many
21 different ways of feeding process control in their
22 plants, then that's why this would not necessarily

1 just be one thing and it would not be -- we're trying
2 to word those in a way that talks about general
3 process controls so that you can take a particular
4 situation and see whether or not it fits under that
5 as opposed to say we must have a certain kind of
6 water temperature control, you must have a certain
7 prerequisite program.

8 Another one is the evisceration/online
9 reprocessing questions, and again these are several
10 questions that would be answered by the inspector as
11 yes or no or needing additional information in order
12 to answer that question, and again we would expect
13 that we will have the guidance and issuances to
14 support inspectors on how to make these decisions
15 and, of course, they will always have the support of
16 their IIC, the District Offices and Headquarters.

17 For chilling, again these are a series of
18 questions, examples of what we'll want to have
19 inspectors to answer.

20 And then finally we're on the potential
21 regulatory citations, and as we said, we understand
22 that establishments have many different ways of

1 having their food safety system and process control,
2 and so in aggregate, it really relates back to
3 process control. And, as you know, generally
4 speaking, process control is not determined by one
5 event or one incident but is when there's multiple
6 incidents that taken together give enough information
7 and enough support to say that this is out of control
8 or this is in control. And some examples of many of
9 them in poultry slaughter will relate back to
10 sanitary dressing, sanitary conditions. They may
11 also relate to the hazard analysis, and that might be
12 where a plant would say that something about
13 *Salmonella* is controlled by a prerequisite program
14 and therefore it's not a CCP. We might expect to see
15 a prerequisite program on that. And again, the in-
16 plant inspector would be looking at how that's
17 executed.

18 Okay. Next, I'm going to move to the case
19 study. In the case study, just to give a little
20 background, this was a large poultry slaughtering and
21 process establishment. Over a period of seven or
22 eight months, there were numerous human illnesses

1 that were caused by a *Salmonella* serotype, that's on
2 the CDC list that is implicated in human illness, and
3 the people that were sick did have the serotype.
4 Some of these people had consumed chicken directly
5 from the establishment. There was overall sufficient
6 epidemiological information to link the illnesses in
7 the humans in the seven states to the plant product.

8 In fact, one of the people that was ill
9 worked at the broiler facility, the grow out, that
10 supplied the slaughter plant, and again, it was the
11 same serotype.

12 The establishment had also conducted its
13 own *Salmonella* data and had been finding a greater
14 than 25 percent rate of *Salmonella*. As you know,
15 this is exceeding the standard that we have in our
16 regulations for *Salmonella* verification, and they
17 also knew that they had that serotype. They had even
18 subtyped it to know that it was that serotype, and
19 yet they really hadn't taken any action and
20 inspection hadn't really taken any action until we
21 really started looking at the human illnesses.

22 So in this case, there were problems with

1 the hazard analysis decisions and support. For
2 example, interventions in the chiller and the final
3 wash were not even identified in the hazard analysis.
4 So it didn't show up in the hazard analysis. They
5 did not have validation of those, of course, and they
6 did not have their conditions of use specified. They
7 had water reuse in the chiller and from the final
8 wash and sent that to the scalding. That was not
9 addressed in their hazard analysis. Water reuse can
10 be a multiplying source of *Salmonella*. They did not
11 adjust their equipment properly for changing bird
12 size. They had excessive fecal contamination that
13 was due to the equipment. They had many things and
14 relating back to the hazard analysis decisions and
15 support.

16 They also had repetitive NRs on the
17 critical limit deviation for required chilling
18 temperature. So they each time would carry out some
19 corrective actions, but they apparently were not
20 effective because there were repeated NRs. And when
21 you are exceeding your chilling temperature, we're
22 setting up the situation where you might have allowed

1 growth of *Salmonella*.

2 Finally, they weren't responding to their
3 own data. They had the two years of data showing
4 that it was failing the standard and the presence of
5 the serotype that was known to cause human illness.

6 So with our new system, with what we're
7 talking about with vulnerable points, we believe that
8 we will be helping to correct or to prevent some of
9 the things that happened in this particular case
10 study.

11 So, for example, when we say we'll focus on
12 the identification of vulnerabilities in the overall
13 food safety system, we would have expected from those
14 NRS that the inspector would have been prompted to
15 look at the vulnerable points, to look at the
16 controls that were in place, and in this case,
17 sanitary dressing may have come up very quickly if
18 they had systematically gone through the vulnerable
19 points and may have resulted in them looking more
20 fully at this and having additional NRS.

21 Under number 2, helping inspection to
22 verify the execution of the decisions made in the

1 hazard analysis, including responding to plant data
2 and prerequisite programs. Again, there may have
3 been a prompt that would have come up, the inspector
4 would have gone and observed those vulnerable points,
5 and then prompted to look at controls and to answer
6 those questions and that would have guided them to go
7 to the hazard analysis to see such basic things as
8 are all the STEPS and the process included in the
9 hazard analysis. And again, this is at a level where
10 we think CSI should be able to do that kind of work.

11 They could have seen at that point that the
12 interventions on the chiller and in the final wash
13 were not even mentioned in the hazard analysis.

14 The third one, on bolstering inspection to
15 link and respond to NRs, again the vulnerable points
16 would help the inspectors to guide them to recognize
17 that there is a potential linkage not only between
18 the repetitive NRs on the chilling but also on the
19 other things that they were finding at the other
20 vulnerable points. For example, that there was
21 successive fecal contamination deposits. The
22 equipment was making cuts that shouldn't have been

1 made because they were not adjusted to the bird size.

2 And finally, the automated monitoring of
3 the inspection results and the built-in alerts of
4 anomalies, that would have come back to the inspector
5 as an alert, and that would have helped them to
6 respond to the in-plant data for example.

7 And that's the end of my presentation.
8 Thank you.

9 MR. TYNAN: Before I'm even up here, I have
10 tent cards up. I'm going to start, just go right to
11 left. I don't know who started out first, but we'll
12 get all the questions in. These are questions to
13 clarify, and we will have another opportunity as I
14 mentioned on the agenda to come back and have a full,
15 a more full discussion after you've heard all the
16 presentations. So with that, I'm going to start with
17 Mr. Kowalcyk.

18 MR. KOWALCYK: Thank you. A couple of
19 questions. One about the overall paper about the
20 within plant allocation of resources at critical
21 points. What consideration has the Agency put
22 towards line speed? It seems like through a lot of

1 these critical points, there's a lot of, an example
2 was the microbial rinses is dependent on water
3 temperature, pressure, nozzle type and arrangement.
4 I would think that the speed of which the carcasses
5 are going through that process would have some
6 relationship and that seems to be also something that
7 a plant could control if they showed a loss of
8 control of anyone of those processes.

9 And then my next follow-up question is in
10 response to the questions that are positioned as
11 yes/no, an example was chiller temperature, you know,
12 whether or not an establishment has controls,
13 established controls, that can be documented and,
14 yes, they have documented process. Would you also in
15 this system require the inspector there to verify
16 that that control is actually within its limits? So
17 a plant has certain control related to chiller
18 temperature, well, yes, they do but would you also
19 want to require, and I would argue that you would,
20 want to require the inspector there to verify that,
21 actually that's easily quantifiable, take a reading
22 of temperature in the chiller. Is it within the

1 critical limit? Are those considerations that you've
2 made in your studies?

3 DR. ARRINGTON: Yeah, to go back to
4 considerations about line speed, we would expect that
5 when we look at the vulnerable points, at whatever
6 line speed a plant is running at, they need to have
7 them in control. And so in that way we have
8 considered line speeds. For the conditions of use,
9 it might be one where we would need additional
10 information to verify whether the time is sufficient
11 for the antimicrobial to have taken place. And
12 again, in plants that have interventions, we expect
13 them to have them validated which would include some
14 in-plant studies where they would show that their
15 intervention is effective and would show what kind of
16 conditions of use that they have to use in their
17 plant in order to have it effective.

18 On the second question about verifying, and
19 we should have brought this out, there are several
20 ways to verify, that FSIS verifies. One of them,
21 which I think you were speaking to, is what we might
22 call a hands-on task, where we might actually take

1 the temperature, where we might actually temperature
2 a bird, the water or whatever. There are also record
3 reviews and there is also review of observation of
4 plant employees. Are they carrying out their
5 procedures? All of those would apply. So we would
6 not necessarily do a hands-on task for every one of
7 these.

8 Also we will have to take into
9 consideration how the plant has decided to do their
10 process control. How are they going to do it?
11 Perhaps for them, the bird temperature of the water
12 -- I mean the water temperature is not as important
13 as something else they're doing, and so in their
14 case, we would be looking more at those other things.
15 Does that make sense to you, that last part I said?

16 I mean, we do have to tailor this to what a
17 plant's doing as well as having these general
18 questions.

19 MR. KOWALCYK: Right, I do want to caution
20 the Agency that having a system where you have a
21 series of positive answers to these simply yes/no
22 questions, where there is a no that would lead

1 somebody to look further, they didn't have an
2 established process, but even if there is a yes
3 answer, I would hope that the Agency would, if a
4 problem continues to occur, if test results are
5 showing that there's something that's out of control,
6 yes, there is a process, well, that may need to be
7 verified independently by the inspector or somebody
8 else from the Agency.

9 DR. ARRINGTON: Yeah.

10 MR. KOWALCYK: That's a provision that I
11 think should be allowed for in this process.

12 DR. ARRINGTON: And what we're trying to do
13 overall is to always read the relay back to what a
14 plant lays out for FSIS for how they will have a plan
15 that has a food safety system that produces safe
16 product. So, if they say in their hazard analysis
17 that they're going to do certain things, we want to
18 verify that they're doing those certain things, if
19 they are not doing those certain things, then they no
20 longer have data, their own data to support why they
21 made the decisions they made in the hazard analysis
22 and as you know, not supporting your hazard analysis

1 could possibly ultimately end up in being an
2 inadequate HACCP plan which is where we're talking
3 about enforcement such as NLIE or suspension. So
4 that's our prior overall goal is to -- we don't want
5 to dictate to plants how to do it, but if they're
6 doing it, they need to be supporting the decisions
7 they make.

8 MR. TYNAN: Isabel, I think Dr. Maczka has
9 a comment to make.

10 DR. MACZKA: Just a point of clarification.
11 We will be documenting line speed, and we will be, in
12 addition to recording yes and no answers, not enough
13 information also.

14 MR. TYNAN: Okay. And, Michael, we'll come
15 back if you have some follow-ups. Dr. Rybolt.

16 DR. RYBOLT: Thanks, Robert. A couple of
17 questions. One is how will NR appeals factor into
18 this, you know, an inspector writes a NR and then he
19 gets a prompt. I think we talked yesterday a little
20 bit a timeframe before the prompts are given or
21 follow up, but how the NRs are built into this? And
22 then the second question, in regards to the questions

1 that the inspector will as, Isabel, you indicated
2 that there will be some guidance material available
3 to the inspectors on how to address it, but will
4 there be included in that, I guess we haven't seen
5 that, but will it be included in that, you know, I
6 think on of the questions for chiller is that the
7 inspector or does the establishment adequately
8 control pH in the chiller but in some situations, the
9 plant may not necessarily need to control pH. So is
10 that included in that material for the inspector?

11 DR. ARRINGTON: Yes, that kind of
12 information has to be included in that material
13 because as I mentioned a minute ago, we're not going
14 to be setting specific standards at each step. Just
15 at this meeting, for example, someone mentioned to me
16 there's some new technology that might help with
17 picking. If that comes about, then that will change
18 how we look at vulnerable points and so forth, it
19 could have an impact on that.

20 And then back to your NR, we will need
21 input on exactly how they handle it when they're
22 appealed. We mentioned we know it's something but we

1 haven't really worked on that fully as to how that
2 would work but any concerns you have about or how it
3 should be, in other words, if there was an appeal of
4 a NR, how should that be handled, we'd like to hear
5 what you think about that.

6 DR. RYBOLT: Just a follow-up back on the
7 questions that the inspector will answer. Is there a
8 mechanism available or is this something that the
9 inspector will visit with the plant on asking these
10 questions so that if there is disagreement on whether
11 or not they have systems in place, they can see the
12 food safety systems obviously, but is there a
13 mechanism in place for the establishment to appeal
14 their answer to the questions if you will?

15 DR. ARRINGTON: Yes, we would expect that,
16 and that is in the realm of additional things that we
17 need to lay out, how we will go about doing that, but
18 we do know that that's certainly something that we
19 have to be considering. Just, for example, having
20 weekly meetings and having the memorandum of
21 interview, those sort of things, that might be the
22 mechanism for things that are not as clear to

1 inspection as to the plant or vice versa, and that's
2 another -- I'm glad you're bringing that up because
3 that is something else we'll need in the guidance on
4 how we will --

5 MR. TYNAN: Isabel, I think Mr. Smith has a
6 follow-up comment to that.

7 DR. ARRINGTON: Okay.

8 MR. SMITH: Well, we always have an appeal
9 process and it would be immediate based on the facts
10 and the people at the plant can make a decision based
11 on if you have a set of facts, encounter those facts
12 and so that can be reconsidered. So that would be an
13 immediate and then you can always go to the next
14 level of supervision, just like any inspection
15 decision, and have a timely response on that.

16 MR. TYNAN: Okay. If you have another
17 follow-up question, we'll catch it on the next go
18 around. Dr. Harris.

19 DR. HARRIS: Thanks, and I know we're going
20 to get more opportunity, so in the interest of time
21 and all the cards I see, I will limit it to only one
22 question for now. We'll do the rest later.

1 On slide number 9, the third question says,
2 is the establishment implementing prerequisite
3 programs at scalding, as per their hazard analysis?
4 Is there adequate supporting documentation? Is that
5 not outside the realm of what we have traditionally
6 expected in-plant inspectors? We've been told for
7 years that that was the purview of the EIAOs, was to
8 determine adequacy and design of systems.

9 DR. ARRINGTON: Okay. We'll take that as
10 information providing us.

11 MR. TYNAN: Okay. We can revisit that
12 question again in the roundtable. Mr. Covington.

13 MR. COVINGTON: Thank you. I think to
14 follow on Dr. Harris' question, in the case studies
15 that we've been presented the last two days, I think
16 these are probably examples that are not of the
17 mainstream plant. I mean there are some excessive
18 violations here that are obvious that the decisions
19 the Agency would need to make. My question is how
20 will the Agency determine those aggregate answers?
21 Where's the breaking point there, and I guess a lot
22 of that would come with the guidelines in the

1 training material in order to answer these questions
2 and determine if process control is in place? In
3 particular, one, if a fecal contamination is
4 observed, how many of these questions would have to
5 be answered with no before you determine that, you
6 know, another regulatory citation needs to be issued?
7 Thank you.

8 DR. ARRINGTON: Yeah. Yes, on how many of
9 them would need to be answered no, I think we will
10 have to have guidance on that, and we are going to
11 have to have more discussion within the Agency about
12 where that breakpoint is. I think of it to some
13 degree about sanitary dressing, for example. When is
14 the process out of control for that?

15 But to answer your question, yes, we need
16 to work on -- I don't know if we'll actually come up
17 with a number or what, but we definitely need very
18 good guidance on how to do that.

19 MR. TYNAN: Dr. Henry.

20 DR. HENRY: Thank you, Robert. Relative to
21 the particular case study, Isabel, that you provided,
22 obviously public health is the issue, a question.

1 When was the last FSA conducted at this facility?
2 You referenced eight months worth of records and
3 based on that FSA, were there enforcement actions
4 taken prior to the terminal event which led to the
5 foodborne illness? Thank you.

6 DR. ARRINGTON: I don't know if there were
7 prior. There was a FSA during the time of the
8 illnesses, and that's where a lot of this information
9 was uncovered.

10 MR. TYNAN: Mr. Smith, you had a follow up
11 on that.

12 MR. SMITH: The particular history on that
13 particular case was there was not a FSA prior to the
14 event.

15 DR. ARRINGTON: Okay. Not --

16 MR. SMITH: It was during the -- as a
17 result of the outbreak is when the FSA was done.
18 There was not one done prior to that.

19 DR. HENRY: So that speaks to the
20 credibility and value certainly of the FSA going
21 forward as to when they would be done in order to set
22 the baseline. And just one last follow-up question,

1 did that plant have any indication from the
2 inspection staff or anyone else as to the serotypes
3 of concern that should have been addressed in their
4 program prior to the event?

5 DR. ARRINGTON: I don't know that they did
6 but do you know?

7 DR. HENRY: Therefore, the serotype that
8 was brought to bear as a result of the illness is a
9 little bit after the fact.

10 DR. ARRINGTON: I'm not sure what you mean
11 by that.

12 DR. HENRY: Well, you can't prevent which
13 you don't know about.

14 DR. ARRINGTON: Oh, you mean whether the
15 plant knew they had the serotype?

16 DR. HENRY: Right. I mean if you --

17 DR. ARRINGTON: It was sort of my
18 understanding that they did know they had it.

19 DR. HENRY: But I mean that's not the
20 question. The point is there's lots of serotypes.
21 The question is if you're trying to develop an
22 intervention that's effective against given

1 *Salmonella* or in this case, the serotype in question,
2 you need to know about it in advance. So, you know,
3 was there any communication between the Agency
4 knowing that information at least in this plant
5 because obviously the testing was just not real
6 current, and had to have been going over time. So,
7 you know, you need to know in advance. So that's the
8 question, you know, did the Agency have any
9 information conveyed to the plant or plants in
10 general regarding concern for a particular serotype
11 such as the one in question?

12 DR. ARRINGTON: I don't think at that time.
13 At the same time, when you're exceeding 25 percent in
14 your own testing, even without the serotype.

15 DR. HENRY: It seems as though enforcement
16 is in question.

17 MR. TYNAN: Okay. We can have a further
18 discussion of that as the larger issue.
19 Mr. Elfering.

20 MR. ELFERING: Thank you. This is Kevin
21 Elfering. Your scenario begs a lot of other
22 questions, and I think that's one of the things that

1 we always have to look at when we look at a risk-
2 based inspection system, is looking at cause and
3 effect. You talk about an employee that became ill
4 that worked on the farm. Were they ever tested as
5 being a shedder? Did they prepare any food? And
6 there's a lot of things involved in all this where we
7 really have to determine what cause caused the
8 illnesses.

9 And I think that's one of the things that I
10 look about at some of these is you already have a
11 situation where you have multiple NRs. You have a
12 plant that has two years of data showing that they're
13 failing in the *Salmonella* performance standards.
14 What is this prompting going to do? I mean there
15 should have been something done in this plant way
16 before. What is a little checklist of questions
17 going to do to improve food safety that's not already
18 been done or should have been done? And this doesn't
19 look any different than the old decision tree that
20 used to be used for writing PDRs or the way custom
21 exempt facilities are inspected.

22 So I don't see how this is going to improve

1 if you don't have an inspector who's taking charge in
2 the plant or at least turning it over to a
3 supervisor. I don't see how a little prompting
4 checklist is going to do anything. I mean how is
5 that going to improve what wasn't done in this plant
6 already.

7 DR. ARRINGTON: Well, if -- go ahead.

8 MR. TYNAN: Excuse me. I was going to let
9 Mr. Smith, I think he was -- I saw his button -- his
10 finger on the button. So --

11 MR. SMITH: You're right about what you've
12 said about the history associated with this
13 particular scenario, and that's why we're saying the
14 other day, we do have automated checks now. We do
15 have in the system that will alert people. So there
16 is a lot of data that has to be mined by the in-plant
17 people as well as the supervisors, and in this case,
18 when the system is doing it and sending up flags,
19 they're sending back to people. This needs to be
20 looked at. And it's also sent to supervisors. It's
21 also sent to the District. It could also be sent
22 into Headquarters, that these anomalies are going off

1 and so you just can't, one, you have the information
2 analyzed for you and then, two, making sure there's
3 follow up. So that's the difference here.

4 MR. TYNAN: Mr. Schad, your turn.

5 MR. SCHAD: Thanks, Robert. I have the
6 same concern that Joe did. I just kept my tent card
7 up because I just wanted to back that up or ditto
8 that because it was my understanding and has always
9 been my understanding, that in-plant inspectors in
10 general do not have the training to evaluate a hazard
11 analysis, and I think that would really cause
12 problems out in the field. Thank you.

13 MR. TYNAN: I'm getting direction. I think
14 Mr. Smith has some additional comments.

15 MR. SMITH: These are all very, very valid
16 points but our Ph.V.'s are the IICs in these plants.
17 They're our most highly trained and educated folks.
18 They have also been going through the EIAO training.
19 So the thought process there, they can put in direct
20 applicability in these type situations, and also in a
21 lot of these questions, it would be whether they have
22 data or not, if inspectors need support in making an

1 adequate determination and they have the resources at
2 the Agency to ask questions, but a lot of it will be,
3 is there something there or not, and that's different
4 than making an adequacy determination.

5 In this scenario that Isabel brought up,
6 though we do again have our most highly trained
7 people there on the spot to assess those things.

8 MR. TYNAN: Mr. Painter, before I come to
9 you, I'm going to ask Mrs. Foreman, a member of the
10 Committee to -- I think she has some questions as
11 well. Mrs. Foreman, are you on the line?

12 MS. TUCKER-FOREMAN: Yes. Can you hear me?

13 MR. TYNAN: Carol?

14 MS. TUCKER-FOREMAN: Can you hear me?

15 MR. TYNAN: Yes, we sure can now.

16 MS. TUCKER-FOREMAN: Sorry. I was chatting
17 away with mute on and I'm -- this morning.

18 MR. TYNAN: You're multitasking.

19 MS. TUCKER-FOREMAN: I have a couple of --
20 I actually have some general questions that go back
21 to Carol Maczka's earlier presentation and because
22 there's so many good questions on this issue, tell me

1 when I would have a chance to ask those instead of
2 going through them right now?

3 MR. TYNAN: Well, we will have an open
4 dialogue with the full Committee on all the topics
5 that we're going to talk about this morning. So
6 there will be another opportunity then. If you have
7 a specific question now that you'd like to address,
8 we could take one and hold the others until that time
9 on the agenda which actually it will be right after
10 our break at about 10:30.

11 MS. TUCKER-FOREMAN: Okay. Thank you. I
12 want to endorse the comments and concerns that have
13 been raised about how we're going to have inspectors
14 do all of the things that they're supposed to do
15 here. Much of this involves more than just getting a
16 prompt on a computer program. How are they going to
17 review more documentation and data? Are the plants
18 going to have to provide all this in a very specific
19 plan that can be easily analyzed? And I think this
20 was raised yesterday and it's still relevant, how do
21 you have the inspectors respond to the questions that
22 aren't yes and no questions?

1 MR. TYNAN: I'm not sure I caught the end
2 of that. Hopefully, Isabel or Bill, did you?

3 DR. ARRINGTON: I didn't.

4 MS. TUCKER-FOREMAN: I can repeat. How are
5 the inspectors going to answer things that aren't yes
6 and no? The prompts drop down. The inspector
7 doesn't have time to stand there, nor does the IIC
8 have to stand there on the line and address
9 complicated, detailed questions and not all of these
10 things I think can be reduced to a yes or no
11 question.

12 MR. TYNAN: So your question has to do with
13 how are they going to document other than the yes and
14 no issues? Did I understand that correctly?

15 MS. TUCKER-FOREMAN: Yes. The answer to
16 that is yes, and how are they going to go into all of
17 the detail that this seems to presume that they will
18 have to do? Where do they get the time to do this?
19 Is the assumption that the plant will not demonstrate
20 problems and therefore the questions will all have
21 simple answers?

22 MR. TYNAN: Let me see who would like to

1 answer that. Dr. Arrington, did you want to start it
2 off?

3 DR. ARRINGTON: I think you're asking how
4 will they -- when they are working on whether they're
5 going to answer yes or no, do they need to document
6 that or not and, of course, if what they're answering
7 is leading to a NR, they would document it there.

8 MS. TUCKER-FOREMAN: Let me, let me -- I
9 didn't myself -- let me try once more. Inspectors as
10 far as I can tell already have timed jobs. They are
11 stressed being able to do all the things they need to
12 do on the line in a given day. You're talking about
13 increasing the line speed and having the inspectors
14 address additional issues that involve analysis. How
15 can they do all of those things?

16 DR. ARRINGTON: Okay. Well, one thing I
17 wanted to mention and this is not really in my
18 presentation, but we do expect when we have the
19 different levels, some inspection, that if we are
20 directing them to do these vulnerable points, that we
21 would de-emphasize other inspection tasks.

22 For the documentation, they're already

1 doing that. When they do their inspection tasks,
2 they have to think about what they're seeing, what
3 they're observing or what they're measuring, and then
4 they use that information, depending on whether or
5 not they're writing a NR. So that part would be I
6 think very similar to what they're doing now.

7 MR. TYNAN: Mr. Smith, and we have
8 Dr. Engeljohn at the table. Did either of you have
9 any comments?

10 Okay. Does that help, Mrs. Foreman?

11 MS. TUCKER-FOREMAN: Yes, thank you.

12 MR. TYNAN: Okay. We'll catch your other
13 questions on the broader discussion later on.

14 MS. TUCKER-FOREMAN: Thank you.

15 MR. TYNAN: Okay. I'm going to let
16 Mr. Painter have his comment, and then I'm going to
17 finish up with Dr. Negron.

18 MR. PAINTER: Yes, Stan Painter with the
19 National Joint Council. My concern as some of the
20 others have raised goes with page 5 of this slide 9,
21 and I want to say as well that comments that have
22 already been made about line speeds is a concern to

1 the inspectors in the field, not only for food
2 safety, for personal safety as well. And something
3 that Ms. Arrington or Dr. Arrington said to Michael
4 Kowalcyk earlier, we want to have the line speeds at
5 a level in which the antimicrobial chemical can work.
6 Presently the Agency does not require plants to use
7 an antimicrobial agent, and I'm wondering what that
8 comment is. Is the Agency going to require plants to
9 use an antimicrobial agent such as TSP or some other
10 form, and it appears as though in 9, the scald vat
11 which it takes a few short minutes to become fecal
12 soup, is to be used as an antimicrobial. Am I to
13 assume that that's the intent of this slide 9?

14 MR. TYNAN: Okay. And again, slide 9 is
15 the one that refers to the scalding questions.

16 MR. PAINTER: That is correct.

17 MR. TYNAN: Okay. Dr. Arrington, do you
18 want to respond to that?

19 DR. ARRINGTON: Yeah, we're not planning on
20 requiring plants to have specific antimicrobials. We
21 do require plants to have food safety systems that
22 are in control and produce safe product.

1 MR. PAINTER: Okay.

2 MR. TYNAN: I'll give you one follow-up
3 question, Stan.

4 MR. PAINTER: No, I don't need a follow-up
5 question. I just need the second question answered.
6 Is the scald vat going to be used as an
7 antimicrobial, and if so, how? Because like I said,
8 you take a chicken that eats, sleeps, craps and
9 everything in one little space, they enter the scald
10 vat dirty, and it takes only a few minutes to become
11 just brown fecal soup. So is it the intent of the
12 Agency to use the scald vat or an attempt to use the
13 scald vat as an antimicrobial area of the plant?

14 DR. ARRINGTON: Okay. I think I can answer
15 that. From the literature, we found that at
16 scalding, if there are controls put into place,
17 generally it reduces microorganisms compared to other
18 steps. Now, it wasn't necessarily the biggest
19 reduction, but it is and that's part of our
20 definition of what a vulnerable point is. If not
21 controlled, it would be microbial contamination or
22 growth.

1 MR. PAINTER: What type of controls?

2 DR. ARRINGTON: Well, these questions kind
3 of summarize those, things like are they doing
4 anything to reduce the amount of dirt that might go
5 in, you know, do they do anything about knowing what
6 the water temperature is. Those would be those kind
7 of questions.

8 MR. PAINTER: Well, we get to dirt,
9 inspectors have been told don't use a word like dirty
10 or filthy or something like that. You have to be
11 more specific. Now, the Agency's going back to
12 something like dirt and, you know, we're talking an
13 animal that has laid in its own feces and now we're
14 using the term dirt. I'm confused.

15 MR. TYNAN: May I interrupt you, Stan, for
16 just a second. If Dr. Negrón will bear with me for
17 just a minute. I'm going to let Dr. Bratcher have a
18 comment or a question real quick.

19 DR. BRATCHER: Well, there are a lot of
20 things that go on in these poultry plants that are
21 not -- they're directly tied to the scalding area but
22 not necessarily in the scalding, and a lot of plants

1 are using multi-hurdle approaches to reduce the
2 microbial levels on these birds. Some of those
3 include chlorine rinses prior to the scalding. It may
4 just be a water rinse just prior to the scalding.
5 Chlorine rinses or antimicrobial rinses after the
6 scalding or prior to the pickers, and in some of the
7 plants in my circuit, we've seen two, three, four log
8 reductions in microbacteria on just using some of
9 those steps which are very common and very easy to do
10 and then reverse flow scalders and overflow in
11 scalders is another area where they can get
12 reduction. And those are just a part of a multi-
13 hurdle approach that a lot of these plants are using
14 which include other microbial interventions once they
15 come into the processing area. So I think when we,
16 when we prompt the questions on the scalding, we're
17 just asking the inspector, and I think I'm right,
18 just to look and see if they have identified these
19 interventions that are in place to see if they're
20 actually doing those things because they may have
21 identified that there are certain other interventions
22 that may be working just as well and they're changing

1 these things all the time. So I think that's the
2 intent of what these prompts are for.

3 MR. TYNAN: If we could, if you have some
4 follow up, Stan, we'll do that as I suggested to
5 Mrs. Foreman, we'll catch those additional ones when
6 we have an open discussion.

7 DR. ARRINGTON: Yeah, let me say real
8 quickly. We can point out in the literature where it
9 describes some of these things, about that particular
10 one.

11 MR. TYNAN: Okay. That's fine.
12 Dr. Negron, I'm going to let you have the final word.

13 DR. NEGRON-BRAVO: Yes, I have a question.
14 Vulnerable points are set up by the Agency and the
15 vulnerable points are set up by the industry. Will
16 you expect them to -- somewhere or will you find some
17 vulnerable points and maybe the industry do not have
18 them, and point to a point that will guide them to
19 modify the prerequisite program? How do you expect
20 that to happen?

21 MR. TYNAN: Dr. Catlin, did you want to
22 respond to that please?

1 DR. CATLIN: Okay. You're correct that the
2 industry does determine what the critical control
3 points are within their HACCP plan. They also in
4 some of their prerequisite programs would identify
5 control points but they would not actually be written
6 up as critical control points. I would expect,
7 although I haven't looked at everyone, that many of
8 our vulnerable points might be identified as control
9 points but not necessarily critical control points in
10 the HACCP plan.

11 MR. TYNAN: So essentially the vulnerable
12 points and the critical control points are not the
13 same. Does that, does that help?

14 DR. NEGRON-BRAVO: I know they are not the
15 same.

16 MR. TYNAN: Oh, I'm sorry.

17 DR. NEGRON-BRAVO: I will expect them to be
18 kind of the same of the control points that the
19 establishment has set up, but if they are not, then
20 that might be some control points that were not
21 addressed by the establishment that could not be
22 addressed and somehow guide them because if not, they

1 will get to be a critical control point because they
2 are not being controlled in the process.

3 MR. TYNAN: Dr. Engeljohn, did you want to
4 make a comment?

5 DR. ENGELJOHN: Yes, this is Engeljohn with
6 the Policy Office, and you're exactly right. And the
7 Agency's intention is to make available what it
8 considers to be vulnerable points, and that would be
9 in the form of compliance guidelines, and the
10 inspector as part of this new system that's being
11 designed, would be capturing what is in place in the
12 establishment. So the establishment may, in fact,
13 have identified numerous other control points that
14 they find to be effective, that we hadn't identified,
15 and those would be captured in the profile and would
16 trigger, for instance, if the information would lead
17 the Agency to have information that the system may
18 not be properly controlled, such as was identified
19 that there may be repetitive NRs or ineffective
20 corrective action. That information would filter up
21 through the supervisory channel ultimately into
22 Washington where we would be looking to see if those,

1 in fact, need a more thorough review and may trigger
2 the district manager or through another action, that
3 a more in depth review would need to take place to
4 see if, in fact, those are appropriate and effective.
5 And the Agency would modify its guidance to the
6 industry as we learn that there are other effective
7 controls in place. But there would be a mechanism to
8 capture what's actually in place, compare it against
9 what the Agency used, to be also effective.

10 MS. NEGRON-BRAVO: Thank you. That's what
11 I will expect.

12 MR. TYNAN: Okay. Great. I'm going to
13 close out the discussion for now. So, if there are
14 other questions that come to mind, please write them
15 down and hold them for the broader discussion later.

16 And with that, I'm going to introduce
17 again, for day two, Dr. Curtis Travis, who again is a
18 consultant with the Science Applications
19 International Corporation, and he's going to talk
20 about the across establishment ranking algorithm.
21 Dr. Travis.

22 DR. TRAVIS: Thank you. The beginning part

1 of this presentation is similar to what I gave
2 yesterday, and the middle part is similar to what I
3 gave yesterday, except that it's focused on chicken
4 slaughter. So I'm going through the beginning part
5 fairly quickly. It's somewhat condensed.

6 I'm going to start with the goal of the
7 ranking system, which is the same as what we had
8 yesterday. The general idea here is that if you look
9 at pathogen levels at the end of the line, they're
10 necessary but not sufficient to tell you if the plant
11 is operating efficiently with regard to pathogen
12 control.

13 The reason they aren't sufficient is you
14 can't take measurements all of the time.
15 Measurements are only made part of the time. So the
16 next step is to focus on process control. You want
17 the establishments to maintain process control all of
18 the time. That guarantees that they can have their
19 pathogen levels under control in between pathogen
20 verification testing. So that's sort of the goal
21 here. The first part of the algorithm is to focus on
22 establishments with evidence of lack of process

1 control.

2 Now, we have various health-based criteria
3 to help us identify those plants like that they've
4 had a positive *E. coli* or had a positive *Salmonella*.
5 They're in Category 3 *Salmonella*. They've had high
6 NR rates, recalls, that kind of thing. All of those
7 are health related. So we're using those criteria to
8 identify the plants that have lack of process
9 control.

10 And then once you've identified them, we go
11 into this in-plant focus on vulnerable systems, the
12 vulnerable areas of the food safety system, and
13 that's sort of to verify that these plants are
14 actually doing what they're supposed to be doing at
15 these control points. Are they really implementing
16 their HACCP plans and their food safety analysis
17 results?

18 And it alerts the inspectors to pay more
19 attention to these places and verify that. Also we
20 would be doing food safety assessments at those
21 plants that seemed to have some problem with process
22 control.

1 So it seems to me that the overall flow of
2 this is fairly logical, that is you're relying on
3 measuring pathogen levels but you recognize that
4 that's not totally sufficient. You're increasing
5 your focus on overall process control by identifying
6 plants that possibly have a lack of process control,
7 using these health based criteria and once you
8 identify them, you're going to do more FSAs and more
9 focused inspections at these plants to verify whether
10 or not they're process control systems are working
11 efficiently.

12 Okay. Next slide. This is the same slide
13 we saw yesterday. You basically separate the plants
14 into three groups or levels of inspection based on
15 these indicators of process control which are the
16 health-based criteria that we have, that I'll be
17 reviewing here for poultry slaughter, and then in
18 Level 2, we're going to separate them based on public
19 health impact.

20 I want to make a couple of points about
21 those lines. First off is within a product category,
22 like the one we're considering today, young chicken

1 slaughter, attribution plays no role at all because
2 they all have the same attribution. They're all the
3 same product category. So this ranking that appears
4 after LOI 2 does not depend on attribution. When we
5 do ground beef, it doesn't depend on attribution
6 there either. Every time we do a product category,
7 attribution plays no role in it whatsoever in terms
8 of that ranking because we're within the same product
9 category. Attribution only plays a role when you're
10 looking between categories.

11 So there have been many recommendations
12 that regulatory focus should be greater on products
13 that contribute more to human disease. So, for
14 instance, you have young chicken broilers and you
15 have ground chicken. Well, which of those two should
16 receive slightly more regulatory focus? Well, we
17 know that ground chicken contributes more to human
18 disease for *Salmonella* than broilers does. So we
19 ought to be focusing a little more regulatory
20 attention on the ground chicken.

21 That means we have to use attribution to do
22 that. I mean that is what attribution is. When you

1 say we should be focusing more on those products that
2 contribute more to disease, you're saying we should
3 use attribution.

4 So the next question is, where do you get
5 your attribution data? We went over that yesterday,
6 that the basic sources of attribution data are the
7 expert elicitations and the outbreak data. And
8 really you can think of outbreak data as just a
9 verification of the expert elicitations.

10 The expert elicitation that we have for
11 FSIS that breaks it down into 25 categories, is our
12 best source of attribution data. Why is that? It's
13 the only one that breaks it down into all of the food
14 categories that FSIS is interested in, the 25 food
15 categories. The other ones are very gross. They
16 just say beef, chicken, deli meats. That's not a
17 fine enough breakdown. So really the best source of
18 attribution data is the FSIS expert elicitation.

19 Using the outbreak data is just a way of
20 verifying that that is a reasonable data set, using
21 the resources for the future database is also a way
22 of verifying that it's a reasonable data set. So

1 those are some of the points I wanted to make.

2 And one further point I wanted to make is
3 that you're never going to have perfect attribution
4 data, but you don't need perfect attribution data to
5 make these kinds of decisions. Your overall goal is
6 to focus more regulatory attention on the products
7 that contribute most to human disease. So, if we're
8 looking at chicken broilers and ground chicken, which
9 one should we focus on more? Well, we don't have to
10 know attribution to two decimal points for each of
11 those categories to answer that question. We only
12 have to have, in general, know that ground chicken
13 contributes more to human disease than whole
14 broilers, and we can focus more attention.

15 So those are some of the points I wanted to
16 make about attribution. One, attribution doesn't
17 come into play when you're ranking single food types
18 like we're doing here with young poultry broilers.
19 And, two, you don't have to know the numbers exactly
20 in order to use them.

21 Okay. So now we'll move onto in-depth
22 inspection which is the next slide. These are the

1 criteria. Now, these criteria are very similar to
2 what we had yesterday for defining an in-depth
3 inspection level, the LOI 3, except that they're now
4 paired down to only apply to young chicken slaughter.
5 So an establishment is in *Salmonella* Category 3. So,
6 if you're in Category 3, we want to give you more in-
7 depth inspection which would mean that you're going
8 to get a higher priority for doing an FSA.

9 And establishment is linked to a foodborne
10 disease outbreak. These are the same as yesterday.
11 The establishment has the same structure damage due
12 to a natural disaster. There's been an enforcement
13 action or adulterated or misbranded product shift
14 which includes recalls. Those are identical to
15 yesterday. Next.

16 The next is they're in the highest
17 percentage of health-related NRs. We're going to
18 talk about what percentage that is in our example
19 later on. Again, the use of NRs is justified
20 through the Carnegie Mellon predictive analysis. The
21 time window for the health-related NRs, that is are
22 we considering just a month of data or some other

1 time period and the cut points which is are we
2 considering the top three percent or what? Those are
3 open to discussion. But I'm going to show you some
4 of the preliminary choices we made and what the
5 implications of those are. As some of you made the
6 point yesterday, it's hard to tell where the cut
7 point is until you see how they work when you run the
8 algorithm, what kind of results you get.

9 Then another criteria is repetitive
10 *Salmonella* serotypes of human health concern or the
11 PFGE matches.

12 One other point I wanted to make is that
13 the very first criteria we had here was that
14 establishment was in *Salmonella* verification Category
15 3. The Agency is developing a baseline for
16 *Campylobacter*. When they do that, they'll have
17 categories for *Campylobacter* just like for
18 *Salmonella*, a Category 1, a Category 2, a Category 3.
19 They'll be independent. So an establishment might be
20 in Category 3 for *Salmonella* and it might be in
21 Category 2 for *Campylobacter*. But, anyway, you're
22 going to have these same kinds of categories and we

1 can add that as a criteria to get into LOI 3. If
2 they're in *Campylobacter* Level 3, a Category 3, they
3 could be in the in-depth inspection.

4 Now, there's some other things that you
5 could look at which is the interplay between those
6 two. Do you sort of want to come up with an overall
7 score between *Salmonella* and *Campylobacter* to come up
8 with a single score so that it can be used as moving
9 up, or do you use them independently? Those are some
10 other issues that need to be addressed, but I just
11 wanted to point out that *Campylobacter* will be
12 included once a baseline is established and the
13 categories are established. We can include it in the
14 ranking system.

15 Okay. So now we move to the routine level
16 of inspection. Again, these criteria are the same as
17 they were before except paired down just for
18 *Salmonella*. Did not have an enforcement action or
19 adulterated or misbranded product in commerce in the
20 past four months. This captures recall. It didn't
21 have a recall in the past four months. It's in the
22 lower percentile of percent positives and the most

1 recent *Salmonella* verification sample set, or
2 unannounced sampling or other *Salmonella* testing
3 programs. It wasn't linked to a disease outbreak in
4 the last six months. It's in the lower percentile of
5 health-related NRs and again we're talking about --
6 we'd like input on the time window and the cut points
7 that could be used. Next slide.

8 Lower percentile on the most recent FSA
9 score, a lower percentile of scores on focused in-
10 plant verification questions, and this is the part
11 where the inspectors are, because we've identified a
12 plant is having possible problems with process
13 control, the inspectors are now spending more time
14 with these focused inspections, going back. They're
15 getting triggered to go back and look at the
16 vulnerable points and see if plants are doing what we
17 would expect them to be doing at those points.

18 This isn't something that's different than
19 what inspectors have normally been doing. The
20 overall inspection system is the same. It hasn't
21 changed, and all three levels. It's just that at the
22 plants that appear to be more vulnerable for loss of

1 process control, we're alerting the inspectors to pay
2 more attention to these vulnerable points. That's
3 always been part of their duties, and it's part of
4 HACCP. It's just that now they're getting triggered
5 to do it, saying go prompt it to do it, go look at
6 these points and verify that these kinds of
7 activities that should be done are being done.

8 But, I mean, one point I think that we lose
9 in all of the details of all this is that the
10 inspection system is the same as it was, and the
11 routine level of inspection, it's exactly the same as
12 it was. We've just identified some plants up at the
13 top that possibly have a lack of process control, and
14 we want the inspectors to pay more attention to them.

15 Okay. These criteria, this is the middle
16 criteria and as I said yesterday, it's the ones that
17 aren't in 1 or 3. I think I won't go through all of
18 these criteria again. It's the same as yesterday and
19 we know which ones they are. They're the ones that
20 aren't in 1 or 2.

21 So let's move to slide 12. Slide 12 is
22 ranking them on public health impact. So this is the

1 same as yesterday in that the ranking is based on
2 fractional volume times attribution. But since we're
3 in a product category, which is young chicken
4 slaughter, the attribution is the same for all
5 plants. The attribution has to do with the product.
6 It's broilers. So it's the same for every single
7 one. So attribution is the same. So attribution
8 does not play a role in the ranking of these plants.
9 It just says that the ranking is based on volume.

10 Now, some of you might not like that, but
11 if you think about it, you've got these plants where
12 you think there may be a lack of process control
13 because of our health-based indicators, our criteria
14 that we're using that are health based. We've
15 identified some plants that have higher NR rates or
16 higher *Salmonella* levels, or had some recalls. So
17 we've said they may have some problems with process
18 controls. So we want to focus on them more.

19 Well, now you want to prioritize those.
20 Well, which ones would you want to focus on more?
21 The large volume plants because they would have the
22 biggest impact if they had a loss of process control.

1 Now, there are other ways to do it, but
2 that's a fairly reasonable way to identify a ranking
3 of your plants within a product category.

4 Okay. Now, let's look at our example. We
5 assembled a data set on 128 of the approximately 190
6 young chickens slaughter establishments. We're still
7 working on filling out 190. I mean, bringing it
8 between 128 and 190. It's just an incredible amount
9 of data that we have to get together.

10 Once we get this automated system in place,
11 all of this stuff is going to be done in an automated
12 fashion, and it'll be updated every single month, but
13 doing it right now means going onto the system,
14 pulling out individual databases. Some of these take
15 hours to pull off the system because they're very
16 big, and to break them down and deal with them is
17 big. So we're in the process of verifying all this
18 data.

19 So this was our preliminary cut on this,
20 128 establishments, for which we have data on all of
21 the establishments. We're also doing other product
22 categories as I mentioned yesterday. We're doing

1 ground beef. We're doing ground turkey, ground
2 chicken, deli meats, some big categories. Ground
3 meats and deli meats are large categories, that is a
4 large number of establishments are doing them.

5 So we'll have a pretty good database to
6 look at how this algorithm road tests, and what kind
7 of impact various cut points have on the overall
8 results.

9 Now, on this one, young chicken slaughter,
10 these were the cut points we used for *Salmonella*. To
11 get into LOI 3, it was that it had *Salmonella*
12 Category 3 level. This is just for LOI 3 relative to
13 *Salmonella* scores. So, if you're in *Salmonella*
14 Category 3, you went into LOI 3. If you were between
15 90 and 97 percentile, on the distribution for all
16 establishments on *Salmonella*, this is only young
17 chicken broiler establishments, we're looking at
18 their *Salmonella* results and we choose the top
19 between 90 and 97 percentile, they would go in
20 Category 2 -- excuse me -- Level of Inspection 2.

21 And Level of Inspection 1 would be the
22 lower 90 percentile on the *Salmonella* positive rates.

1 So the points to make are, one, we're only comparing
2 the distributions on young chicken broiler
3 establishments. We get a different distribution for
4 ground beef, a different one for RTE. So you only
5 compare within a product category.

6 So for *Salmonella*, we're looking at the
7 *Salmonella* verification test. We see what positive
8 levels they've got, the percentile, and we get a
9 distribution. And the bottom 90 percent is in LOI 1.
10 The ones that are in *Salmonella* Category 3 are at the
11 top, and the in between is between 90 and 97
12 percentile.

13 Okay. Now, what about health-related NRs?
14 We did the same thing, used the same cut points. So
15 these LOI 3 was the top 3 percent of health-related
16 NRs, and the LOI 1 was the bottom 90 percent. So as
17 long as you were in -- in terms of your health-
18 related NRs, as long as you were doing as well as 90
19 percent of the other facilities, you were in a
20 routine level of inspection relative to this one
21 criteria. Remember, to get into LOI 1, you have to
22 satisfy all the criteria. So this is one of them.

1 So this isn't a really stringent criteria.
2 We're only picking out the top 10 percent of plants
3 to put them into LOI 3 or LOI 2, and only on this one
4 criteria. And only the top 3 percent of plants up at
5 the very top that say we need to prioritize when they
6 get a food safety inspection. Okay. Next.

7 This was the results, the final results
8 where we included everything which is the *Salmonella*
9 levels, the NR levels, the recalls, the enforcement
10 actions, all of our criteria were put together. This
11 is how it turned out, that we had about four percent
12 of the plants were in LOI 3, about 37 percent of the
13 plants were in LOI 2, and about 60 percent of the
14 plants were in the normal routine level of
15 inspection.

16 And this is where changing the cut points
17 would affect these answers. If we change the cut
18 points, instead of using basically 90 and 97, we
19 could affect how many plants get in these various
20 criteria, but this was our first cut on it. It's
21 basically to identify those plants where we have some
22 indication based on these health-based criteria that

1 there may be a problem with process control, and we
2 want to have the inspectors pay more attention to
3 those plants to verify whether there is a problem or
4 there isn't a problem, and we want to prioritize food
5 safety assessments at those plants that we think
6 there may be a problem, to again find out if there's
7 a problem or not because food safety assessments are
8 one of the best ways to identify whether or not
9 plants have efficient food safety process control.

10 Okay. In summary, the algorithm's designed
11 to focus inspection on establishments most needing
12 attention, focus inspection on the most vulnerable
13 food safety system areas. The first one tells you
14 which plants may need more attention. The second
15 says go to the vulnerable points and verify that
16 things are being done as they should be. And, the
17 overall purpose was to verify that food safety
18 systems are working optimally. Thank you.

19 There's one more slide, I guess. Somehow
20 it's not on the copy I have but this is a summary
21 slide that also was on yesterday's. Approaches, this
22 approach has multiple advantages. One is

1 transparency. The transparency comes from the fact
2 that you have these three levels of inspection and
3 these health-based criteria for assigning plants to
4 those levels. The transparency is that we, you know,
5 we know what the criteria are. You can see them.
6 You can decide whether you think they're appropriate
7 or not.

8 It focuses on plants with evidence of lack
9 of process control. All plans with high pathogen
10 levels are ranked high. All plants with health-
11 related problems, those are recalls, outbreaks,
12 enforcements, are ranked high.

13 The categorization is independent of
14 product volume. The final breakdown within Category
15 2 isn't. And it's compatible with the FSIS sampling
16 programs.

17 Okay. Now I can say thanks.

18 MR. TYNAN: Okay. With that, I'm going to
19 turn it over. I know there's questions here but I'm
20 going to start off with Mrs. Foreman on the phone
21 this time and, Carol, did you have any questions for
22 Dr. Travis?

1 MS. TUCKER-FOREMAN: I do have some
2 questions but I want to be sure that you can hear me.

3 MR. TYNAN: Yes, we sure can.

4 MS. TUCKER-FOREMAN: Okay. Thank you.
5 First, this is really not a question but because
6 Dr. Travis expressed again his frustration about the
7 Committee's lack of acceptance of the --

8 MR. TYNAN: Carol, you're fading out just a
9 little bit on us.

10 MS. TUCKER-FOREMAN: Okay. Dr. Travis has
11 suggested that we just don't understand the value of
12 the expert elicitation and I think that that requires
13 a comment -- our standards, consumer groups, have
14 two standards. I think the industry groups are the
15 same. We want to know if it is going to produce
16 safer food, and we want to know that what the Agency
17 proposes is going to work better than what we have
18 now. We don't want perfect data. If you're going to
19 call something risk-based or public health based, you
20 have to have sufficient data to tie those two
21 together. FSIS continues to exclude *Campylobacter* in
22 its consideration of whether or in its assertion that

1 this program is based -- risk-based.

2 We have big problems with the expert
3 elicitation. We referred the Committee to the
4 article in the Journal of Food Protection by
5 Dr. Hoffman that says large heterogeneous expert
6 elicitation groups can take the place of preferred
7 ways of determining risk and the -- sentence is
8 here's where you go when you don't have anything
9 else. It is never the first pick. If you're going
10 to use it, the group needs to be large and
11 heterogeneous. USDA's expert elicitation does not
12 meet either of those standards. We have problems
13 with the way it was structured and again, it does not
14 consider nor does CSPI's outbreak data, the pathogen
15 that is frequently associated with illness related to
16 poultry. So those are the problems we have with, or
17 at least the Consumer Federation of America has.
18 We'll just continue to repeat those until the Agency
19 responds in some way that meets our concerns.

20 Now, you talk about being transparent.
21 What is not transparent in the presentation up to
22 this point is the impact of increasing line speed.

1 If we were to accept this as a risk-based model, and
2 if we were to accept the levels of ranking, LO 1, LO
3 2, LO 3, nothing that the Agency has put -- indicates
4 how you maintain that assurance when you change the
5 most basic factor in a plant, that is when you
6 increase the line speeds and, you know, it's a funny
7 thing in all the Data Subcommittee meetings, we never
8 did discuss increasing line speed and yet that
9 emerges a major issue in this. The Agency does
10 intend to permit increased line speeds.

11 So there's going to have to be some
12 presentations about how the Agency can quickly, on a
13 day-to-day basis, adapt its -- to increased line
14 speed and what happens when problems begin to occur
15 in increased line speeds and how quickly the Agency
16 can change and tell a company that's got a bunch of
17 eight week old broilers sitting out front, oh, you
18 have to slow your line down.

19 I would suggest, I'm not a scientist, but I
20 sure have been doing this for a long time and I do
21 understand that this proposal is not transparent and
22 it doesn't address some very serious problems. And

1 you're going to have to before we're going to support
2 it.

3 DR. TRAVIS: I'll give a few responses to
4 that. I can't answer all of those questions because
5 they're not exactly the area that I've been working
6 on, particularly the line speed issue.

7 MS. TUCKER-FOREMAN: That's part of the
8 problem. That's part of the problem. Your
9 presentation is segmented as though these other
10 issues don't exist and there is nothing on the
11 program that --

12 DR. TRAVIS: Well, let me say that I agree
13 with you that we'll never have perfect data. We both
14 agree on that. I also agree that *Campylobacter* needs
15 to be included, and I think the Agency is moving in
16 that direction.

17 In terms of the expert elicitation, I also
18 agree that it has its problems but I also think that
19 it's the best we've got. We now will show that the
20 CDC data agrees pretty well with the expert
21 elicitation. We've shown that the Center for Science
22 in the Public Interest database agrees with the

1 expert elicitation, and we've shown that the
2 Resources for the Future expert elicitation agrees
3 with the FSIS expert elicitation. That's about as
4 good as we can do now. So it just comes to the point
5 are you going to use this kind of data or are you
6 not? If you don't use it, you can't link these --
7 you can't do the focus on products that contribute
8 most to health disease, and we think that at this
9 point we can use this data and we'll try to improve
10 it as we go along.

11 MS. TUCKER-FOREMAN: Now I have two
12 comments please while we're on this, Bob.

13 MR. TYNAN: Okay. Go ahead, Carol. And
14 Dr. Engeljohn is here and has a comment that he
15 wanted to make.

16 MS. TUCKER-FOREMAN: I'm trying to respond
17 please. But you can't do it on the timeline, the
18 artificial timeline that FSIS has introduced here.
19 The problem we keep running into is the parity to do
20 this when you could, when you get to *Campylobacter*
21 baseline data, you can move in that direction, you
22 don't have it, and you're not going to have it by the

1 time this program is proposed to start, and you don't
2 have it as you shape the program.

3 Let me, let me go back to the expert
4 elicitation again. CSPI's data do not include the
5 single righteous problem in poultry slaughter that is
6 *Campylobacter*, and RFF have sent you a memo saying
7 that it does not believe that FSIS has used its --
8 appropriately in several cases. So you have raised
9 issues about whether there is agreement -- RFF and
10 FSIS, and it's exactly that kind of problem causes me
11 to come back again and again questioning it because I
12 keep getting these little problems that grow very
13 large when they are multiplied -- and they are
14 multiplied by the -- tight timeline that the Agency
15 is insisting on here.

16 You can submit questions to the Micro 3
17 Committee and have them tell you, you want to avoid
18 methodological problems in the use of these data and
19 have them be acceptable for how you want to use them,
20 you can do that, but you can't do it and put out a
21 rule by July.

22 MR. TYNAN: Okay. Thank you, Carol. I'm

1 going to give Dr. Engeljohn, if he -- he had a
2 comment before.

3 DR. ENGELJOHN: Carol answered it in part
4 in her follow ups but I did want to make clear so
5 that it is on the record that the Agency's full
6 intention is to fully address *Campylobacter* as a
7 public health concern for the Agency and there will
8 be standards applied, and we will be addressing
9 enforcement related to that as quickly as the Agency
10 is able to establish what those standards are.

11 There is a baseline that's underway now,
12 and as we can build that data and information into
13 our systems, those will be addressed. So
14 *Campylobacter*, although it hasn't been addressed to
15 this date, will be. So I'm just making that
16 reiteration.

17 And then also, as well, for the line speed
18 issues, the Agency has, in fact, put in place a
19 mechanism by which we will be assessing and making
20 data available on the impact of line speeds, on the
21 impact of number of lines that are in the various
22 operations so that we can get the data presented to

1 you to provide you with what we believe to be how
2 those issues affect public health. And so with all
3 intentions, the Agency will and is committed to
4 incorporating those into the conceptual design of
5 this system. So I just need to make that very clear.

6 MR. TYNAN: Okay. Dr. Maczka, you had a
7 comment as well.

8 DR. MACZKA: Yes. Just one other comment
9 that I'm eager to get the resources for the future
10 comments, and we will revisit what we've done in
11 response to their comments.

12 MR. TYNAN: Okay. Mrs. Foreman, if you
13 have any other comments, if I could, in the interest
14 of time, if we could hold them until the general
15 discussion. We're a little bit behind schedule on
16 our calendar, and we have a few more folks here in
17 the room that would like to make comments. So I'm
18 going to call on Dr. Murinda, if you had a comment or
19 a question. It looks like you're going to have to
20 pull the whole table apart to get the --

21 DR. MURINDA: Just a few -- two little
22 questions. The first one is with relevance to the

1 non-inclusion of attribution data. I still don't
2 understand why attribution data is not important.
3 Even though we are talking about production of young
4 broilers, I think the market is not the same
5 throughout, and we also have some -- markets like
6 kosher poultry processing which is fundamentally
7 different from conventional processing.

8 The other little question is about
9 *Campylobacter* data being included in the algorithm.
10 Is the Agency planning to include all *Campylobacter*
11 or this is *Campylobacter* data of public health
12 significance like *Campylobacter jejuni* and
13 *Campylobacter coli* only vis-à-vis looking at all
14 *Campylobacter*.

15 DR. ENGELJOHN: This is Engeljohn. I'll
16 take the second question on the issue of
17 *Campylobacter*. The intention and expectation will be
18 that we will be looking at all species of
19 *Campylobacter* in establishing criteria much like
20 we've done with *Salmonella* where we rely upon CDC
21 data in particular to identify which have the
22 greatest public health impact, but all will be

1 determined as well the quantitative level of
2 *Campylobacter*. So those will be components that the
3 Agency will be addressing, but any species of
4 *Campylobacter* and that would be dependent in part
5 upon which particular product class we're looking at
6 because turkeys is generally different than broilers,
7 but the Agency will be tracking all of them and
8 making public health decisions based on the public
9 health significance of the individual serotypes.

10 MR. TYNAN: Okay. Dr. Travis, you had a
11 comment as well.

12 DR. TRAVIS: On the attribution question, I
13 acknowledge that what you said, is different types of
14 young chicken slaughter may have different
15 attribution numbers associated with them, but we
16 don't have that data. That's one of the dilemmas
17 that we have in attempting to do this is that on the
18 one hand, various advisory committees recommend,
19 including attribution data for finer and finer
20 categories. You know, this one is slightly different
21 than that. We need a new attribution number for it.
22 But then as soon as you do it, the Advisory

1 Committees say you don't have enough data to make
2 those distinctions. That's absolutely true. We
3 can't get down to these kinds of fine details that
4 you're talking about. Basically, we can get down to
5 chicken broilers. We can't get down farther than
6 that without making even more assumptions because we
7 don't have data on that kind of attribution.

8 MR. TYNAN: Okay. I'm going to ask the
9 participants, Dr. Murinda, does that get to the heart
10 of your question?

11 Okay. If I could, and again in the
12 interest of time, if the questions are urgent, I'll
13 take them. Otherwise, could we hold them until we
14 get to the general discussion for the remainder of
15 the folks, Brian and Kevin, Michael. Can we hold the
16 questions until later or do we need to ask now?

17 MR. ELFERING: --

18 MR. TYNAN: Okay. Go for it please.

19 MR. ELFERING: Just a real quick question.
20 One of the criteria for LOI 3 is if the product is
21 linked to a foodborne illness outbreak, and I'm just
22 wondering if there's any criteria that would

1 establish like a matrix or something, what that
2 linking would be. For example, you may have a
3 product going from a slaughter plant to a further
4 processing plant to a retail store that may be
5 associated with a foodborne illness outbreak. Would
6 that still link that slaughter plant to that
7 foodborne illness outbreak? Because there's been
8 precedent set in the past for like ground beef
9 products.

10 MR. TYNAN: Okay. Mr. Smith?

11 MR. SMITH: That's a very good question,
12 and I think once you're into this arena, you're into
13 an investigative mode and you have to meet the rules
14 of that evidence and evidentiary file and chain of
15 custody and all that to make that specific link. It
16 just can't be -- if you're going to affect levels of
17 inspection, you have to have solid information, a
18 case file to make that determination.

19 MR. ELFERING: So in other words, these
20 would all be taken case by case and then Headquarters
21 would probably make the determination if they go into
22 LOI 3.

1 MR. SMITH: There will be a determination
2 -- whatever establishment it would be linked to, that
3 information would be fed into the system and then
4 that would trigger the determination.

5 MR. TYNAN: Okay. Brian, you had a
6 question. Let's go ahead and we'll deal with it now.

7 MR. COVINGTON: As there's been a lot of
8 talk of the *Salmonella* categories and as we come on
9 the two year anniversary of the February '06 Atlanta
10 meeting which the Agency outlined their points in
11 which to reduce *Salmonella*, can you just refresh us
12 on the decision making process to break Category 1, 2
13 and 3 down with the broilers and then how that
14 decision making process may or may not be used with
15 the other processing categories that have *Salmonella*
16 standards?

17 DR. ENGELJOHN: This is Engeljohn. I'll
18 answer that. The *Salmonella* categories were
19 established by first having a standard which for the
20 case of broilers was a 20 percent positive rate
21 standard. Twenty percent was the standard, and I
22 believe that was 13 positives out of 51 samples if my

1 memory serves me correctly.

2 When the Agency established the categories,
3 1, 2 and 3, a Category 3 would be a standard that
4 would exceed the 20 percent which, in this case,
5 would have I believe greater than -- 13 or greater
6 positives. Half of 13 then would have been 6 1/2
7 positives in that sample set. And so the Agency
8 rounded down so that a Category 1 plant would have 6
9 or fewer positives out of the 51 sample set. A
10 Category 2 would be greater than 6 but less than the
11 13. And so that was how the establishment of
12 categories were done for broilers, and it would be
13 the same conceptual design for all the other classes
14 so that if the standard was 40 percent and there were
15 X number of positives, then we would use the division
16 to make those categories. So did that answer your
17 question for what is Category 1, 2 and 3?

18 MR. TYNAN: Does that help, Brian? And,
19 Michael, I'll let you finish up if it's a quick
20 question.

21 MR. KOWALCYK: Okay. This is a question
22 about using the cut points. Can you talk a little

1 bit about your rationale for the top 3 percent of
2 health-related NRS as being your cut point? Is that
3 driven by the underlying data, the distribution of
4 the NRS or is that more along the lines of a
5 management decision based on your goal of resource
6 neutrality? And then a follow up to that is the
7 *Salmonella* Category 3, again that seems to represent
8 about 3 percent of the plants in this example. How
9 dynamic do you see that being? In other words, when
10 this is updated, your distribution of *Salmonella*
11 results will change as will your distribution of NRS,
12 and what steps is the Agency taking in the analysis
13 of this process to manage that variance that will
14 happen?

15 DR. TRAVIS: Let's see. Your first
16 question was about the top 3 percent of --

17 MR. KOWALCYK: The top 3 percent of NRS.

18 DR. TRAVIS: Well, basically looking at
19 both of these distributions, they, they start out
20 low. In other words, most plants are performing with
21 a low percent number. So low percent outbreak
22 related NRS. So it might be zero. Some of the

1 plants are zero. They didn't have any health-related
2 NRs. And so you go along, if you're looking at a
3 probability distribution, you have zero, zero, zero,
4 zero, and then they start creeping up. They get a
5 half a percent, you know, three-quarters of a
6 percent, and they stay pretty level as you're moving
7 across over to about 90 percent, and then they start
8 increasing. There's sort of an acceleration in the
9 number of health-related NRs, until we got up to
10 around 3 percent in which case it went up even
11 faster. So there were some natural breaks in this
12 data, both for the *Salmonella* and the NR data that
13 short of indicated where you might want to
14 distinguish between plants. They sort of came along
15 and then they went up a little faster, and then at
16 the very end they shot up. The last few plants had
17 fairly high rates. And so that was how we did our
18 first cut.

19 MR. TYNAN: Dr. Engeljohn.

20 DR. ENGELJOHN: Just to follow up on the
21 second part of the question then, with regards to the
22 dynamics of the changing in the *Salmonella*

1 performance, the Agency has made clear that our
2 intention is for continuous improvement for the
3 control of *Salmonella* and then ultimately for
4 *Campylobacter* as well when we establish those
5 standards.

6 And so we would expect there to be constant
7 movement from between categories, and as has happened
8 with broilers, a larger number of plants continuously
9 move from either Category 3 into 2 into Category 1,
10 and so the intention is to get -- in our case, we've
11 identified at least 90 percent of the plants within a
12 particular class into Category 1 by a time period.

13 The Agency well recognizes that each
14 completed sample set may change the performance of an
15 establishment, and so that would be taken into
16 account in terms of how frequently we would make the
17 changes in categorization or establishing levels for
18 establishments. But I did want to make sure that
19 everyone was aware of the fact that as the Agency
20 establishes new standards, and in this case, a new
21 baseline would establish a new standard, there would
22 be some progress in terms of how we would reestablish

1 a plant's categorization because under the old
2 standard, if we had 90 percent of them in Category 1,
3 which would be the success that we would want to get
4 to, a new standard would realign the categorization
5 and we would start that process. And so the
6 implementation of the categorization when a new
7 baseline is established also is dependent upon there
8 being presently at least two FSIS sample sets
9 completed before we categorize an establishment.

10 So, if we were to establish a new standard,
11 it would, in fact, reestablish the categories, but
12 there would also need to be a reassignment of plants
13 in that period of time. So this would be a dynamic
14 shifting change that would be taken into account with
15 this algorithm.

16 MR. TYNAN: Okay. Dr. Travis, you had
17 another comment?

18 DR. TRAVIS: Yes. I wanted to point out
19 that -- well, these slides aren't numbered, but the
20 one that talks about the *Campylobacter* -- excuse me
21 -- the *Salmonella* cut points, this is your question,
22 I realize that these criteria aren't quite right.

1 They're not quite what we did. I got carried away
2 with the 97 percentile but the Level 3 is a
3 *Salmonella* Category 3, but Level 2 is not the ones
4 between 90 percent and 97 percent because as you
5 identified, that would put the top 3 percent in
6 Category 3, but what we did was it's really above 90
7 percent but not including Category 3. So we don't
8 run into that problem you're talking about.

9 MR. KOWALCYK: So you're really using the
10 distribution of all the plants net Category 3?

11 DR. TRAVIS: Right.

12 MR. KOWALCYK: And then you make your cut.

13 DR. TRAVIS: Right.

14 MR. TYNAN: Okay. With that, I'm going to
15 try and close out the discussion for these particular
16 topics. I would suggest given we're a little bit
17 behind, I've got 12 after. If we could get back to
18 start again at 10:30 exactly, we'll talk about the
19 risk assessment and then go to the performance
20 standards. Mrs. Foreman, we're going to take a break
21 until 10:30, and I have about 10:12, right now.

22 (Off the record.)

1 (On the record.)

2 MR. TYNAN: The next presentation relates
3 to risk assessment, and I have Ms. Janell Kause who's
4 the Director of our Risk Assessment Division in the
5 Office of Public Health Science. So I'm going to ask
6 Ms. Kause if she could begin her presentation on risk
7 assessment. Janell.

8 MS. KAUSE: All right. Thank you, Robert.
9 Good morning, everybody. I'm glad that you came back
10 for the second half here. I will discuss the FSIS
11 risk assessment for guiding public health risk-based
12 poultry slaughter inspection, and I look forward to
13 the input from this Committee.

14 With me here today is Dr. Terry Disney.
15 He's a senior analyst, risk analyst with FSIS who
16 developed this model and has many years of experience
17 developing quantitative risk assessments. I had him
18 fly in from Fort Collins so he could be here in
19 person for the Committee here today.

20 In addition, the Committee should have the
21 entire risk assessment report. It's one of the
22 appendices to the technical plan. Next slide please.

1 Okay. Thank you.

2 The purpose of this risk assessment, I'll
3 get into that, FSIS online inspectors conduct hands
4 on appraisals of every young poultry carcass to
5 ensure it is unadulterated, free of feathers, bruises
6 and defects and disease, while FSIS offline
7 inspectors verify that establishments maintain
8 sanitary operations and perform other health and
9 safety related assignments.

10 It is possible that by allowing FSIS
11 personnel to perform additional wholesomeness,
12 sanitation sampling and other offline procedures,
13 tailored to mitigate *Salmonella* contamination on
14 poultry, the number of human illnesses from
15 *Salmonella* can be reduced.

16 To evaluate whether or not this is so, FSIS
17 developed a quantitative risk assessment to evaluate
18 the public health benefits of changes in inspection
19 activities in poultry slaughter plants.

20 Specifically, the risk assessment was
21 designed to answer four risk management questions.
22 In a nutshell, this is, what is the predicted public

1 health impact for changes in inspection activities in
2 poultry slaughter plants? The first question really
3 relates to looking at changes in prevalence on young
4 chicken.

5 The second one is then translating that out to
6 public health impact, and the third one is really
7 important which is knowing what is the certainty of
8 the estimates that our model is producing. Next
9 slide please.

10 The type of risk assessment developed was a
11 stochastic simulation model that included multiple
12 variable logistic regression using pair wise
13 observations. Next slide please.

14 This model models the relationship between
15 changes in *Salmonella* prevalence on young chicken and
16 corresponding attributable human illnesses.

17 I'm going to stop here for a moment because
18 yesterday the issue came up about peer review. This
19 risk assessment was independently peer reviewed
20 according to the OMB peer review guidelines and what
21 that means exactly is back when we developed this
22 initial model in 2005, in January and February of

1 2006, we had it independently peer reviewed. That is
2 we go out and we have a contractor who competed for
3 the contract to conduct the peer review, and we don't
4 actually know who the peer reviewers are. What we do
5 is we provide them criteria.

6 For example, some of the criteria given to
7 the contractor was we needed people who were familiar
8 with probabilistic analysis. Maybe they knew Basen
9 (ph.) analysis. They were familiar with visual basic
10 modeling so they could audit the model themselves.
11 They knew epidemiology. They knew food safety and so
12 on.

13 And giving that criteria to the contractor,
14 they go out and they came back to us with 23
15 potential candidates to which we are actually
16 blinded. We don't know the names of who those
17 candidates are, and what we do know is that their
18 strengths and weaknesses are and they go ahead and
19 pick the top five.

20 And I did want to clarify this because it
21 was sort of a mis-understanding yesterday that maybe
22 somehow we picked the peer reviewers. We actually

1 actually only allowed, according to the OMB
2 guidelines for peer review to select the kind of
3 criteria for the reviewers. And then these peer
4 reviewers go out and they conduct that peer review.
5 They give us comments and then we respond to those
6 comments and after we respond to the comments, we
7 then find out from the contractor who the peer
8 reviewers actually were. In this case, for this risk
9 assessment, we have five groups of reviewers. One
10 was a team. It was Dr. LeeAnn Jaykus with North
11 Carolina State University with a background in
12 quantitative risk assessment, and she had a post-doc
13 named Dr. Mokhtari, and I'm mentioning this because
14 he was a postdoc. Again, I believe Robert probably
15 provided you guys the response to comment documents.
16 It's important to know who our peer reviewers were so
17 you can understand the validity of the peer review.

18 We also had Dr. Joseph Eifert who is a food
19 scientist from Virginia Tech, Dr. Ian Gardner who is
20 with the University of California Davis. He is a
21 professor of epidemiology who is familiar with
22 quantitative risk assessments, and we had Dr. Donald

1 Schaffner who is with Rutgers University, and he's
2 conducted a number of quantitative risk assessments
3 both nationally and internationally. So that's just
4 a little heads up on the peer review process.

5 That peer review, as I said, occurred in
6 2006. As a result of that peer review, the original
7 model had dramatically changed. It's substantially
8 different today as a result of that peer review. So
9 it was a very important part of our process.

10 We are looking for input here today and
11 subsequently we'll undergo a second formal peer
12 review in accordance with the OMB peer review
13 guidelines. The reason why we're doing the second
14 peer review second is it's important to get the
15 input, and if there's additional data to do all the
16 updates at once so we're closer to more of a final
17 model that undergoes the second peer review. Next
18 slide please.

19 The data used in this risk assessment was
20 2,395 paired observations from calendar year 2003 to
21 2005. The type of data that were paired, the
22 *Salmonella* prevalence, was just taken from our FSIS

1 verification testing data from 154 chicken poultry
2 establishments. And then we had paired that up with
3 inspection activities which comes from our FSIS
4 Performance Based Inspection System, also known as
5 PBIS. We also had data from our personnel office,
6 not knowing the names of the people, but we had
7 information on online and offline inspectors for
8 2005.

9 We developed a multivariate
10 regression/stochastic model as I mentioned. The
11 dependent variable in that particular model was the
12 *Salmonella* prevalence. So that's what we're looking
13 at changes in. And the independent variables were
14 structural variables which included characteristics
15 of the establishments, the date, the type of
16 inspection and the volume produced. Next slide
17 please.

18 Additional independent variables included
19 decision-tracking variables, the number of scheduled
20 procedures performed, the number of unscheduled
21 procedures performed. We aggregated those procedures
22 into categories and we had the number of online and

1 offline inspectors.

2 In terms of performance deficiency, what
3 that's referring to in this particular model when you
4 look at the report is the number of scheduled not
5 performed procedures and the number of non-compliant
6 procedures recorded, and those were also aggregated.
7 Next please.

8 Using that model, the last slide I just
9 showed you was looking at changes in *Salmonella*
10 prevalence in young chicken with changes in
11 inspection activities. Well, then what we have to do
12 is we have to translate that out to human illness and
13 this is literally a step-by-step table of how we, how
14 we translate *Salmonella* prevalence on young chicken
15 to human illness.

16 In this calculation, this is a calculation
17 that is in the scientific literature by Powell in
18 2000, and it basically gives you the CDC data for
19 incidence of Salmonellosis among the U.S. population
20 that's adjusted by for by a CDC multiplier. Mead, et
21 al., put that out in 1999. We then take the
22 foodborne fraction that's related to chicken. That's

1 also from the CDC estimate in 1999, and then we use
2 the Resources for the Future/Food Safety Research
3 Consortium estimate to get that down to poultry. And
4 then, of course, we use the Economic Research Service
5 which gave us an estimate of how much of the poultry
6 is young chicken. Then we are able to do the
7 calculations that you see there in steps 7, 8, 9 and
8 10, to get down to total foodborne illness from young
9 chickens because, you see, we're trying to attribute
10 it down to something very specific. Next please.

11 Before I move on to talk about the model
12 estimates, I'll just say changes in the number of
13 annual human Salmonellosis cases due to inspection
14 personnel activities were estimated as a function of
15 predicted changes in *Salmonella* prevalence. A
16 Poisson uncertainty distribution was used to
17 incorporate variability in Salmonellosis per year and
18 uncertain about the relationship between changes in
19 prevalence at the establishment level and
20 corresponding number of attributable Salmonellosis
21 illnesses. As I mentioned, the procedures used in
22 this approach were already in the scientific

1 literature from Powell in 2000.

2 For this risk assessment, *salmonella* tests
3 were not delineated because that data wasn't
4 available to do this particular analysis.

5 The overall of what you're getting out of
6 this model is the public health benefit of FSIS
7 personnel performing additional wholesomeness,
8 sanitation, sampling and other offline procedures
9 tailored to mitigate *Salmonella* contamination on
10 poultry.

11 The model showed an association between six
12 types of offline procedures and a decrease in human
13 illness. And these were, if you have increased
14 unscheduled sanitation procedures, increased
15 unscheduled sampling procedures, decreased
16 unperformed sampling procedures, decreased
17 unperformed HACCP procedures, decreased unperformed
18 sanitation procedures and a decrease in
19 noncompliances for sanitation procedures, you would
20 see a public health benefit. And I'm going to
21 illustrate a couple of those. Next slide please.

22 For example, out of those six, here's one

1 of them. If you have a 75 percent decrease in
2 unperformed sampling procedures, i.e. there were more
3 performance sampling procedures, you would see --
4 this model has 20,000 iterations and what you would
5 see is you would see salmonellosis cases would be
6 reduced by 5,482 cases in this particular model. And
7 we're certain of this benefit 85 percent of the time.
8 Next please.

9 Here's another example. If you had a 75
10 percent decrease in unperformed sanitation
11 procedures, you would see salmonellosis cases would
12 be expected to be reduced by 8,592, and that would be
13 95 percent of the time you'd see this benefit.

14 Finally, here's the last example that I'll
15 just show here today. In this model, when you have
16 run the scenario and you have 75 percent decrease in
17 noncompliances for sanitation procedures,
18 salmonellosis cases can be expected to be reduced by
19 2,321 cases when you run the overall 20,000
20 simulations, 65 percent of the model iterations, give
21 you a benefit.

22 A summary for this is an increase in the

1 number of offline inspection procedures is associated
2 with reduced human illness from *Salmonella* on young
3 chicken.

4 A decrease in the number of unperformed
5 sampling, sanitation and HACCP procedures are all
6 associated with an expected reduction in human
7 illness from *Salmonella* in young chicken. Next
8 please.

9 An increase in the number of scheduled
10 sampling, random facility sanitation, and some
11 wholesomeness procedures are associated with an
12 expected reduction in human illness from *Salmonella*
13 on young chicken.

14 An increase in the number of unscheduled
15 sampling and sanitation procedures are associated
16 with an expected reduction in human illness from
17 *Salmonella* on young chicken.

18 And finally, other procedures that we ran
19 which are scenarios in this model did not show that
20 much benefit in terms of the reduction of *Salmonella*
21 in young chicken or improvements in public health.

22 Are there questions?

1 MS. TUCKER-FOREMAN: This is Carol. I have
2 a question if no one else does.

3 MR. TYNAN: We have a few questions here,
4 Carol, but go ahead and ask yours now that you're on
5 the line.

6 MS. TUCKER-FOREMAN: Okay. The -- I feel
7 like I'm shouting at my end. Can you hear me at this
8 voice level?

9 MR. TYNAN: Yes, we can hear you fine.

10 MS. TUCKER-FOREMAN: Okay. I'm going to
11 some of the questions -- let me first clarify,
12 documents that we have in our material for this
13 meeting, has it been peer reviewed?

14 MS. KAUSE: Carol, I think I heard your
15 question. You said has this risk assessment been
16 peer reviewed? And the answer is yes, and I believe,
17 Robert, have you sent the response to peer review
18 comments to everybody on the Committee?

19 MR. TYNAN: I think Mrs. Foreman
20 specifically requested. She has it now, and I'll get
21 it out to the rest of the Committee if you'd all like
22 to see that.

1 MS. TUCKER-FOREMAN: So the document that's
2 in our material has been peer reviewed. The reason I
3 ask this is that there is reference now in the new
4 risk assessment and that you're working on that has
5 not been peer reviewed. So I don't believe that any
6 of us have had access to the new review.

7 MS. KAUSE: Okay. Carol, I do -- this is
8 Janell Kause. I do understand your question, and
9 that's true. The peer review --the response to peer
10 review comments is in response to the initial model,
11 the version that was developed initially. We had it
12 formally peer reviewed and we received comments, and
13 now the model you're looking at is substantially
14 different because of those comments that we received.
15 Rather than go forward and do a second peer review,
16 which when we do it, it's quite -- it takes several
17 months usually do to a really thorough review of a
18 quantitative risk assessment model in order to get an
19 audience and whatnot, we didn't. We instead wanted
20 to, we talked to OMB. We wanted to see stakeholder
21 input first because it would be important to get the
22 stakeholder input and the NACMPI input and other

1 input on this model as well as see if the other data
2 becomes available before we have it peer reviewed
3 because we're going to have another review of this
4 model regardless. So this is one of the options when
5 we were talking to OMB about a peer review. We can
6 peer review it again immediately but knowing that
7 it's going to change again, it makes more sense for
8 us to go ahead and gather your input here today and
9 gather input from others and then do a carte blanche
10 change to the model before it gets peer reviewed.

11 MS. TUCKER-FOREMAN: When do they expect to
12 have that peer review and make the changes?

13 MS. KAUSE: My expectation for the next
14 peer review would be once I get comments back from
15 this Committee, and perhaps once the data becomes
16 available, maybe some of the data we've talked about
17 here today which is line speed data and maybe
18 incorporating the *Campylobacter* data which will also
19 have enumeration data which will allow us to change
20 the model from contamination up to human illness,
21 then I would want to get it peer reviewed.

22 MS. TUCKER-FOREMAN: And when do you expect

1 to have that data?

2 MR. TYNAN: Ms. Foreman's question is when
3 do you expect to have the data?

4 MS. KAUSE: Carol, I'm waiting because I'm
5 looking -- the data that I think we're looking for is
6 based on the baseline data which Michelle is going to
7 speak to.

8 MS. TUCKER-FOREMAN: Well, you mentioned
9 the baseline data but you also mentioned line speed
10 data and enumeration data, and it was my
11 understanding that you can't do the peer review until
12 you have enumeration data, baseline data, line speed
13 data. So when do you expect to be able to begin that
14 peer review?

15 DR. CATLIN: This is Michelle Catlin. With
16 respect to the baseline data, I want to find out, I
17 just did get an update on that this morning. We are
18 currently QC'ing the data from a six-month
19 preliminary data set. The Agency has that data set
20 from the contractors, and we're currently quality
21 checking that to make sure that it's all in there as
22 it should be. So we'll have those data available

1 probably in the next month or so for the six month,
2 and that will include *Salmonella*, Generic *E. coli* and
3 *Campylobacter* data, both prevalence and enumeration,
4 pre-chill and post-chill.

5 MS. TUCKER-FOREMAN: And will that data
6 then be ready to be used for a performance standard
7 or will it have to be peer reviewed and further --
8 before you can check the performance standard?

9 DR. CATLIN: The data itself from the
10 actual samples that were collected, I don't perceive
11 the data themselves having to be peer reviewed, but
12 anything that went into the -- if that was then used
13 in a risk assessment, that risk assessment as Janell
14 pointed out, would be peer reviewed.

15 DR. TUCKER-FOREMAN: And when do you expect
16 to have then a performance standard?

17 DR. ENGELJOHN: This is Engeljohn with
18 Policy. On that issue, Carol, as was pointed out,
19 the Agency is looking at the preliminary data we have
20 now which is now we have six months data that we're
21 actually going to be looking at and using to see what
22 is the outcome of that information, and then make

1 some determinations as to whether or not and when we
2 will be able to begin also collecting *Campylobacter*
3 samples for analysis.

4 The preliminary information could give us
5 some preliminary information about how we could
6 construct a standard and what that might be but again
7 recognizing that that's preliminary information,
8 it's only six months worth of data, and we
9 traditionally go for a full year in order to make
10 sure we have all the seasonal impact, that would be
11 evident in that study.

12 But as quickly as the Agency is able to
13 begin routinely testing its rinse aids for
14 *Campylobacter* as well as *Salmonella* and as we have a
15 preliminary information about what that standard
16 could be, we would begin collecting that information,
17 and I don't have any firm information for you. We
18 certainly are under discussion within the Agency as
19 to how quickly we can begin routinely testing for
20 *Campylobacter*. I would say that at least within this
21 fiscal year, the feasibility of having constructed
22 sampling protocol underway is not likely but we

1 certainly would do what we can to get something
2 started yet this calendar year if at all feasible.

3 MS. TUCKER-FOREMAN: Thank you. So you
4 think you might start a *Campylobacter* -- you might
5 have a *Campylobacter* performance standard in place
6 this year?

7 DR. ENGELJOHN: This is Engeljohn again.
8 In the Agency's expectation with regards to how we
9 issue the performance standard would be similar to
10 what we did with the turkey baseline and standard
11 that we identified as well as modifications to swab
12 versus excision results that could be used for
13 baseline performance standard purposes. We did issue
14 those in the form of a Federal Register notice to say
15 here's what the standard would be based on the data
16 that we had, and that would be the likely scenario
17 that we would use for the *Campylobacter* as well. As
18 soon as we have that information, and we feel
19 comfortable enough to be able to say this is what a
20 preliminary standard would be, our expectation would
21 be to make that available to stakeholders.

22 MS. TUCKER-FOREMAN: When might that be?

1 DR. ENGELJOHN: Carol, again as I said, we
2 have a six month data we're looking at now. We want
3 to go for the full year, but as quickly as we can
4 identify whether or not that would be a good
5 guidepost for us, and as quickly as the Agency can
6 also begin testing *Campylobacter* which we do collect
7 *Salmonella* samples today. Our goal, if at all
8 feasible, will be for that same sample collected for
9 *Salmonella*, would also be used to analyze for
10 *Campylobacter*, then as quickly as we can begin
11 constructing that and making that happen in the
12 laboratories, that would be our expectation.

13 I'm, as a policy person, saying I would
14 hope that we can have something underway, at least a
15 mechanism for making that happen yet this calendar
16 year. Whether or not we can make that happen is
17 another issue, Carol, but we are intent upon
18 beginning to sample for *Campylobacter* in a routine
19 way with our regulatory testing program as we
20 practically and feasibly can.

21 MS. TUCKER-FOREMAN: Okay. I'm going to
22 come back to this during the general discussion. I

1 apologize to the Committee members for taking this
2 time, but again and again and again, over the past
3 two days, and I'm going to talk about it more in a
4 little bit, explore with FSIS the kind of things that
5 seem to state are, in fact, ready to go as part of
6 the new program, are only in the very beginning
7 stages, and that makes a big difference.

8 It brings me back to one of the issues that
9 the peer reviewers raised, and I think that the
10 Agency should make available the peer review comments
11 to every member of the Committee. I hate to take the
12 time to sit here and read some of these things but
13 some of them are very, very important and one of the
14 comments says that while it's laudable, the FSIS is
15 trying to examine the public health impact associated
16 with potential reallocation of USDA inspection
17 personnel in broiler plants. The effort given to
18 characterize in the public health burden associated
19 with the consumption of contaminated broilers is
20 minimal and the estimates are quite accrued.

21 They go on to say that what the general
22 approach was and then to say the attribution

1 estimates which are derived from several sources --
2 estimate. Even the authors of these estimates admit
3 that they are accrued at best. There's no
4 consideration of the response relationship. One
5 cannot assume that more or less -- reduction in human
6 disease will occur as a function of reduced pathogen
7 load, so on and so forth.

8 I don't want you to think that I'm the only
9 one, since I'm not a scientist, who has some
10 questions about the scientific basis for something
11 that's supposed to be risk-based, public health
12 based. It is raised by the peer reviewers -- thing
13 about the *Campylobacter* performance standard, Dan,
14 I'm going to come back to it soon because the Agency
15 is not ready to implement a performance standard for
16 *Campylobacter*. Dan, how old is the performance
17 standard for *Salmonella*?

18 MR. TYNAN: Okay. Mrs. Foreman, I'm going
19 to ask --

20 MS. TUCKER-FOREMAN: -- updated.

21 MS. KAUSE: Carol, this is Janell. I'll
22 response to two parts of that. This risk assessment

1 is designed specifically to look at inspection
2 activities as they relate to public health. So it is
3 not connected to the performance standards. That's
4 something else.

5 Secondly, as you read from the peer review
6 comments, the question about how we could go from
7 contamination on young chicken out to attributable
8 illnesses, because of that comment, the approach that
9 we've taken has radically changed since that comment
10 was made, and Dr. Terry Disney is here, and he can
11 speak to that specifically on how we changed the way
12 we went about doing attribution for that portion of
13 the model because of that peer review comment
14 submitted in February 2006.

15 MS. TUCKER-FOREMAN: But you don't at this
16 time have the new model that Dr. Disney has prepared.
17 It has not been peer reviewed. So you do not know
18 whether the peer reviewers will be any kinder to it
19 than they were to the last one.

20 MR. TYNAN: If I could interrupt.
21 Dr. Disney, if you want to do a quick response to
22 that, and then we need to move on I think to the next

1 topic. So I'm going to ask the other folks that have
2 their tent cards up, not that I'm sure you don't have
3 a good and important question, but if you could hold
4 them until we get into the general discussion, so
5 that we can at least get to Dr. Catlin's presentation
6 on performance standards and then we can have a more
7 global conversation. Terry.

8 DR. DISNEY: This is Dr. Terry Disney. You
9 are correct. There were several things in the
10 original risk assessment that the peer reviewers
11 pointed out, and basically we've been through two
12 additional versions of the model since then. The
13 model is still structurally the same model but we've
14 enhanced the model to address most, if not all, of
15 the comments that you're reading in those peer
16 reviews that you have in front of you right now. And
17 one of the things that you specifically mentioned was
18 the idea of use of point estimates for the
19 relationship between prevalence in the plants and
20 human illness, and actually on one of Janell's
21 slides, she had the calculation of a point estimate
22 for the number of human illnesses that were

1 attributable to young poultry but, in fact, if you
2 read on down to the bottom of that slide, and I don't
3 remember what slide that was, we talk about how we're
4 now using this Poisson stochastic estimation process
5 for building a distribution around that relationship
6 so that we can go in and do that, and that's all
7 incorporated and explained in the current version of
8 the model that you have in one of the appendices.

9 MS. TUCKER-FOREMAN: And this model has not
10 yet been peer reviewed.

11 DR. DISNEY: This model has been peer
12 reviewed. This version has not been peer reviewed.
13 The model's not changed significantly from the
14 original model. The Poisson process itself has not
15 been peer reviewed but it was taken directly from the
16 scientific literature. So it's not a new process.

17 MR. TYNAN: Okay. I'm going to interrupt
18 here and sort of assert myself as the moderator to
19 sort of cut off the conversation. I know you have
20 more questions, Mrs. Foreman, but we're going to hold
21 them until after Dr. Catlin does her presentation and
22 then we can have a more universal discussion about

1 the whole system.

2 Dr. Catlin, I'm going to turn it over to
3 you.

4 DR. CATLIN: Thank you, Robert, and I am
5 going to talk some this morning about performance
6 standards and specifically on the public health
7 related performance standards that are currently
8 under consideration by the Agency for young chickens.

9 You have started to hear little bits and
10 pieces about performance standards already this
11 morning. It's come up in the discussions. So some
12 of this you will have heard already and some of it
13 will be more novel for you.

14 FSIS is currently considering proposing a
15 number of performance standards, either directly or
16 indirectly, related to public health. Those include
17 updated *Salmonella* standards, *Campylobacter*
18 standards, zero tolerance standards for fecal
19 contamination, some standards for septicemic and
20 toxemic animal diseases, and Generic *E. coli*
21 standards.

22 In addition, the Agency is considering

1 other consumer protection performance standards
2 including standards of identify and non-septicemic/
3 non-toxicemic animal disease standards. I am not going
4 to focus on those standards today because those are
5 not directly related to public health. They're more
6 food quality issues. So I'm going to focus today on
7 the public health related standards.

8 The first one I'd like to talk about is
9 *Salmonella*. As most of you would probably
10 understand, we feel the *Salmonella* is a performance
11 standard that is directly related to public health.
12 It is a public health concern, Salmonellosis. So
13 therefore we feel this is a standard directly related
14 to public health.

15 We have an existing performance standard
16 for *Salmonella*. That standard was established
17 relative to national estimates of *Salmonella*
18 contamination and the prevalence of contamination
19 based on a nationwide baseline study that was done.
20 Those standards are expressed in terms of the maximum
21 number of *Salmonella* positive samples per set, and
22 you heard Dr. Engeljohn refer to that earlier today

1 and if you exceed the standard, and you're considered
2 to have failed the set, if you have 13 out of the 51
3 *Salmonella* samples test positive.

4 We are currently considering requiring
5 ongoing establishment testing for *Salmonella*, and
6 we've alluded to this already. We will be
7 reevaluating the performance standard that's been
8 set, that 13 of the 51 and what the standards are to
9 get into the various categories, whether or not you
10 have half of that failed set standard. We'll be
11 evaluating that as we get a currently underway
12 baseline study completed. That's where I mentioned
13 already that we have six months worth of data that
14 we're QC'ing at the moment. We can start
15 reevaluating that standard based on the six months'
16 data and then when we get the complete year data,
17 that would take into account any seasonal variations,
18 we can update those standards based on what the
19 current national prevalence is based on the baseline
20 data. And if that baseline is not completed at the
21 time of the publication of a proposed rule, I want to
22 emphasis proposed, we could either insert the

1 preliminary data that we have from the six months'
2 study as sort of a placeholder for the new standard
3 or we could state that the actual values would be
4 determined.

5 When we move forward with the new
6 *Salmonella* standard, we currently expect to propose
7 that we continue to segregate performance into three
8 different categories, those that are below the half
9 acceptable number of pathogens in the set. So that
10 would be your top-performing category. Those at or
11 above half but less than exceeding the *Salmonella*
12 standards, and those that exceed.

13 When we look at establishment testing, it's
14 anticipated that the frequency of testing by an
15 establishment would depend on the performance in the
16 *Salmonella* standards. So, if they were the worst
17 performing plant, they would have to do more testing.
18 We are also contemplating requiring more frequent
19 establishment testing for those establishments that
20 exceed a certain to be determined threshold for
21 sample sets that contain a high level of serotypes
22 that are common causes of human illness. So that

1 would be those that are on the CDC's top 30 list for
2 human illness.

3 And we're also still considering ways to
4 obtain and use information on subtyping under
5 conditions where the pathogens are not well
6 controlled.

7 *Campylobacter*, you've heard a lot of
8 interesting *Campylobacter* today, and one of the
9 reasons is because *Campylobacter* performance
10 standards would be the ones that would be directly
11 related to public health. As Ms. Foreman has
12 mentioned on the phone, *Campylobacter* is a human
13 health concern and therefore this is directly related
14 to public health.

15 The performance standard is expected to be
16 established using the data that we're currently
17 collecting in the young chicken baseline. That's
18 what I've already told you about already, that's
19 currently underway. We're getting the data as we
20 speak. It has information on *Campylobacter*, both
21 prevalence and enumeration data. So we'll have the
22 information to develop performance standards.

1 As with *Salmonella*, it is thought that if
2 the baseline isn't completed by the time of
3 publication of a proposed rule, we could either use
4 the preliminary data that we get from six months or
5 we could state that the actual values will be
6 determined when we get the final information in.

7 As with *Salmonella*, FSIS is considering
8 requiring ongoing establishment testing for
9 *Campylobacter*, and we expect to propose a
10 quantitative performance standard for *Campylobacter*,
11 not based on presence or absence.

12 With respect to *Campylobacter*, same story
13 as with *Salmonella*, we expect to propose to segregate
14 the performance standards into three categories.
15 They're not standards but establishments into three
16 categories based on the performance standards. Those
17 that are below half the acceptable number of
18 pathogens in this set, those that are above half but
19 not exceeding their set values, and those that exceed
20 it.

21 The frequency of testing once again would
22 likely depend upon which category the establishment

1 falls into based on their data and FSIS testing data.
2 And as with *Salmonella*, we're considering ways to
3 obtain and use information on subtyping.

4 With respect to fecal contamination, fecal
5 contamination is considered a major vehicle for
6 spreading pathogenic microorganisms, and therefore we
7 do feel that this performance standard is directly
8 related to public health.

9 Current regulations states that poultry
10 carcasses with visible fecal material should be
11 prevented from entering the chill tank. We are
12 currently considering proposing to continue that
13 performance standard, that there be no visible fecal
14 matter on young chicken carcasses before they enter
15 the chilling tank.

16 With respect to septicemic and toxemic
17 animal diseases, once again, we do believe these are
18 directly related to public health and that is because
19 septicemic and toxemic poultry carcasses are likely
20 to contain infectious agents that could be
21 transmitted to humans. Therefore, they're a public
22 health concern.

1 Currently under our regulations, FSIS
2 inspection program personnel are responsible for
3 condemning all toxemic and septicemic poultry
4 carcasses and consistent with that regulation, FSIS
5 is considering proposing that the establishments
6 operate under the new system to meet a zero tolerance
7 for septicemic or toxemic poultry carcasses prior to
8 the chilling tank.

9 Generic *E. coli*, generic *E. coli* are
10 enteric bacteria that can be found or are found in
11 the intestines of animals and are associated with
12 fecal matter. The presence of generic *E. coli* at
13 high levels indicates presence of intestinal
14 material, or filth, and therefore it is a measure of
15 sanitation. Now, although this is not a direct link
16 to public health, we do think that this indication of
17 sanitation and the presence of intestinal material is
18 an indication that is indirectly related to public
19 health.

20 And also, so the presence of generic *E.*
21 *coli* at the end of the chilling process or at the end
22 of the slaughter line could indicate the efficacy of

1 microbial processes in place and be indirectly linked
2 to public health concerns.

3 Under our current regulations, poultry
4 slaughter establishments must sample whole carcasses
5 and test for generic *E. coli* at the end of the
6 chilling process, or if that's impractical, at the
7 end of the line.

8 Now, we've looked at some data that was
9 developed in an ARS study they worked on with us, and
10 the results of those analyses are actually presented
11 in Appendix F of the poultry slaughter report, and I
12 warn you, it's heavy duty statistics. We had some
13 very good statisticians working on that and they
14 delved deeply.

15 But the results of that do indicate that a
16 log reduction in *E. coli* is correlated to a log
17 reduction in *Salmonella* and a log reduction in
18 *Campylobacter*. Now, quite often you'll hear that
19 there is no direct relationship between generic *E.*
20 *coli* and *Campylobacter* or *Salmonella* and we're not
21 saying that there is in this case an absolute one-to-
22 one relationship between those organisms. However,

1 if you look at the reduction of those organisms pre
2 and post-chill, there is a correlation between the
3 reduction you get in generic *E. coli* and the
4 reduction you get in *Salmonella* or *Campylobacter*.
5 And that tells us that that can be an indication as
6 to how well you are controlling not only generic *E.*
7 *coli* by looking at generic *E. coli* but how you're
8 also controlling those other organisms that are
9 directly related to public health.

10 Therefore, we are considering having new
11 performance standards for generic *E. coli* that would
12 reflect those sanitary conditions. We are
13 considering requiring ongoing establishment testing
14 for generic *E. coli* at two points in the process,
15 both at rehang and post-chill, so pre- and post-
16 chill, and that we also are considering specifying
17 performance standards for measured levels of *E. coli*
18 at those two levels as well as the reduction.

19 The incidence and levels of generic *E. coli*
20 at those two sites is currently being measured in our
21 baseline that's currently underway. This is one
22 you've heard about before, where we will have six-

1 month interim data. So we'll have more data to do
2 analyses on, and we'll be looking at the data we get
3 from the baseline and doing similar analyses as what
4 we've done for the data that we have from ARS, so
5 that we will be able to take the data from ARS and
6 determine whether or not it holds true, the results
7 hold true on a much broader amount of data, a much
8 greater amount of data.

9 When we look at the baseline data, we want
10 to establish a performance standard. If we do not
11 have the baseline data as with the other ones, if
12 it's not completed by the time of publication of the
13 proposed rule, we could propose numbers using the
14 interim data from the six months or we could have it
15 be determined.

16 As with the other two pathogens or with the
17 two pathogens, not the other two pathogens, we expect
18 to segregate performance into three categories, same
19 as before, those below half the acceptable number of
20 pathogens, those at or above but less than exceeding,
21 and those that exceed. And the frequency of testing
22 by the establishment would likely depend upon which

1 category the establishment falls within based on
2 their data and FSIS data. Questions?

3 MR. TYNAN: For this round, I'm going to
4 start with the people here in the room, and then I'll
5 come back to you, Mrs. Foreman, if you have any
6 comments or questions. We have two parts now. So
7 we're sort of getting clarifying questions related to
8 performance standards, and then we can have a broader
9 discussion of the entire concept. So, if we could
10 for just a moment focus on the performance standards,
11 and then we'll flip over and talk about everything
12 we've discussed previously this morning.

13 Mr. Kowalcyk, I'll start with you.

14 MR. KOWALCYK: Yes. Can you discuss a
15 little bit about how the Agency is going to determine
16 the acceptable level in developing the new
17 performance standard? Can you elaborate on that? I
18 mean it says half the acceptable level. How is that
19 acceptable level going to be determined?

20 DR. CATLIN: Well, we want to look at the
21 data from the baseline to get more information and
22 confirm what we've seen in the ARS study, but there's

1 a lot of analyses in Appendix F, if I remember
2 correctly, that show what types of reductions you're
3 getting from your generic *E. coli* and how they
4 correlate to reductions in *Campylobacter* and
5 *Salmonella*. So we could tie the reduction in generic
6 *E. coli* to the levels that you would be getting
7 corresponding -- the corresponding reductions you
8 would get from the pathogens and sort of have it
9 linked up to the other standards that way.

10 MR. KOWALCYK: Okay. But for any of the
11 pathogens, like currently it's 13 positives out a
12 sample set, is that going to change and if that is
13 going to change, how are you going to determine what
14 it should be?

15 DR. ENGELJOHN: This is Engeljohn. The
16 construct of the original performance standards for
17 broilers, as an example, was based on a national
18 prevalence baseline study, and to make it very
19 simple, because it's a complex issue, but to be
20 simply said, the standard was established in essence
21 the average was, for the industry, at that time with
22 regards to *Salmonella* control. So at that time, it

1 was the national average with some statistical
2 parameters around it which is in essence established
3 that if you were performing at the standards, there
4 was an 80 percent likelihood that you would pass. So
5 there's a construct around it which gave us the
6 measures as to how many positives would be in a
7 sample set, how large the sample set had to be from a
8 practical perspective, and then how many positives
9 were in that. So that same construct is what the
10 Agency's intention is to do with the design of this
11 baseline study. So we can certainly make more
12 information about how the original baseline was
13 established but to also be simple on this, the new
14 baseline, if it happens to be at a lower level,
15 national lower level than what was present in 1996 or
16 so when that standard was established, and we do
17 believe that it will be lower, then the new criteria
18 for the sample set likely would be constructed in the
19 same way, such that I would imagine we would stay
20 with the same sample size but the number of
21 acceptable positives would change as a consequence of
22 there being a lower standard established. Okay.

1 MR. TYNAN: Dr. Rybolt.

2 DR. RYBOLT: Thanks, Robert. Dr. Catlin, I
3 want to go to the discussion about the categorization
4 for all, I guess all three of them, *Salmonella*,
5 *Camphy* and *E. coli*. The current categorization
6 scheme, as I recall, was based on a risk assessment
7 or an assessment I guess of the data that the Agency
8 conducted and directly related to or related to
9 public health outcome. I believe Dr. Altekruse
10 presented this at the February '06 public meeting.
11 Will the Agency, when they redo the performance
12 standard, recreate the categories, will there be the
13 same risk assessment done on assessment or will there
14 just be a cut as you've outlined up here half the
15 performance standard, and will that relate to public
16 health, similar to what Dr. Altekruse presented?

17 DR. CATLIN: What we'll be doing is we'll
18 be looking at the data from the baseline and looking
19 at it and examining it in the context of the risk
20 assessment that's been previously done. If the data
21 is so different that it warrants updating the risk
22 assessment, we'd do that, but if not, we would be

1 able to use the same risk assessment.

2 DR. ENGELJOHN: This is Engeljohn. I would
3 just also offer that part of the design of the
4 categorization for the performance standard was to
5 ensure that we had a mechanism in place to
6 continuously have improvement for control over the
7 pathogens. So by establishing -- in our case, we
8 established three levels for reasons which were --
9 the analysis indicated that there would be
10 appropriate breaks at those measures. But now that
11 we would have more and better information, a risk
12 assessment could inform us differently as to how to
13 establish those categories but the construct for the
14 Agency is that by putting establishments into
15 categories, and by identifying a goal of moving the
16 establishments into Category 1, forces there to be
17 continuous improvement for control, and that will be
18 the construct that we go forward with in the new
19 approach.

20 MR. TYNAN: Mr. --

21 DR. RYBOLT: Will the --

22 MR. TYNAN: I'm sorry.

1 DR. RYBOLT: Is it okay?

2 MR. TYNAN: No, no, please follow up.

3 DR. RYBOLT: If it is redone, will this
4 Committee have the opportunity to review that, the
5 risk assessment or make the risk assessment available
6 fully. I think during the Subcommittee, I think, I
7 shared the PowerPoint from Dr. Altekruse, and I'm
8 just making sure, in the interest of public health,
9 we're doing this for the right reason.

10 DR. CATLIN: Yeah, they would be made
11 public and be reviewed.

12 MR. TYNAN: I apologize for interrupting
13 you. Mr. Covington.

14 MR. COVINGTON: No, it's -- because I think
15 Dr. Rybolt had asked basically my question which was
16 how does the risk assessment that was performed to
17 determine the *Salmonella* breakdown for broiler
18 establishments applied to *Campylobacter* and now
19 generic *E. coli*?

20 And my last question is a very simple one.
21 The slide set indicated it. Is generic *E. coli* now
22 considered a pathogen?

1 DR. CATLIN: No, it shouldn't have said
2 that. It's considered an indicator of the other
3 organisms and an indicator of process control.

4 MR. TYNAN: Dr. Bratcher?

5 DR. ENGELJOHN: If I could just because I
6 know the question will come up, so I may just as well
7 identify the issue. The Agency is well aware that
8 infectious processes and other things do affect the
9 level of generic *E. coli* in carcasses, and that will
10 be accounted for in the Agency's design of its
11 construct for how we would do enforcement or lay
12 forward that strategy but again the issue is we know
13 there's some correlation there as well but that will
14 be accounted for.

15 MR. TYNAN: I'm sorry. Dr. Bratcher.

16 DR. BRATCHER: On slide number 8, on the
17 last bullet, you state that you're going to have a
18 zero tolerance for septicemia/toxemia in the plants.
19 That brings into question who's going to make the
20 final determination on the birds that are appealed or
21 questioned by either the plant or by the inspection
22 team in the plant. And I would assume that that

1 would be made by the veterinarian, the Ph.V. in the
2 plant, but you need to also consider that with the
3 staffing that we have now, it's not uncommon that the
4 veterinarians are double covering in a lot of these
5 plants, or if they're out doing their 25 percent
6 tasks like EIAO work, EIO trained Ph.V.'s, that we
7 may not have a veterinarian in the plant when these
8 issues come up.

9 DR. ARRINGTON: We would still have the
10 veterinarians making final determination of the --

11 MR. TYNAN: Mrs. Foreman, do you have any
12 comments or questions regarding the performance
13 standards?

14 MS. TUCKER-FOREMAN: I did but I think that
15 I'd prefer to just let the group go into the general
16 discussion because I've taken so much time.

17 MR. TYNAN: Okay. Well, why don't we do
18 that. Did you have some comments for the general
19 discussion? You can start us off with that. I don't
20 see any further questions on the performance
21 standards.

22 MS. TUCKER-FOREMAN: Yes, I do. To start

1 off, I did not hear Carol Maczka say this morning
2 that the Agency heard, she was talking about things
3 that we had heard yesterday. I did not hear her say
4 that the Agency had heard our concern about calling
5 these risk and public health based -- in the absence
6 of underlying basic public health data especially on
7 *Campylobacter* in poultry. That was specifically part
8 of our recommendation yesterday. I'd like to know
9 that the Agency did hear that.

10 MR. TYNAN: Yes, we did. Carol is
11 confirming that.

12 MS. TUCKER-FOREMAN: I know you don't have
13 to follow our recommendations, but I wanted to be
14 sure it had been heard.

15 MR. TYNAN: Okay. We did hear you.

16 MS. TUCKER-FOREMAN: We support, Consumer
17 Federation of America supports the concept of
18 reorienting inspection so that it's based on risk and
19 public health. In order for us to support this --
20 don't have to have perfect data but we have to have
21 sufficient, high quality data that are not tainted by
22 questions of credibility before we will support the

1 Agency going forward. We do believe -- I believe
2 deeply that the unintended negative consequences come
3 out of regulatory programs that are driven forward on
4 some calendar that is not related to the one that is
5 being stated -- again and again and again has been
6 shown through history to be a disaster when it gets
7 out into the field and I think that that is a big
8 problem that I am having here with the Agency, to
9 understand. We've got a timeline from the Agency --
10 that comments, the documents that were published in
11 the Federal Register a couple of weeks ago have to be
12 filed with the Agency by the end of this month. That
13 is less than three weeks away. It means that the
14 Agency -- I mean that in itself, considering the
15 amount of data that the Agency has put online, is
16 just shocking. Some -- may not think that we're
17 going to read the technical report, but that's not
18 true. The people who really care about this deeply
19 and want to comment in detail, have to go through
20 these thousand pages of documentation and the Agency
21 is expecting us to do that in a matter of a few
22 weeks. It's truly not acceptable. We will ask for

1 an extension on that.

2 This also means the Agency intends to have
3 a proposed rule on poultry slaughter completely
4 written and submitted for Agency review within the
5 next month. How can they possibly consider any
6 comments that they get from the public and have the
7 rule ready to go for Agency review in the next month?
8 The timeline that we were given yesterday assumes
9 that all work on the risk-based inspection on
10 processing will be complete next month and will go
11 through all clearances the end of the summer. How
12 can the Agency consider the information that it's
13 gotten from comments the last two days and deal with
14 our recommendations and go through all the public
15 comments and consider them and still have this done
16 by the end of summer?

17 Also the schedule that's been put out means
18 that the Agency is going to go forward without any
19 comments from the National Advisory Committee on
20 Microbiological Criteria for Food -- because you have
21 to have something ready to go in a month and finish
22 it by the end of the summer and have those comments.

1 The Agency, as has just been acknowledged, is going
2 to go forward with a proposed rule absent the new
3 baseline, any baseline data on *Campylobacter* and
4 without performance standard -- without any baseline
5 data, new baseline data on *Salmonella* in poultry.

6 MR. TYNAN: Mrs. Foreman, could I interrupt
7 for just a moment so we don't lose some of your
8 thoughts. We have some folks that would like to
9 respond, and I'm going to ask Dr. Maczka to maybe
10 begin and then Dr. Engeljohn, if he could join in.

11 DR. MACZKA: Yeah, I did want to make the
12 comment, and I think I made it yesterday, that the
13 timeline that we put out is draft, and we're more
14 than -- we realize that we may have to revise that
15 timeline. We also are more than happy to extend the
16 comment response period so that we can get all the
17 important comments and give you sufficient time to
18 review the materials. And I think, Dr. Engeljohn,
19 did you want to say something?

20 DR. ENGELJOHN: Yes. This is Engeljohn.
21 To also add onto what Carol Maczka just added was
22 that the -- again, the information that the Agency is

1 receiving through this public meeting informs us as
2 to how to construct and develop the rulemaking that
3 we do intend to continue to develop, and because a
4 rulemaking is an extraordinarily complex issue, that
5 has multiple facets to be dealt with, the issue is to
6 get this into the public forum, get comments such as
7 we're doing with this Committee, then get it into the
8 development so that the concepts of what we are
9 proposing are adequately flushed out so that they can
10 be presented in the form of a proposed rule. It's
11 a proposed rule, not a final rule. So it does
12 provide additional opportunities for the public's
13 input, and that's -- the intent of the Agency is to
14 get this information out, get feedback so that we can
15 make modifications where we can and we have, and
16 we'll continue to do so as we develop this particular
17 rulemaking.

18 MS. TUCKER-FOREMAN: If I could just make
19 one more comment, then I will get off or be quiet
20 here for a while. It is an experience based on more
21 years than we want to talk about -- Agency puts out a
22 proposed rule, has strongly committed to a specific

1 course of action and the assumption within the Agency
2 and within the Court is that the Agency has made a
3 decision and has the data to support the decision and
4 the burden for changing that decision is on the
5 commenters and it has to overcome a burden that
6 presumes that the Agency knew what it was doing when
7 it put out the proposed rule and is one -- with the
8 particular line of thinking. There is very little
9 room for change after a proposed rule is made.

10 I think, given the nature of -- given the
11 uncertainty level and the lack of information, that
12 is a far more appropriate course of action would be
13 for the Agency to lay out the technical plan and
14 these data and say in the form of an advanced notice
15 of proposed rulemaking, so that you have a formal
16 process for collecting all of the comments and that
17 you say to the Agency is -- to hearing other ways to
18 proceed. History and Court cases will show there
19 doesn't get too much change between proposed rules
20 and final rules and I would think that advance notice
21 is a far better way.

22 The problem is that I have now said that to

1 FSIS at least four times since we've been working on
2 the Data Subcommittee four months ago.

3 My final comment is I'm really disappointed
4 in the changes that have been made as a result of the
5 time and consideration given to these issues, under
6 great time pressure by the Agency over the past four
7 months. What I have seen so far is rebuttal
8 suggestions that came out of the Subcommittee -- what
9 we were suggesting was not relevant to what you're
10 doing. That does not give one much hope that the
11 Agency is open to comments in a proposed rulemaking.
12 I really think it's important to go back and --
13 because you are already committed to a course of
14 action that any of us take is not supportable.

15 MR. TYNAN: Okay. Carol, I'm going to
16 allow Dr. Maczka to respond.

17 DR. MACZKA: Well, I just did want to make
18 one more comment that I didn't make the last time I
19 spoke which is that we actually have been talking to
20 the National Academy of Sciences about bringing some
21 of the issues forward to them, such as issues on
22 attribution and just other targeted issues. So we

1 have started talking to the Board of Environmental
2 Studies and to IOM about some of the issues which
3 we'd like to engage them in.

4 MR. TYNAN: Dan.

5 DR. ENGELJOHN: Just one short follow up
6 from Engeljohn to address the issue of -- because
7 Carol has raised the issue about the National
8 Advisory Committee for Micro Criteria for Foods.
9 This Committee, several committees ago, or charters
10 ago, did ask that an issue go forward to the National
11 Advisory Committee for Micro Criteria for Foods. It
12 was specific to *Campylobacter* in which this Committee
13 asked the Micro Committee to provide guidance back on
14 utility of *Campylobacter* and the relationship with
15 *Salmonella*. The National Advisory Committee for
16 Micro Criteria for Foods did do that and has since
17 taken on a number of other issues related to the
18 construction of the performance standards that the
19 Agency develops for pathogens, specifically focused
20 on *Salmonella* but as well more recently on the
21 methodology that we would use for *Campylobacter*. So
22 we have taken those issues under advisement in that

1 Committee and the Committee has provided back
2 recommendations to the Agency which to the maximum
3 extent practical and feasible, we did incorporate
4 their guidance into the design of the document, and
5 we'll continue to do so as that Committee provides us
6 guidance.

7 MR. TYNAN: Okay. Dr. Bratcher, you had a
8 comment or a question?

9 DR. BRATCHER: My comment was on the first
10 presentation, again on slide number 8, and if you
11 look at that, number 3, step number 3, there is an
12 under reporting multiplier from CDC and in your
13 presentation you said that that was from 1999. I'm
14 not sure. I guess the question I have is we're
15 almost 10 years out from 1999, and there are a number
16 of veterinarians that work at CDC and I know there's
17 been a lot of discussion about under reported cases
18 and that multiplier, and I thought they had changed
19 the multipliers for all foodborne illnesses, maybe
20 they haven't, but I know that discussion is taking
21 place because they feel the medical profession is
22 doing a much better job of reporting the cases than

1 they had been in the past.

2 So has that multiplier changed not only for
3 this, for *Salmonella*, but for some of the other
4 foodborne diseases that we are doing or working with
5 now? And, two, if it has, then that's going to
6 drastically affect the bottom line or the number of
7 cases that you're going to have that you say are
8 being eliminated by changing the inspection
9 methodology.

10 MR. TYNAN: Is this the slide you were
11 referring to, Dr. Bratcher?

12 DR. BRATCHER: Yes, it sure is. Number 3,
13 under reported multipliers 38.

14 MS. KAUSE: Thank you very much. You're
15 absolutely correct. CDC is supposed to come up with
16 new multipliers. They have not released them yet.
17 I've talked to CDC just last week about that. They
18 should be releasing them fairly soon. I think I'll
19 let Dr. Disney respond to how that might impact the
20 results.

21 DR. DISNEY: Well, I think there's no
22 question that it could impact the results but I don't

1 think the impact would be as drastic as you might
2 suggest that it would be. I mean that's just one of
3 the factors that's going into this calculation. It's
4 true the point estimate might change somewhat from
5 the 424,000 that's there now, but by the time we run
6 that through our uncertainty distribution, we
7 wouldn't see big changes I don't think. That's just
8 my first inclination but, yeah. I mean this model is
9 designed to change that assumption at anytime and
10 stick a new number in there and see how it would work
11 out. So I agree. I think it might change it
12 slightly but I don't think the changes would be that
13 significant.

14 MR. TYNAN: Dr. Catlin, you had a comment?

15 DR. CATLIN: Yeah, and I'm sorry, this
16 actually addresses something that Ms. Foreman said
17 earlier. I don't want people being left with the
18 impression that we're totally ignoring everything
19 that the Subcommittee has said to us because we have
20 actually made a number of changes in response to some
21 of the comments that they made, and some that just
22 came to our minds where we did take suggestions, that

1 we reorganized the report a little bit and separated
2 out the public health based performance standards
3 from the non-public health performance standards. We
4 also provided data on the algorithm runs and that was
5 a direct response to comments made. We also changed
6 the layout of the prompts to make them easier to
7 understand, and we clarified some of the information
8 on performance standards in response to comments that
9 were made.

10 So I didn't want people to be left thinking
11 that we were totally ignoring everything that was
12 said because we have been modifying it in response to
13 comments made from the Subcommittee the same way we
14 modified from the previous risk-based inspection
15 algorithms that were presented based on stakeholder
16 input.

17 MR. TYNAN: Okay. Thank you, Dr. Catlin.
18 Earlier I know there were a series of questions we
19 had on one of the topics and unfortunately it does
20 not come to me, and I cut you all off. So you
21 apparently remember the questions. Okay. So I will
22 ask maybe to raise those questions at this time, and

1 I'll start with Dr. Murinda.

2 DR. MURINDA: My question was with
3 relevance to that very same slide. So it's
4 convenient but it's still out there. We are using
5 terms like incidence and prevalence. Can you
6 distinguish the meanings of those terms? Myself, I'm
7 a microbiologist. Those terms have very disparate
8 meanings. When we talk about prevalence data, we are
9 essentially talking about how many samples out of so
10 many samples, say 10 were positive. Incidence data
11 deals with prevalence over timeframe of a year. So
12 are you distinguishing the type of information you
13 are, you are getting -- the types of information you
14 are getting from the literature here when you analyze
15 the attribution data to formulate your observations?

16 DR. ENGELJOHN: This is Engeljohn, and I'll
17 take the first stab at that, and then Dr. Disney, if
18 there's additional issues related to this particular
19 slide that you raised.

20 And from a practical perspective, from the
21 Agency, when we talk about prevalence, generally we
22 are talking about either a national baseline study

1 where we're looking for its incidence, the presence
2 of the organism in a sample we collect and it's
3 level. So we have prevalence related to that.

4 Incidence oftentimes gets confused there as
5 well because it depends if we're talking about
6 regulatory samples. So we generally look at a
7 percent positive rate just so we don't use the term
8 incidence or prevalence, but generally if we're
9 talking about a baseline study, we are talking about
10 prevalence because we're looking for its true
11 presence in the sample population that we're looking
12 at and at its level.

13 For purposes of this disease attribution,
14 the incidence relates to the CDC data and the number
15 of cases that are associated with it.

16 DR. MURINDA: So timeframe is not a
17 component of that analysis?

18 DR. DISNEY: The timeframe in this case is
19 annual I think for the incidence in terms of human
20 illnesses and for the prevalence numbers,
21 specifically in this risk assessment, we're talking
22 about prevalence based on monthly data.

1 DR. MURINDA: Oh, okay.

2 DR. DISNEY: So in the case of the human
3 illnesses that you're looking at here on this slide,
4 we're talking about an annual incidence rate for 2003
5 but when we talk about prevalence in the model, we
6 have monthly observations on prevalence, and we
7 calculate it as a percent.

8 DR. MURINDA: That answers the question.

9 MR. TYNAN: Does that respond to your
10 question, Dr. Murinda?

11 DR. MURINDA: Yes. Thank you.

12 MR. TYNAN: Okay.

13 MS. TUCKER-FOREMAN: This is Carol again.
14 Could I ask a question that just arose?

15 MR. TYNAN: Well, yes, if it's a follow-up
16 to that one, sure.

17 MS. TUCKER-FOREMAN: And to Dan's comment.
18 My recollection is that the performance standard for
19 *Salmonella*, and I know I'm going to be mixing apples
20 and oranges here a little bit, but the performance
21 standard for *Salmonella* that was set up seven years
22 ago is not really public health based. It was set up

1 based on an industry average of ability to exercise
2 best control. *Salmonella* was used, the indicator of
3 whether or not the industry, a plant was controlling
4 its process. There are not to my knowledge any real
5 data that say that the performance standards at that
6 level has reduced *Salmonella* and *Campylobacter*. I
7 know that that's been claimed before but, in fact,
8 the CDC says that since 2001 there hasn't been any
9 improvement in *Campylobacter* and the *Salmonella* has
10 been up and down all through this period.

11 So I think it's important. Am I
12 misunderstanding something here because I know that
13 was the history of the current performance?

14 MR. TYNAN: Dr. Engeljohn, can you respond
15 to that?

16 DR. ENGELJOHN: I can. Thank you. Yes,
17 Carol, you're exactly right in terms of how the
18 standard was originally set and the Agency's
19 expectation is to continue to use that construct for
20 establishing the standard, although we take input on
21 that and make some decisions about that. But the
22 Agency also has established the categorization

1 whereby we're moving establishments into the lower
2 percentile of percent positive rates and using the
3 best available attribution data that we have to make
4 some decisions about what is the public health impact
5 of establishments performing at the different percent
6 positive rates.

7 So unlike what was originally done when
8 this HACCP pathogen reduction rule was issued where
9 we did not have the type of data that we have today,
10 it was based on an assumption that if we simply
11 reduced exposure to the public of a pathogen, in this
12 case, *Salmonella*, that it would likely have some
13 public health impact. The Agency's goal is to
14 demonstrate that by constructing the performance
15 standards and the mechanism of moving establishments
16 into continuously better control for that, and
17 continuously resetting those performance standards
18 with new baselines over time, that we will, in fact,
19 be able to demonstrate a public health effect from
20 the construct of our inspection systems. So that's
21 what this system is designed to actually demonstrate.

22 MS. TUCKER-FOREMAN: Thank you.

1 MR. TYNAN: Okay. Mr. Stromberg, you had a
2 question.

3 DR. STROMBERG: Yes. My question goes back
4 to the presentation on risk assessments. Several
5 points in that presentation, the statement was made
6 that increased sampling activities would reduce human
7 illness from *Salmonella*. Could someone provide me
8 with the rationale or the thought process for this
9 assumption?

10 DR. DISNEY: Well, what basically the model
11 says is that there is an association between the
12 microbial load in the plant and the number of samples
13 that are taken in the plant. And when you say that
14 it would -- we're not establishing a cause and effect
15 relationship here. We're just going to the point of
16 saying there is an association in the data between
17 the observation that we get on microbial
18 contamination and the number of samples that are
19 taken.

20 So, if you could imagine walking into the
21 plant, taking a snapshot over a period of a month,
22 what were we doing in the plant? What were the

1 microbial samples looking like coming out of the
2 plant? And basically what the model does is it
3 allows us to make that association for any pair of
4 variables.

5 So in this case, I want to be careful to
6 say we're not going to the extent of saying cause and
7 effect. There is no cause and effect relationship
8 here. We're just observing an association.

9 DR. STROMBERG: So the result would be more
10 from intervention as a result of the increases
11 sampling rather than you're not stating that
12 increased sampling in and of itself is going to
13 reduce illness?

14 DR. DISNEY: That's correct.

15 DR. STROMBERG: Okay. That's good.

16 MR. TYNAN: Mr. Kowalcyk.

17 MR. KOWALCYK: Thank you. I have a couple
18 of questions about the risk assessment as well, and
19 it follows along the lines of the sampling. There's
20 two classifications of sampling. You have scheduled
21 and unscheduled and the models are indicating that
22 there's an association of increasing both of those,

1 has a positive relationship with your dependent
2 variable. Can you explain a little bit in more
3 detail the difference between a scheduled sample and
4 an unscheduled sample? I'm trying to understand the
5 difference between the two.

6 DR. DISNEY: I can explain it from my
7 perspective and then maybe I could ask someone down
8 here for more of a plant perspective. As far as
9 modeling goes, as I understand it, the scheduled
10 procedures are those procedures that are on the
11 books. I mean the inspector knows that he's going to
12 be going into that plant and on a regular basis he's
13 going to be checking this, this, this and this, this
14 many times. The unscheduled procedures are scheduled
15 more based on the individual things that are going on
16 in that plant, and they may not be on the long-term
17 schedule, but I think Isabel might be able to answer
18 that a little more directly.

19 The idea is that the scheduled procedures
20 are scheduled well in advance and the unscheduled
21 procedures might be based on something that's
22 occurred in the plant or something that wasn't --

1 MR. TYNAN: I saw Dr. Arnold come up to the
2 table. So I think she probably wants to respond to
3 that question as well.

4 DR. ARNOLD: I have a lot of experience
5 working with the current PBIS system. So I think I
6 can assist in answering that. There are certain
7 parameters that are built in currently to the
8 Performance Based Inspection System that schedules
9 the public health procedures at certain frequencies.

10 It also schedules certain of the other
11 consumer protection procedures as well. There are
12 also what are called each occurrence procedures which
13 are not scheduled, and so the system is going to take
14 into account, as indicated, those procedures that are
15 scheduled and those procedures that are each
16 occurrence but in addition to that, inspection
17 personnel also have the flexibility to perform
18 unscheduled procedures. So, if in the case of an
19 establishment, where there may be food safety
20 concerns, an inspector can decide that they want to
21 perform an additional food safety related
22 procedure, and this often occurs with establishments

1 that are working overtime. And so they're producing
2 product. There are no scheduled procedures during
3 overtime hours. So you may see a lot more
4 unscheduled procedures in those establishments that
5 are producing more product because they're working
6 more hours, and that's how we, you know, consider
7 those procedures. Does that answer your question?

8 MR. KOWALCYK: Yeah, well, I'd like to
9 better understand the actual mechanism for collecting
10 the sample, when it actually happens. Is it the same
11 or is there something different about how an
12 inspector or somebody from the Agency goes into that
13 plant and harvest a sample, is that mechanism the
14 same in these two circumstances, and the only
15 difference is how they're scheduled and the frequency
16 of the schedule?

17 DR. ARNOLD: Okay. So actually what you're
18 talking about directed samples which there's a
19 specific procedure code for that, that's used which
20 is actually the 05B02, which is when samples are
21 directed from Headquarters, and those samples,
22 depending upon what type of sample it is, if let's

1 say it's ready to eat plant, there's several
2 different sampling frames that contain the
3 establishments that may produce that type of product,
4 and OPHS in concert with ICIO, the lab sample data
5 management staff, well, then there's an algorithm
6 depending upon like the sampling program is, that
7 they utilize and then those plants that are in that
8 frame are then randomly selected because most of
9 these are random programs, and then the forms are
10 sent to the establishments where the inspectors are.
11 They're producing those specific products.

12 So, if they're producing raw ground beef
13 for example, currently in the PBIS profile, we have
14 an indicator that tells us that that plant needs to
15 be in the sampling frame because they're producing
16 that product that's subject to that sampling frame.
17 So as a random list, a certain number of plants are
18 selected each month to be sampled. Those forms go
19 out and then the inspection personnel have a window.
20 There is on the form a certain window in the case of
21 the *E. coli* 0157 sampling program, that we currently
22 have, the window is 30 days. So over that 30-day

1 period, they are instructed through our current
2 directives to randomly sample. Does that help?

3 MR. KOWALCYK: Yes.

4 MR. TYNAN: I see Mr. Painter down there.
5 We have Dr. Bratcher and Mr. McKee, all of people
6 with field experience. So I don't know if I can see,
7 Stan, you wanted to make a comment?

8 MR. PAINTER: Yeah, Stan Painter with the
9 National Joint Council. I'm an inspector myself and,
10 you know, it was clear that Michael Kowalcyk raised a
11 good question and people went to scrambling over
12 here. There are no unscheduled *Salmonella* sampling.
13 The inspectors in the plants and the supervision in
14 the plants receive a foam insulated box with your
15 bag, with your peptide solutions, with your sample
16 cups, things of that nature. You can't take an
17 unscheduled sample. You have to wait on the lab to
18 send you those things and then once you receive your
19 supplies, then you can take the sample. But it's
20 clear from this side of the table that the Agency is
21 trying to say there's an unscheduled sampling when
22 there is no unscheduled *Salmonella* sampling.

1 Yes, there's unscheduled other tasks but in
2 my 22 year career, and I was in the field in the
3 beginning of the *Salmonella* sampling, I have never
4 saw one unscheduled sampling because you do not have
5 the supplies.

6 MR. TYNAN: Mr. McKee.

7 MR. McKEE: We may be dealing with
8 semantics to some extent. While the bulk of samples
9 are generated and asked for by the computer, if in-
10 plant personnel have a sense that sampling needs to
11 be increased, they can request it and get additional
12 forms and supplies. So in that sense it would be an
13 unscheduled sample. So we do have latitude to
14 request that increase at the in-plant level.

15 MR. TYNAN: Dr. Arnold, did you want to
16 comment again?

17 DR. ARNOLD: Yes, I'd like to further
18 clarify my comments because we're actually talking
19 about a different procedure code. In this case,
20 we're talking about the 05A03, which relates to the
21 *Salmonella* performance standard collection which is
22 on each occurrence and it is not scheduled. The

1 inspector when they collect the sample will actually
2 mark and add it to their schedule that they performed
3 it by indicating a performed on their schedule. So
4 it is not scheduled. It is an each occurrence as I
5 originally described.

6 MR. KOWALCYK: I guess, the concern I have,
7 and maybe this is related to the baseline sampling as
8 well, when -- and I guess Dr. McKee is right, that
9 we're talking about semantics a little bit. It seems
10 like the mechanism for collecting, harvesting that
11 sample is the same mechanism that in the plant, the
12 inspector collects a sample, something happens. Now,
13 is this blind to the producer or does -- is that
14 material arrive to the plant prior to the actual
15 sample being taken because in experimental design and
16 experimental control, you know, in the pharmaceutical
17 industry does this a lot and double buy in sampling,
18 where you don't know when the sample is taken, you
19 don't know if it's every 2,000th birth, every
20 80,000th, you know what I'm getting at. Is it
21 selected randomly and blind to the producer so that
22 you really get a good representation because there

1 can be some bias constructed from a sample where I'm
2 producing widgets and I know that my quality control
3 guy is going to take a sample during the first shift
4 on Wednesday morning, I may take some interventions
5 to make sure my numbers look better. Is the producer
6 blind to when those samples are being taken for, one,
7 developing the baseline and, two, for these sampling
8 requests?

9 MR. TYNAN: Dr. Arrington, did you want
10 to --

11 DR. ENGELJOHN: Yes.

12 MR. TYNAN: -- or Dr. Engeljohn.

13 DR. ENGELJOHN: I just wanted to get at the
14 issue of the Agency's sampling program, and there
15 have been a number of questions raised about
16 announced versus unannounced testing of the Agency's
17 program sampling. For the *Salmonella* program, it's
18 my understanding and I certainly have experts here
19 that will clarify this if I get it wrong, but it is
20 one for which it's unlike our *E. coli* O157 testing
21 where it's an adulterant and there is advance notice
22 of pulling the sample there, and the Agency

1 recognizes the limitations and bias associated with
2 that.

3 But for the *Salmonella* testing program,
4 there is no defined preannouncement of when the
5 sample is being taken. So that's one issue.

6 With regards to the 51 sample sets, that
7 is, in fact, taken 51 consecutive days. So -- and
8 the Agency constructed that performance standard in
9 that way to get a perspective of the process control
10 over time. So that's part of the reason why 51, in
11 the case for broilers, was established as a sample
12 set.

13 With regards to addressing the issue which
14 has been raised by the stakeholders about how we go
15 forward with our *Salmonella* programs into the future,
16 the Agency has constructed a mechanism whereby we
17 intend to, as well, rely in part on industry data and
18 if they're in the optimal performing categories, such
19 as Category 1, and the Agency would be doing
20 unannounced testing of when we will be collecting a
21 *Salmonella* sample that would be in supplement to what
22 the industry's data would be.

1 So we would have our determined time period
2 for when we're going to do a *Salmonella* set which
3 once we start it, you know it's going to be for 51
4 consecutive days but the samples are randomly taken
5 throughout that shift. That is how the construct of
6 that is.

7 But for the *Salmonella* Category 1
8 provisions that we announced in the Federal Register
9 last week, we identified that we were going to be
10 adding an additional component which would be
11 unannounced testing by the Agency whereby it would be
12 our intention to take the 400 mil sample that the
13 establishment would be taking for their rinse -- for
14 their own data to support their *Salmonella* testing,
15 the Agency would ask to take half of that sample. So
16 that would be one for which the establishment would
17 not know when we're going to take that, and it would
18 be done at random times throughout the year to get
19 some perspective as to whether or not the provisions
20 in place within that program have likely changed as a
21 consequence of the Agency not doing its *Salmonella*
22 set but once every two years which we said we would

1 do for Category 1.

2 I would also add that the design of the
3 Agency's Public Health Information System that was
4 described in more detail this morning is intended to
5 identify what control procedures are in place within
6 an establishment in that plant profile. And the
7 intention as well would be that if an establishment
8 were to turn off an intervention as may be the case
9 for a particular supplier not wanting their product
10 treated with a particular antimicrobial as an
11 example, if that were to be the case, then our
12 expectation would be that we would have instructions
13 to the employees to document that, to record that in
14 the system so that we know that the establishment is
15 modifying their procedures either when we're not
16 taking our *Salmonella* sample set or that they are
17 modifying it throughout the day or over the course of
18 time such that we need to take a closer look at the
19 validation for the design of that food safety system.

20 So to get at some of the issues of the
21 construct of a regulatory testing program, we have
22 built in unannounced testing whereby we would also be

1 able to look at the design of that system to see if
2 there's changes made when we're not doing the pre-
3 identified 51-day sample set.

4 MR. TYNAN: Dr. Bratcher, I know you had a
5 comment, and I think it relates to this question. So
6 I'll let you kind of finish up on this.

7 DR. BRATCHER: Well, I was just going to
8 say that's exactly what's happening in my circuit. I
9 have large plants that are doing sampling. The
10 plants are notified usually 1 to 2 weeks in advance
11 that they're going to do a 51 set sample. So they
12 know when it's coming. The inspectors then use a
13 random number generator to determine whether it's
14 going to be a sample in what production timeframe on
15 the 1st or 2nd shift. So all the plant knows is that
16 there's going to be one sample each day. They have
17 no idea what time that sample's going to be taken,
18 and it could be the first 15 minutes of the
19 production day. It could be the last 15 minutes or
20 anything in between because it's totally random.

21 And then if the -- and we have had one
22 situation where a plant did shutdown a major

1 intervention that they had in the plant, and so we
2 could not do an extra *Salmonella* set in that one
3 plant. So there are some things that can be
4 manipulated.

5 The other part of that is like Stanley
6 said, you do have to have the supplies and things on
7 hand. Sometimes that could be a bit of a problem,
8 and in a scheduling thing with the lab, it can be a
9 bit of a problem because they can only run a certain
10 number of *Salmonella* sets. And so it may be that you
11 have to get pre-staged or the lab can complete the
12 sets that you're doing, and we just recently had a
13 problem getting materials to the plants. And so it
14 was like two or three weeks that it set the testing
15 back in three of those plants in my circuit because
16 the lab didn't have the capacity to run them until
17 two or three weeks later.

18 MR. TYNAN: Okay. Thank you. You just got
19 Sampling 101.

20 MR. KOWALCYK: Okay. I've got one more
21 question about this first presentation in the model
22 estimates on slide 9. You indicate HACCP and

1 sanitation procedures, and I know this is looking at
2 poultry slaughter, and I'm just trying to understand
3 because on page 20 of the appendix, it has a list of
4 various procedures, and some of those look like
5 they're outside of slaughter.

6 MR. TYNAN: Excuse me, Michael. May I
7 interrupt? Is this the slide you were referring to?

8 MR. KOWALCYK: Yes.

9 MR. TYNAN: Okay. Thank you, Ricardo.

10 MR. KOWALCYK: Can you discuss a little bit
11 about that because it seems like there's interactions
12 actually after you're collecting information about
13 your dependent variable. I'm just having a hard time
14 reconciling that.

15 DR. DISNEY: There's actually two questions
16 inside your question there, and one of them I
17 actually had myself. And that was why does it appear
18 that there's some processing activities involved
19 here?

20 MR. KOWALCYK: Right.

21 DR. DISNEY: And actually I went to
22 Dr. David LaBarre who is on our staff and a

1 member of the team that worked on this. He actually
2 spent several years in some poultry slaughter plants.
3 He's a statistician, and he said, you know, he sort
4 of reminded me, you know, even if you have a
5 slaughter plant that does absolutely no processing,
6 they still have to do something with the birds. So
7 they end up putting them in boxes and boxing them
8 out. And there is some procedure codes for
9 inspection that technically are classified as
10 processing for procedure codes. So that might
11 explain part of it I think.

12 The other part of your question though is a
13 little more difficult and it is something that I
14 thought about early on in this process, but I mean
15 maybe some of these other guys can clarify. Most of
16 our procedure codes are identified by procedure code,
17 but some of these things we don't know at what point
18 in the process this actually occurs. It can occur at
19 various points along the line. Some of them occur
20 before the actual sample gets taken. Some of them
21 occur after the sample gets taken. And I don't have
22 a really good way right now within the model of

1 distinguishing those things. So I would be very
2 interested to hear suggestions from the Committee
3 here today on how I might do that.

4 MR. KOWALCYK: Okay. So that's certainly an
5 issue you are aware of which --

6 DR. DISNEY: I'm aware of it. I don't know
7 how to fix it right now is the problem.

8 DR. ENGELJOHN: This is Engeljohn. I know
9 how to fix it and the issue is that the new system we
10 designed will actually identify what procedure was
11 performed at what point in the operation, and whether
12 there was compliance or not which today, the Agency
13 simply only knows what was actually looked at, if
14 there was a non-compliance. A NR was written that
15 describes what and where that activity occurred. An
16 acceptable performance of a procedure as Dr. Disney
17 said could have been any number of things related to
18 anything in that plant associated with that
19 particular code.

20 But the new system will explicitly identify
21 what was done and where, so that we will actually
22 have more refinement to be able to answer that

1 question specifically.

2 MR. KOWALCYK: And once you're able to
3 refine it, you'll be able to update the model
4 estimates because obviously the coefficients will
5 change.

6 DR. DISNEY: Exclude all those that occur
7 after the sample gets taken.

8 MR. TYNAN: Dr. Negrón.

9 DR. NEGRÓN-BRAVO: I just have a single
10 question. The 154 chicken poultry establishments,
11 were they taken randomly, all sizes, all category for
12 the *Salmonella* prevalence?

13 DR. DISNEY: Right now in the model, we're
14 using all the available data. So we have three years
15 worth of data for just over 150 plants. We're using
16 all of it. So everything we have, we're using in
17 this current version of the model.

18 MR. TYNAN: Mr. Covington, you're going to
19 have the last word.

20 MR. COVINGTON: That may be a letdown then.
21 I just have a simple clarification question. Based
22 on the presentation, there's a discrepancy in the

1 breakdown of the categories used for *Salmonella*
2 versus the Federal Register notice that was published
3 last Monday, and that is the Category 1 is at or
4 below half the standard whereas the presentation
5 indicated that below half is the designation. It's
6 semantics when it comes to the number of positives in
7 most cases but, Dr. Engeljohn, could you comment on
8 that please?

9 DR. ENGELJOHN: I could and it is a
10 semantics thing here. We just didn't catch it on the
11 slide but the analysis was not done differently to
12 get at the issue and just for broilers, just so you
13 know, with 13 -- I believe 13 was the number. So
14 when you divide that in 2, that's 6 1/2 and we round
15 it down so that it's 6 or fewer. And so just to be
16 clear, the analysis and what we've done and
17 everything that's been presented, is on that
18 parameter, not on something other than that.

19 MR. TYNAN: That wasn't a let down. That
20 was fine. We're at the point where we need to begin
21 the Subcommittee discussions. I would remind
22 everybody that we're keeping the same groups and the

1 same leaders. I know that's a little bit of an extra
2 task on Mr. Elfering and Dr. Dickson, but the, the
3 breakout sessions, I thought it would be beneficial
4 to keep the same groups in order to not try and
5 reorganize and re-get acquainted. So I think that
6 will work out better for purposes of this meeting.
7 We may do it differently at another.

8 But, Mr. Elfering, if you would be in this
9 room and again, Mrs. Foreman, if you could join that
10 group, we'll have the telephone available for you.
11 Dr. Dickson, you would be in the other room and
12 Kevin, you'll be taking the within establishment
13 inspection system questions, issue number 1, and
14 Dr. Dickson, you'll be taking the supporting data
15 analysis and performance standards.

16 And if we have not provided the committee
17 with the questions, we should have copies of them out
18 on the table outside, and you can work from those.

19 The Subcommittee deliberations, I would
20 allow the Chairpersons to decide how they want to
21 proceed. We had a block of time for the
22 Subcommittees to start -- excuse me please. We had a

1 block of time for the Subcommittees to begin their
2 work before lunch. I would suggest, I'll leave it
3 totally up to you how you want to proceed, if you
4 want to take lunch now and get your group back, but I
5 would think in the interest of time, 1:15 would be
6 about as late as you want to start, and based on the
7 agenda, we'll have the reports, instead of at 3:30,
8 at 4:00. So that will give you a little extra time
9 if that will be helpful to you.

10 Break for lunch now. Okay. So we'll
11 reconvene in the breakouts at 1:15.

12 (Whereupon, at 12:15 p.m., a luncheon
13 recess was taken.)

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1 through a little bit better, and I'd also like to make
2 sure that I am thanking all our Committee members.

3 One of the difficult things in doing this is
4 trying to separate all the complexities that fall
5 within many of these processes, and I think one of the
6 issues that we had discussed was that we can be
7 looking at poultry slaughter and there are certainly
8 going to be some prompts and some issues related to
9 poultry slaughter. Then you turn around and you look
10 at another issue of a fully cooked ready-to-eat
11 product and you really are looking at two completely
12 very different complex products, and especially when
13 you're starting to look at the complexity of some of
14 the processes that go into a fully cooked ready to eat
15 product as opposed to just -- what's a little bit more
16 simplistic is poultry slaughter.

17 So with all of that in mind, and I think one
18 of the things that I want to do because we weren't
19 able to go through a lot of the steps and all of the
20 prompts, we do want to reserve the right to be able to
21 make some modifications to our report as we were kind
22 of cramped for time at the very end. We have two

1 people on the Subcommittee that are not here and
2 joined us by telephone but it was a little bit
3 difficult to try to put all these things together
4 within the time limits that we had.

5 So with all of that, the questions were what
6 recommendations does the Committee have regarding how
7 to better use and identify the prompts identified for
8 within establishment inspection system? And, what
9 recommendations does the Committee have with the
10 design of the vulnerable points identified for the
11 within establishment system?

12 And we were asked to look at only two
13 processes and that is the poultry slaughter which is
14 the O3J and also fully cooked, not shelf stables, O3G.

15 Prompts should be externally reviewed by
16 subject matter experts, and I think that's one of the
17 things that we really felt were critical, and results
18 released for review. FSIS must test this system in
19 the exercises which includes in-plant inspection
20 staff. I think that it's -- we all thought it was
21 really critical to make sure that the people who are
22 going to be using this in the field are included in

1 working with some kind of a pilot project.

2 And it must be implemented in the field in a
3 number of different plants to make sure that
4 flexibility is built into the system. By having more
5 options, you have more flexibility in the plan.

6 The Subcommittee recognizes that the
7 questions may not resolve the cause of the prompt, and
8 therefore additional questions may need to be asked by
9 the inspectors. Conversely, some questions may not
10 apply at all. So I think that all of these situations
11 are going to be different.

12 The questions should not be used in a manner
13 that dictate the process for establishments to control
14 the process. Rather, they should be used as a
15 critical thinking guide.

16 Education and training is critical to make
17 sure the inspectors have the knowledge and the
18 authority to insure the success of the program. The
19 inspectors must have the ability to use critical
20 thinking to carry out this system. Inspectors must
21 understand the food safety principles, how to apply
22 these questions properly and involve people at other

1 levels of the Agency if necessary. This must also act
2 as a management control system so management can
3 insure that inspectors are applying the methods
4 properly.

5 FSIS should remove words such as appropriate
6 and adequate or proper since they're hard words to
7 interpret and instead use more definitive terminology.

8 Prioritize vulnerable points within product
9 categories. FSIS should put a priority on vulnerable
10 points based on public health concerns and to better
11 utilize resources. For example, sanitation in a cook
12 process should be given a higher priority and post-
13 lethality even higher.

14 As an inspector responds to a prompt using
15 the vulnerable points in questions, it's advisable
16 that a systematic approach is utilized as the
17 questions are addressed. First look at the previous
18 process step where the prompt was generated. The
19 issue may be addressed by working backwards in the
20 process until a stop point is reached.

21 The Subcommittee would like time to fully
22 look at each prompt specifically and make comments.

1 And one final one is that neither prompts
2 nor process control can be expected alone to protect
3 public health. The Agency must be able to demonstrate
4 that the system is based on public health data and
5 actually results in products with less microbial
6 contamination. And that finalizes our report.

7 MR. TYNAN: Thank you, Kevin. I'm going to
8 open it up to the other members of the Subcommittee if
9 there's anything that they want to add at this
10 particular point or to the full Committee to raise any
11 questions that they may have on the report.

12 (No response.)

13 MR. TYNAN: I see no comments or issues. So
14 can I infer from that the report is accepted as
15 recommendations of the entire Committee? Anyone
16 object to that?

17 MR. ELFERING: No, but I guess I just want
18 to reiterate that we do as a Subcommittee do want to
19 be able to look at this a little bit closer and still
20 make some modifications if needed.

21 MR. TYNAN: Okay. We'll provide an
22 opportunity to do that. Dr. Harris.

1 DR. HARRIS: Just a question on that. Then
2 would we receive a copy of any revisions that are made
3 and submit approval via e-mail or something?

4 MR. TYNAN: Yes, we'll find a way to work
5 that system out. I have not done that in the past
6 other than to send the Subcommittee reports back to
7 the chair people for them to take one quick look to
8 make sure that we captured everything the way they
9 want it but in this particular case, because we have
10 so much to do, we'll find some way to do the
11 modifications and get it out to the full committee.

12 MR. ELFERING: I don't think the substance
13 is going to change greatly, but I -- we were just kind
14 of getting a little bit rushed at the end and we just
15 want to make sure that we're putting out a good
16 report.

17 MR. TYNAN: When we do that, however, in
18 response to Joe's question, we'll do that but we do
19 have to have some type of a time constraint. So it
20 will have to be a pretty quick turnaround. So I'm
21 going to put the burden on the chair people for the
22 Subcommittee to help facilitate that.

1 MR. ELFERING: If I can have Ellyn e-mail
2 that report to me, and I will get it out to the
3 Subcommittee members within the next day or two.

4 MR. TYNAN: Okay.

5 MR. ELFERING: And we'll have a very quick
6 turnaround time.

7 MR. TYNAN: Okay. If you'd like, we can
8 send it out to all the Subcommittee members.

9 MR. ELFERING: That would even be better.

10 MR. TYNAN: Okay. All right, so this one is
11 accepted pretty much as is. We'll do a little bit of
12 cleaning up, and then we'll get it out to the full
13 Committee to be sure that everybody's in agreement.
14 Is that agreeable to everybody?

15 (No response.)

16 MR. TYNAN: Cool. Okay. Dr. Dickson, can I
17 put the burden on you to report on Subcommittee Number
18 2?

19 DR. DICKSON: And again on my behalf, I'd
20 like to thank the Subcommittee members who were very
21 gracious in their participation. Also the FSIS staff
22 was very helpful in our discussions, and we also

1 appreciated the comments of those who were in the
2 audience as well. We had a number of good comments
3 that were from individuals who were simply in the
4 audience.

5 The questions that we were asked related to
6 supporting data analysis and performance standards.
7 The introduction basically talked about proposed
8 public health risk-based inspection system and data
9 analyses supporting those studies.

10 The first question was, given your knowledge
11 of contamination events, are there additional
12 activities, inspection activities, performance
13 standards, FSIS should consider to improve the
14 proposed public health risk-based inspection system?

15 And from an overall standpoint, this is sort
16 of a global question to ask, essentially what did FSIS
17 overlook? And we have a number of minor points here
18 that we wanted to highlight. First off, relating to
19 *Campylobacter*, and I do apologize this has not been
20 reviewed by the Subcommittee, so if I missed anything,
21 we will have this -- have further editing of this.

22 Not all *Campylobacter* species are considered

1 to be pathogenic to humans. The current performance
2 standard being proposed is a quantitative measure of
3 all species of *Campylobacter*, and while it was a
4 general agreement that a quantitative assay was more
5 informative than a qualitative of presence absence
6 assay, there was some discussion as to whether or not
7 it should include all species of the bacterium.

8 There was a discussion of fecal
9 contamination and whether there was a definitive link
10 between fecal contamination of young chicken carcasses
11 and public health. This was identified as a data gap
12 and similar comments were made at other points in the
13 discussion in reference to the presence of pathogens
14 on the carcasses. And I will elaborate on that point
15 in a little bit.

16 MS. TUCKER-FOREMAN: Hello.

17 DR. DICKSON: There was a discussion posed
18 to the hypothetical question on the interaction of the
19 various performance standards. As an example, what if
20 an establishment within compliance with both the
21 *Salmonella* and *Campylobacter* performance standards but
22 was out of compliance with the *Escherichia coli*

1 Biotype 1 or 2 performance standard? And this was
2 identified as something that the Agency might want to
3 consider further as far as how all of the individual
4 performance standards interact with each other.

5 There was a question about whether various
6 serotypes of *Salmonella* would be treated differently.
7 FSIS replied that at the present time, the answer is
8 no. The performance standard is viewed as historical
9 and meant to represent the overall operation and not
10 meant to represent a specific lot of product. Comment
11 was made over the significance of *Salmonella* serotypes
12 on carcasses, serotypes which are found, which are not
13 within the CDC's top 30 list of human serotypes.

14 A further concern was raised over the
15 present *Salmonella* performance standard as a
16 qualitative measure and that it might not fully
17 capture the effectiveness of interventions. That is
18 if that the *Salmonella* population on samples was below
19 the infectious dose, what is the significance of the
20 prevalence within the sample set. The Subcommittee
21 urges FSIS to develop quantitative methods for
22 *Salmonella* and to consider incorporating these into

1 the development of new performance standards.

2 Line speeds came up several times during the
3 discussion and many issues were discussed as potential
4 concerns but it was generally agreed that the Agency
5 does not currently have an analysis of the impact of
6 line speed on public health factors. FSIS agreed that
7 this was a critical factor and that this issue needs
8 to be evaluated. In addition, there was a concern as
9 to whether specific interventions are validated at the
10 appropriate line speeds, not that there wasn't
11 validation on an intervention, but whether it was
12 appropriate at the line speed appropriate for the
13 plant.

14 There was discussion about FSIS' definition
15 of fecal and how this contamination impacts public
16 health, specifically the difference between feces and
17 ingested needs to be evaluated to determine what
18 impact these have on public health.

19 A point of clarity here, no one was arguing
20 in favor of allowing fecal contamination or for a
21 change in the current regulation requiring no visible
22 fecal contamination on the carcasses as they enter the

1 chiller. This was more of a hypothetical discussion
2 about do we have data that supports the performance
3 standards that says no visible fecal contamination on
4 carcasses.

5 There was a further discussion on the
6 correlation of *Escherichia coli* Biotype 1 and 2, and
7 the reduction of *Salmonella* and *Campylobacter*. My
8 personal comment, biology of this correlation is
9 plausible in comparison of the rehang and post-chill
10 samples is valid. The Subcommittee expressed caution
11 in using preliminary data in the development of new
12 standards and suggested that the baseline data be
13 reviewed by the National Advisory Committee on
14 Microbiological Criteria for Foods.

15 The second question was are there
16 additional data sources or variables that FSIS should
17 consider? The Subcommittee agreed that there were no
18 additional data sources or variables that the Agency
19 should look at beyond those already included in the
20 discussion.

21 Recommendations, first off, fill in the
22 identified data gaps, that is the association between

1 fecal contamination and human health, the association
2 between *Salmonella* and *Campylobacter* levels in public
3 health, and analyze the impact of line speed.

4 The Subcommittee commended the Agency on
5 its risk assessment work. The Subcommittee
6 recommended that the risk assessment be further
7 refined with the addition of new data and brought
8 back to the committee as a final product. Peer
9 reviews and the responses to the reviews should be
10 shared with the Committee.

11 As examples, line speed should be
12 incorporated into the assessment as well as
13 differentiating between NRs which occurred before and
14 after the sampling point. Currently, that is not a
15 differentiation between those although Dr. Disney
16 indicated that that could be done. In addition, the
17 effect of *Salmonella* populations could be
18 incorporated into the assessment.

19 The Agency is encouraged to develop new
20 enumeration methods for *Salmonella* and to consider
21 enumeration in the establishment of new performance
22 standards.

1 The Agency is encouraged to test the new
2 system with historical examples. What would the new
3 system tell us about what has happened previously?
4 What changes in inspection would occur as a result of
5 the new system if it were applied to some of these
6 historical examples and compared that to what
7 actually did happen under the previous system.

8 In the absence of cause and effect studies,
9 the Subcommittee generally supported the overall
10 lowering of *Salmonella* and *Campylobacter* levels in
11 broilers. The Agency was encouraged to continue to
12 pursue and approach based on science and to consider
13 the significance of population and infectious dose on
14 samples when the incidence decreases to very low
15 levels.

16 And without any editing or comments from
17 the Subcommittee, that's what we have at this point
18 in time, subject to your questions.

19 MR. TYNAN: Okay. I'm going to open it up
20 to the Subcommittee, since that was the case, and to
21 the full Committee to ask any questions or have any
22 comments that you might have at this particular

1 point.

2 DR. DICKSON: Mr. Tynan, if I may make one
3 other comment. For those of you who are still here,
4 I have already lost some of my Subcommittee. We will
5 have hard copies for you to take with you so you can
6 mark them up and either fax them or e-mail me back
7 your changes so that we can get this done no later
8 than Monday morning. Everybody nod your head yes.
9 Great. Thank you.

10 MR. TYNAN: You can give them the hard
11 copies and we'll also e-mail that one out to the
12 Subcommittee members as well. Any comments at this
13 particular point though from the Subcommittee or the
14 Committee?

15 MS. TUCKER-FOREMAN: This is Carol. I do
16 not yet have a copy of the document, and so I tried
17 to listen as best I could, but it was way too long
18 for me to do that. I may have some comments on it
19 since I haven't yet had an opportunity to read it.
20 Hello?

21 MR. TYNAN: Sorry. I was taken away from
22 the microphone for just a moment. We will try and e-

1 mail you a copy if we can at this particular point.

2 MS. TUCKER-FOREMAN: Okay. What I said was
3 that I may have some comments when I've had the
4 opportunity to read it. Thank you.

5 MR. TYNAN: Okay. That's fine. And again
6 I think Dr. Dickson is looking for the comments to
7 come back to him. So we'll get them out to the full
8 Committee so that all of that can be captured by
9 Dr. Dickson. Any other comments at this particular
10 point?

11 (No response.)

12 MR. TYNAN: Okay. We'll consider this one
13 still a little bit up in the air, but I'll assume
14 when I receive it from Dr. Dickson, it will be final
15 and everybody will have agreed.

16 There was a report that we had from
17 yesterday. Jim, I don't know if you are prepared to
18 talk about that or --

19 DR. DICKSON: I do have the final report
20 from yesterday and unfortunately I just closed it out
21 of my computer. So, if you'll give me one minute to
22 find it. Here we go. There are really no major

1 substantive changes in the report from yesterday.
2 There are some corrections. We did under the answer
3 to question number 1, we had some questions about the
4 Carnegie Mellon analysis. One of those questions we
5 deleted simply because it was, in fact, redundant
6 with some of the information that was already
7 incorporated into the report.

8 Under question 4, we did some editing
9 there, and I'd like to read this paragraph here.
10 There was a general sense that other information that
11 might be available within a specific establishment
12 such as the presence of external quality assurance
13 programs mandated by customers of the establishment,
14 could be captured within the algorithm. However,
15 there was not consensus on this point, and some felt
16 that this might not be relevant. It was suggested
17 that this could be part of the establishment's
18 profile but not part of the algorithm.

19 And that's probably the most substantive
20 change in the entire report.

21 Other than that, under FSIS staff, we had
22 the wrong acronym in there. We referred to a

1 training program when, in fact, we intended to refer
2 to a management control system and that's under
3 question number 4.

4 Beyond that, that is the complete report
5 incorporating all the changes that I have been given
6 to this point.

7 MR. TYNAN: Okay. Any comments at this
8 point? I think we accepted Jim's report yesterday
9 but just in case, to revisit it, I think we are all
10 in agreement that that was acceptable for the entire
11 committee. Is that correct?

12 (No response.)

13 MR. TYNAN: Okay. We're fine. So we only
14 have Jim's that's probably up in the air at this
15 point. So we'll get that out and make sure there's
16 all the editing and questions that you have will be
17 brought together within the next week.

18 Any other comments on the reports at all at
19 this point before we go into the public comment
20 period?

21 (No response.)

22 MR. TYNAN: Okay. I'm going to close that

1 out, and we're going to begin the public comment
2 phase of the meeting for today. We have several
3 folks that have signed up for -- to make a short
4 presentation, the first one being Dennis Johnson.

5 Mr. Johnson, if you could come up to the
6 microphone, again identify yourself and your
7 affiliation.

8 MR. JOHNSON: Dennis Johnson, Olsen, Frank
9 and Weeda. Mr. Tynan, if it's all right with you,
10 Mr. Tynan, I'd like to submit my written comments for
11 the record. That way no one has to listen to me read
12 them. This way I can make it a lot shorter and
13 sweeter.

14 MR. TYNAN: That would be perfectly fine.

15 MR. JOHNSON: I appreciate that, sir.
16 First of all, I want to get this clarified right off
17 the bat. We are in support of a modern inspection
18 system which is based on science, and which can
19 advance the public health. We have reviewed a good
20 chunk of the material that this Committee has
21 received, pages upon pages, and we're a little
22 surprised that we did not see any reference in there

1 to the *Salmonella* incentive program which goes back a
2 couple of years. And I would like to respectfully
3 direct the Committee's attention to this project
4 because I believe it does provide guidance on how we
5 should proceed with the public health risk-based
6 inspection system.

7 For those of you who remember back in the
8 early days of 2006, the *Salmonella* incident rate on
9 broilers was approximately 20 percent, which is the
10 performance standard. In February of that year, Food
11 Safety and Inspection Service issued a Federal
12 Register notice which basically told industry you
13 have two choices. You're going to get your act
14 together and we will consider positive incentives, or
15 you will not get your act together and we're going to
16 post the names of every establishment that does not
17 meet categories, at least 3, or 2.

18 Industry responded to this challenge in
19 less than a year. The *Salmonella* incident rate from
20 FSIS and industry data was cut in half. But the
21 basis for that was not any threatened negative
22 incentive. The basis for that was the positive

1 incentives that were promised.

2 And perhaps I can best put this into
3 context with the story from one of my clients going
4 back about four years ago, when I was trying to
5 persuade that client that it was time to reduce
6 *Salmonella* numbers, that the numbers were increasing.
7 And he said, well, okay, DJ, I can do that. We're
8 running at about 8 percent. Now, I can get it down
9 to 0, 1 percent but it's going to cost me a quarter
10 per bird, a quarter cent per bird. Can you call my
11 Chairman and tell him why we should spend that extra
12 quarter a bird when we're already running at 8
13 percent which is less than half the *Salmonella*
14 performance standard, and I really had a hard time
15 coming up with an explanation as to why he should
16 because unless there are incentives being available
17 to establishments who spend the extra money, who
18 dedicate themselves to reducing *Salmonella*, then
19 there is no benefit and you're not going to get the
20 same degree of reduction you otherwise would.

21 We do note that the SIP was recently
22 published in the Federal Register notice, and I have

1 to say we were regrettably disappointed in the
2 product as written, and basically it is negative
3 incentives, negative incentives and negative
4 incentives. Under the posting of Category 2 and 3,
5 that's not exactly unexpected. The negative
6 incentive for any establishment operating in an OLR
7 system, an online reprocessing system, if you are in
8 a Category 2 or 3, as written, your approval will be
9 terminated notwithstanding the fact that the waivers
10 themselves do not expressly grant termination in the
11 event of failure to achieve a particular *Salmonella*
12 category.

13 For HIMP plants, which are in Category 2 or
14 3, as written in the *Salmonella* incentive project
15 notice, you will lose your HIMP status and if you are
16 a Category 2 and 3. If you are in Category 1, you
17 are going to be asked to do additional data to be
18 submitted to the Agency for purposes which we're not
19 quite sure how the data's going to be used, and if we
20 don't, you know, do that, we could lose our waivers
21 for online reprocessing or HIMP if we're in Category
22 1.

1 Now, industry is spending about \$500,000
2 per plant per year to get *Salmonella* controlled.
3 Now, I'm not talking about making Category 2 or even
4 making it Category 1. The bulk of that money is
5 designed to take the establishments from 10 percent
6 down to 1 or 2 percent. If there are no incentives
7 that are being provided, the marketplace, there is a
8 disincentive for those folks who are doing it in the
9 marketplace. They're going to have higher production
10 costs for products which are just as acceptable.

11 So basically we are disappointed in the SIP
12 as it was proposed. I am here to say that we are
13 going to -- we have reduced *Salmonella*. We're going
14 to continue to reduce *Salmonella* but we are not going
15 to allow termination of our waivers on the basis of
16 conditions which are not included in the waivers
17 themselves. We are not going to conduct any
18 additional testing unless and until we understand the
19 purpose for that.

20 Now, I understand earlier today, a comment
21 was made that maybe we should extend the comment
22 period on SIP. We would support that, and we would

1 request that in such a case, that the termination
2 provisions for the waivers and the additional testing
3 likewise be extended. Otherwise, we will have no
4 choice but to oppose SIP in any and all forms which
5 we can.

6 And I'd just like to close with one
7 comment. Someone once told me that when failure is
8 punished more disproportionately than incentives are
9 rewarded, the best you're going to end up with is
10 mediocrity. I think if we move forward on a public
11 health risk-based inspection system, I think
12 everybody needs and should require the very best.
13 Thank you.

14 MR. TYNAN: Thank you, Mr. Johnson. The
15 next person we have signed up to make a comment is
16 Mr. Stan Painter. Stan, if you wanted to stay right
17 there, I know you have a microphone right there. So
18 I'll leave it to you.

19 MR. PAINTER: Thank you, Robert. Stan
20 Painter with the National Joint Council.

21 MR. TYNAN: Stan, pull it over just a
22 little bit closer to you so that the transcriber can

1 hear and --

2 MR. PAINTER: What about now?

3 MR. TYNAN: Pull it over. There you go.

4 MR. PAINTER: Hello.

5 MR. TYNAN: There you go.

6 MR. PAINTER: Okay. All right. First of
7 all, I want to say that I appreciate being able to
8 attend the meeting and be a part of the process and
9 that it's certainly good to be a part of the new
10 initiatives within the Agency. And I do want to get
11 back to something that was said yesterday that I
12 haven't been able to address.

13 When we were talking about the satellites
14 and the Internet hook up and things of that nature in
15 the plant, and when I brought up the fact that the
16 plants were under the satellite system were
17 unplugging and going to dial up and Bill Smith said,
18 that he didn't think that was the case, and I can
19 tell you, Mr. Smith, that is the case. And I do
20 applaud the Agency for making an effort but when
21 you've made an effort and it don't have the desired
22 outcome, the best thing to do is to admit that it

1 doesn't have the desired outcome and then move
2 forward. You know, and with that process as well, in
3 trying to work with the Internet system and trying to
4 work with the computers, although the Agency had cut
5 back on the farm help, that process has been
6 lengthened somewhat and -- but we don't have anything
7 over the weekend, and a lot of plants work six and
8 seven days a week. You have plants that are working,
9 you know, 12 hours, and when it takes an inspector
10 sometimes 10 hours to download a process and they
11 need to call farm help, a weekend is a good time in
12 order to do that. You don't have as much activity
13 over the Internet and hopefully you will be able to
14 do that, but if you need something from farm help,
15 that's not happening.

16 Staffing is always an issue. I've saw yet
17 again an explosion in upper level management.
18 Twenty-five percent of the inspection staff,
19 USDA/FSIS, is management, and over half of that, of
20 the monies go to that 25 percent. If we were a hive
21 of bees, we would have 25 queen bees to every 100
22 people, and the percentage of the ratio, it just

1 don't match up. And then that 25 percent would be
2 eating over half of the honey. So, you know, the
3 ratio of the people in the field actually doing the
4 work for the upper level management, from the
5 District level above, is just totally
6 unproportionate.

7 The line speed issue has been brought up a
8 number of times. You know, we have a number of
9 factors in trying to do your job and it only stands
10 to reason if, if I'm an inspector, and I'm going to
11 use an example of what's going on and something I
12 know, of a line running almost 200 birds a minute,
13 you are not able to do what you need to do, and
14 heaven help you, if you get your finger hung in a
15 shackle because you're either going to lose that
16 finger or you're going to be going up the line.

17 The issue with the survey that came up,
18 regarding the yes or no questions, I asked a question
19 in the Subcommittee and I said, you know, the answers
20 are yes or no, and it came back to me, oh, no, it's
21 not yes or no, but when you're an inspector in the
22 field, and you're trying to write an NR, the answer

1 is yes or no.

2 And lastly I want to congratulate
3 Dr. Catlin on getting her green card. I know that's
4 been difficult to work within the Agency and work
5 within a Government agency and not having the proper
6 documents in order to do so, and I want to
7 congratulate her on that achievement. Thank you.

8 MR. TYNAN: Stanley, I want to assure you
9 we don't have any illegal aliens working on our
10 staff.

11 MR. PAINTER: And I never said that anyone
12 was an illegal alien.

13 MR. TYNAN: Okay. I'm sorry. The next
14 person we have on our list for comments is Felicia
15 Nestor. Felicia. Again, if you could identify
16 yourself and your affiliation please.

17 MS. NESTOR: Felicia Nestor, Food and Water
18 Watch. I just want to say initially it's strange to
19 come up here and be the one that's going to be kind
20 of like the soft cell, but thanks to Dennis and Stan,
21 I'm starting off differently than usual.

22 I have a lot to say, and I think it's

1 important to get it on the record for consumers. I
2 mean consumers are going to go to the website, the
3 Agency's website and read this transcript to find out
4 what's going on.

5 I want to talk about the process. If the
6 Agency is going to be making assertions, it should
7 state the explicit limitations of the data. I don't
8 know how many people here knew that the Agency was
9 saying that certain inspection tasks lead to
10 *Salmonella* reductions, and didn't know that the
11 Agency was calculating inspection tasks that happened
12 after the *Salmonella* set was taken because their data
13 system cannot at this point distinguish.

14 Reading the risk assessment, I think the
15 whole discussion this morning between -- in response
16 to Mike Kowalcyk's question about unscheduled
17 sampling was extremely misleading. There was a lot
18 of conversation about unscheduled being these
19 discretionary tasks that inspectors can perform in
20 response to some observation and some concern about
21 that observation. And then when we get down to it,
22 what the unscheduled tasks we're referring to was the

1 routine *Salmonella* sampling. You know, those samples
2 are not discretionary. The inspectors don't take
3 them when they make an observation.

4 If the Agency is saying that under this new
5 system you are contemplating giving the inspectors
6 the authority to take microbial samples when they
7 have a concern, I would endorse that but I don't
8 think that's a proposal that's on the table.

9 Dr. Bratcher asked, you know, what do we do
10 if -- how are -- are the vets going to make the final
11 disposition? And, how are they going to do that if
12 they're not in the plant? And Dr. Arrington said the
13 vets will make the final decision. I don't see how
14 that question was answered, you know, and for people
15 that are too afraid to ask, maybe they think, oh,
16 well, the Agency's going to take care of it. The
17 Agency is not going to take care of it.

18 Dr. Bratcher told me he's going back to
19 inspect to supervise. He's got five large poultry
20 plants with two vets to cover the five large poultry
21 plants. So this is, you know, this is now not only a
22 question of misleading the public, this is my second

1 issue here is how much responsibility does FSIS take
2 for these experimental programs that they put into
3 place? We've got two vets to cover five plants and
4 the three broiler plants are making approximately a
5 quarter of a million birds a day. You know, that's
6 not sufficient, and I've already talked about the
7 insufficient inspector staffing.

8 You want us to have faith in your new
9 experiment, and yet if we look at what you're doing
10 with HIMP, there are some reasons to really raise our
11 eyebrows. Establishment 360, a pork plant in
12 California, came under HIMP in January 2006. Now, I
13 mean I would -- does anybody from FSIS want to say
14 how long would be an appropriate period of time
15 before you would start a *Salmonella* sample at a plant
16 that's going from traditional to HIMP inspection?
17 Does anybody from FSIS want to take a crack at it?
18 What would be appropriate? You have an experimental
19 system, consumers are going to be eating this meat.
20 It's not labeled. How long would it take you to
21 start your first *Salmonella* set?

22 MR. TYNAN: This portion, Felicia, is for

1 you to comment.

2 MS. NESTOR: Okay. No answers. Well, I'll
3 tell you when they started. They started in January
4 of 2006 and under HIMP, the first *Salmonella* set was
5 taken the last week of June in 2007. So, if the
6 Agency is intending to do this, you know, more
7 experiment, and that's the kind of oversight you're
8 going to do, we're going to have a problem with it.

9 If you're going to do an experiment like
10 the hog HIMP experiment where the carcasses are
11 marked at the beginning of the line, the plant is
12 making 8,000 carcasses a day, FSIS is going to
13 inspect, you know, closely look at 24 of them, and
14 they're all going to be marked at the beginning of
15 the line so that every worker knows, oh, these are
16 the 24 that we're going to get graded on, you know,
17 that doesn't sound like a good experimental design,
18 and I would suggest that if you're going to do a
19 pilot on this program, that it have more integrity
20 than that.

21 Let's see. I've got questions about the
22 risk assessment. Maybe you answered this. I don't

1 know why the data is only from 154 plants if you've
2 got -- I think you have 200 poultry plants. You
3 know, was there self-selection bias in that?

4 The way that the risk analysis was done, we
5 can't really tell whether the *Salmonella* reduction
6 was from the decrease -- no, the increase in
7 sanitation inspection tasks and HACCP tasks and
8 sampling or whether those -- the increases in those
9 were an indication that this was a plant where the
10 processing inspector was not pulled to the line, and
11 that that processing inspector was probably offline
12 the whole day and able to oversee all production.

13 If zero tolerance is going to be a part of
14 this program, I think you really need to rethink the
15 limiting definition of zero tolerance. You know,
16 it's got to be a certain color. It has to be a
17 certain texture. It can't have this. It can't have
18 that, and I talked to poultry inspectors and hog
19 inspectors that have told me, you know, they have
20 said, look, let's go. We'll cut open the cut.
21 Here's the intestine. Here are the feces and you can
22 see it doesn't match the definition that you're

1 holding us to. So that's not good enough.

2 The Agency says about the HIMP inspection
3 that the carcass inspectors are making the final
4 judgment on those carcasses. Consumers have to
5 understand what that means. The birds are going by
6 at 200 birds a minute, the inspector is prohibited
7 from looking inside, not allowed to look inside. The
8 shackles don't turn. So even if they wanted to, they
9 are not allowed -- they couldn't turn to see the
10 front of the bird. So basically what they're doing
11 is watching birds fly by at 200 birds a minute to see
12 fecal on the back side of the carcass, and if they
13 see it, it's got to be the right color.

14 I think I'm almost done. Oh, yeah. I am
15 done except to say that I had a very nice
16 conversation with the Agency's data analysis people,
17 the risk analysis. I know that they're doing the
18 best job they can with the data that they're given,
19 and, you know, for myself, I'm going to do what I can
20 to make sure that they get better data, you know, to
21 whatever extent I can. Thank you.

22 MR. TYNAN: The next individual that signed

1 up for a short presentation is Mitch Jones.
2 Mr. Jones, are you still here? Okay. If you could
3 come to the microphone and identify yourself and your
4 affiliation.

5 MR. JONES: Right. It's Mitch Jones with
6 the United Food and Commercial Workers International.

7 First off, I'd just like to thank the
8 Committee for the opportunity to give voice to some
9 of the concerns of the workers in the meat and
10 poultry industry as you develop this new system.

11 The UFCW has a long history of involvement
12 in food safety issues. Our predecessor unions were
13 involved in drafting inspection legislation back in
14 the fifties and sixties. UFCW itself was
15 instrumental in the formation of the Safe Food
16 Coalition in the 1980s. We remain involved in food
17 safety issues today.

18 It might not surprise you, however, that we
19 also are concerned with worker safety. This plant
20 with its move to deregulate line speeds in young
21 chicken slaughter plants, we believe will have a
22 direct and negative impact on worker safety.

1 We're aware that FSIS does not and never
2 has taken worker safety into consideration in its
3 regulation of line speeds. We're also aware that
4 OSHA has not and is not likely to begin to regulate
5 line speed. Therefore, we would really appreciate it
6 if FSIS would consider worker safety as it moves
7 forward in the formation of this plan.

8 When we survey our members who work in meat
9 and poultry slaughter and processing, the number one
10 issue of concern that they name isn't salary. It's
11 not time off. Their number one issue for concern is
12 line speed. That's their number one issue.

13 A study done in the mid nineties showed
14 that a typical worker in a poultry slaughter or
15 processing plant could perform as many as 40,000
16 repetitive motions in just a single working day.
17 40,000. That study was done in the nineties. Since
18 then, line speeds have only increased. This plan
19 would see them increase even more.

20 Additionally, FSIS has said in its risk
21 assessment for this plan that they're counting on
22 plants to increase their technology if they are given

1 line speed deregulation. This was said so that we
2 wouldn't be concerned about the food safety impact of
3 increasing line speed. Plants will go in and they'll
4 make the investment so they can run at faster speeds
5 and this technology will also improve food safety.
6 That's what we're told to believe.

7 A 2005 GAO report on worker safety in meat
8 and poultry claims accurately that when you increase
9 technology in meat and poultry processing and
10 slaughter plants, you actually increase the number of
11 repetitive motions that a worker has to make. So
12 this plan will not only increase line speed, which in
13 and of itself will increase the amount of repetitive
14 motions made in a single shift, but the increase in
15 the technology will itself increase the number of
16 motions a worker has to make. So we're talking about
17 well beyond the 40,000 motions that was found in the
18 mid nineties.

19 Having to make the same motion tens of
20 thousands of times leads to workers getting crippling
21 MSDs, musculoskeletal disorders. These impact not
22 only their ability to continue to perform their jobs

1 but their well-being and livelihood once they leave
2 working in the plant. These are lifelong illnesses
3 that these workers suffer.

4 Moving forward with this plan, we believe
5 will contribute to an increase in workers being
6 subjected to the exact types of working conditions
7 which lead to MSDs.

8 Furthermore, as these two days of meetings
9 have made clear, we don't believe that these changes
10 are going to stop in broiler plants. They'll move to
11 turkeys and pork and beef. We're deeply concerned
12 that this move will happen before any sort of
13 consensus has been reached outside of the Agency as
14 to whether or not the plan for young chickens is
15 itself well thought out.

16 So because of the concerns that were raised
17 by our partners in the Safe Food Coalition, including
18 Felicia's comments just a second ago, and because of
19 the concerns that we have with worker safety,
20 especially as tied to line speeds in slaughter
21 establishments, the UFCW cannot and will not be able
22 to support the Agency's plans to move forward with

1 this plan. Thank you.

2 MR. TYNAN: Thank you, Mr. Jones. The next
3 person that has signed up to make a short comment is
4 Dr. Sandra Hoffman. Dr. Hoffman, if you would come
5 up and identify yourself and your affiliation.

6 DR. HOFFMAN: My name -- is this on?

7 MR. TYNAN: I believe so.

8 DR. HOFFMAN: My name is Sandra Hoffman.
9 I'm with Resources for the Future, and I'm making
10 comments for myself and Dr. Paul Fishbeck of Carnegie
11 Mellon University. They're really just a very minor
12 comment on Appendix A.

13 We authored an attribution study, an expert
14 elicitation attribution study that's cited and used
15 extensively in this, and we had some concerns about
16 the way the attribution measures are aggregated
17 across studies, in particular how it's aggregated
18 with outbreak data.

19 Total caseload, of course, is outbreak plus
20 sporadic cases. The purpose of the expert
21 elicitations was to try to get some sense of a
22 measure of those sporadic cases. So it's not clear

1 to us that simply averaging between the outbreak
2 based attribution and the expert elicitation is an
3 appropriate way to get at an aggregate measure, and
4 I've spoken with Dr. Engeljohn, and we would be happy
5 to work with the Agency in trying to develop a better
6 algorithm for that.

7 The other comment I have is with my hat as
8 a public health economist, and that is that this
9 program, as many other federal efforts to improve
10 public health. When you're thinking about trying to
11 measure the risks that we're reducing, it doesn't
12 take into consideration the cost of reducing those
13 risks. And I'm concerned about that from a public
14 health perspective in this sense. If you change the
15 cost of one product, relative to another, it can lead
16 to changes in relative prices of products that
17 consumers face, and it can lead to consumers making
18 different choices about the bundle of food that
19 they're consuming which leads to different exposure
20 pattern than what you're expecting. So I'll just put
21 in my parental plea, while it may not be possible at
22 this point given the state of data or analysis to do

1 that, it's something one should be looking towards in
2 the future, to take into account the impact of costs
3 on relative prices consumers face in your exposure
4 assessment. So thank you very much, and in general,
5 Paul and I both very much applaud the effort you're
6 making to move towards a risk-based approach to
7 inspection and to food safety policy across the
8 board.

9 MR. TYNAN: Thank you, Dr. Hoffman. Before
10 you sit down, and you may have said it, but you're
11 with Resources for the Future. Is that your
12 affiliation?

13 DR. HOFFMAN: Yes, that's correct.

14 MR. TYNAN: Okay. Thank you. And I think
15 last but not least, Dr. Harris, you just -- okay.
16 Okay. You just decided -- okay. I understand. I
17 understand. It's been a long day. With that, I
18 think we've concluded the -- I'm sorry. Mr. Corbo.

19 MR. CORBO: Tony Corbo with Food and Water
20 Watch. A couple of short comments. Last year when
21 the Agency submitted its budget to Congress, in its
22 explanatory notes, it estimated that the

1 implementation of the change in poultry slaughter,
2 risk-based inspection in poultry slaughter, would
3 generate \$14 million in annual savings. I've asked
4 this question before. I have submitted a Freedom of
5 Information Act request nine months ago. I would
6 still like to see that breakdown, how the Agency
7 arrived at that because I think some of this is being
8 budget driven rather than improving public health.
9 That's number one.

10 Second observation, I brought this up
11 before, there still is a consumer representative
12 vacancy on this Committee, and I would urge that that
13 vacancy be filled because of the magnitude of the
14 issues that this Committee is taking up. Thank you.

15 MR. TYNAN: Okay. Thank you, Tony. At the
16 risk of saying we're through with this portion, is
17 there anyone else in the public that didn't sign up
18 that would like a comment to this point?

19 (No response.)

20 MR. TYNAN: Okay. We're going to close out
21 the public comment portion. Before I turn it over to
22 Mr. Almanza maybe for a quick closing remark and

1 adjournment, I did want to mention that we have
2 tentatively set out next meeting, and I see everybody
3 reaching for their BlackBerries. We're tentatively
4 looking at June 24 and 25, 2008, for our next
5 meeting. So we'll confirm that with all of you to
6 make sure that's acceptable to your calendar. We've
7 tentatively got locked it on some of our key people's
8 calendars here, and I thought rather than do it the
9 way we've been doing it, having a little notice for
10 you all would be helpful. So we'll work toward the
11 24th and 25th, and we'll get locations and everything
12 out to you and a little bit more specific
13 information. But please let me know if that does not
14 work, and again, if we have the majority of the
15 Committee cannot make it, we'll look for another
16 date.

17 And with that, I have no other comments to
18 make other than to thank you all for working so hard
19 the last couple of days on these topics, for the
20 employee organization representatives who came in and
21 have dedicated their efforts to make this a
22 successful meeting. And with that -- and I should

1 thank some other people as well. I don't know if
2 Faye can hear me, but Faye Smith and Sheila,
3 Ellyn, Mary Catherine, have done just a terrific job
4 in helping me get this thing organized. So, if I
5 look good, it's all because of them. So I appreciate
6 their efforts and hope as you go out you'll thank
7 them, too.

8 And with that, I'm going to turn it over to
9 Mr. Almanza.

10 MR. ALMANZA: Did anybody say you looked
11 good?

12 MR. TYNAN: Al just asked me if anybody
13 said that I looked good.

14 MR. ALMANZA: I guess not. No, I just want
15 to close this by saying that I appreciate everybody
16 in this room being here because I learned a lot of
17 stuff over the last two days, and in the closeouts, I
18 was pulled away to do some other things, but I did
19 get to make it to both the closeouts, and very
20 interesting dialogue, very interesting observations
21 on everybody's part. And we're going to move forward
22 and it isn't lost on us. What you said and the

1 things that you brought to us are not going to be
2 ignored because that's the only way that we're going
3 to get to where we need to go, to include everybody
4 into the final product, and I think that that's the
5 healthy way to move forward. So thank you all for
6 coming, and have a safe trip home.

7 (Whereupon, at 5:00 p.m., the meeting was
8 concluded.)

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C E R T I F I C A T E

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

NATIONAL ADVISORY COMMITTEE ON
MEAT AND POULTRY INSPECTION
PLENARY SESSION

Arlington, Virginia

February 6, 2008

were held as herein appears, and that this is the
original transcription thereof for the files of the
United States Department of Agriculture, Food Safety
and Inspection Service.

TIMOTHY J. ATKINSON, JR., Reporter
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