

UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

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ADDRESSING SAMPLING AND TESTING
METHODOLOGIES, COMPLIANCE GUIDELINES
AND N-60 LABELING

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October 14, 2008

1:30 p.m.

L'Enfant Plaza Hotel
Ballroom D
480 L'Enfant Plaza, S.W.
Washington, D.C.

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

2 (1:30 p.m.)

3 MR. ALMANZA: So good afternoon, everybody.

4 I, if I can get used to this thing, I want to
5 welcome everybody to this meeting. I know that it's
6 a very important topic that we're going to be
7 discussing this afternoon and certainly tomorrow
8 morning, but you being here is very important to me
9 and important to the Agency.

10 We're going to be taking a look at
11 sampling, at testing procedures, as a way to fight
12 one of the Agency's most pressing concerns which is
13 *E. coli* O157:H7, which I'll just refer to as *E. coli*
14 from here on out.

15 I want to stress that today's meeting, this
16 is an information sharing and information gathering
17 session. We're looking to come away from this
18 meeting with an understanding of sampling and
19 testing from all angles, the Agency's standpoint,
20 the industry's perspective and, of course, we're
21 interested in what consumer groups have to add to
22 the discussion.

1 You can see from looking over the meeting's
2 agenda that we've done our best to hear all sides of
3 the issue.

4 Over 25 years after this strain of *E. coli*
5 emerged on the scene, we're still learning more and
6 more about it and looking for ways to eliminate this
7 threat to food safety.

8 We have made some progress, and we've
9 learned that 34 percent of illnesses from *E. coli*
10 come from ground beef which helps us target our
11 efforts. We've also put some controls, like
12 sanitary dressing procedures in place, and some of
13 you in the room may know the numbers, that up until
14 last year, we reduced the number of regulatory
15 samples testing positive for *E. coli*, but you also
16 may know that last year's illnesses and recent
17 recalls that we have to work with, we have work to
18 do as well.

19 We've also learned and we found that even
20 our controls on food safety systems and targeted
21 efforts do not completely and consistently prevent,
22 eliminate --

1 CONFERENCE COORDINATOR: Hello.
2 Mr. Almanza?

3 MR. ALMANZA: Yes, ma'am.

4 CONFERENCE COORDINATOR: This is the
5 conference coordinator. Can anybody hear me in the
6 room? Please check your mute button.

7 MR. ALMANZA: I don't have a mute button
8 (laughter) yet.

9 OPERATOR: If you're on a speakerphone,
10 please pick up the handset.

11 MR. ALMANZA: Or maybe I had a mute button
12 that I didn't know I had. Bryce, you want to come
13 up and tell some jokes or stories, so long as
14 they're not about me.

15 (Pause.)

16 CONFERENCE COORDINATOR: Okay. I'm not
17 hearing anything.

18 MS. JOHNSON: You're not hearing us. Are
19 you hearing us?

20 CONFERENCE COORDINATOR: I hear you very,
21 very faintly and muffled.

22 MS. JOHNSON: Faintly and muffled, okay.

1 CONFERENCE COORDINATOR: Hello.

2 MS. JOHNSON: Yes.

3 CONFERENCE COORDINATOR: I'm not hearing
4 anything.

5 MS. JOHNSON: Mr. Almanza, can you talk and
6 see if she hears you.

7 MR. ALMANZA: Can you hear me?

8 (No response.)

9 MR. ALMANZA: No, I guess not. My mute
10 button is still on.

11 MS. JOHNSON: Operator?

12 CONFERENCE COORDINATOR: Yes, I can hear
13 you briefly.

14 MS. JOHNSON: All right. Well, we need to
15 get going. We'll get back to you.

16 CONFERENCE COORDINATOR: Hello.

17 MS. JOHNSON: We'll get back to you, okay.

18 CONFERENCE COORDINATOR: Okay. I'm going
19 to hang out right here and just come back to me.

20 MS. JOHNSON: Okay.

21 CONFERENCE COORDINATOR: Thank you.

22 MR. ALMANZA: Okay. So where was I --

1 UNIDENTIFIED SPEAKER: You're done.

2 MR. ALMANZA: Yeah, I feel like I'm done.
3 It's warm up here.

4 So as I was saying, we're working hard to
5 fight this pathogen, and as an Agency we're trying
6 to figure out ways to use data to predict problems,
7 problem areas and building an inspection
8 infrastructure that takes us to a more proactive
9 rather than reactive approach to food safety.

10 We believe that testing raw beef products
11 for *E. coli* is one piece of a larger puzzle to make
12 sure contaminated meat doesn't make it into any of
13 our grocery stores or homes. We're also looking
14 forward to hearing from you from all sides on this
15 issue. During this meeting, we'll take a critical
16 look at sampling and testing procedures. We want to
17 move us toward a more uniform and consistent
18 approach across the board or should I say across the
19 field.

20 We want to inform you on our testing
21 methods, like the laboratory enrichment procedure
22 we've been using since January of this year, that

1 will probably impact sensitivity for finding more
2 positives in beef. In addition, we want to gather
3 input concerning some of the guidance documents we
4 give to industry about testing beef trimmings and
5 using labels that have testing claims.

6 CONFERENCE COORDINATOR: Hello. Can you
7 hear me?

8 MR. ALMANZA: And we also want to --

9 CONFERENCE COORDINATOR: Sheila?

10 MR. ALMANZA: -- discuss some areas of
11 training that FSIS and industry alike give to Agency
12 and plant employees testing for *E. coli*.

13 All of those parts, methodology, training,
14 technology, are technical and complex but our goal
15 is simple. We want to make sure that we're doing
16 everything we can, the best way we possibly can, to
17 protect public health through food safety.

18 Some of you who may have heard me speak
19 before know that I stress communication. It's the
20 best practice for FSIS to communicate with the
21 public, with consumer groups and with industry.
22 These public meetings are an important forum to help

1 us hear from you.

2 So we look forward to your comments over
3 the next day and a half, and thank you for being
4 involved in our public policy process. Let's put
5 our heads together to find ways, like sampling and
6 testing, to protect the public from *E. coli*. Thank
7 you.

8 MR. ENGELJOHN: Thank you, Mr. Almanza. My
9 name is Daniel Engeljohn. I'm the Strategic Risk
10 Manager for FSIS, and it's my responsibility to help
11 strategize as to how we can protect public from
12 adverse consequences from the products that we
13 regulate. And so today we're going to talk about *E.*
14 *coli* O157:H7 and much of what we have in place today
15 with regards to sampling and testing, getting a
16 perspective from stakeholders as to the issues that
17 we need to put on the table, and hopefully gather
18 comments that we can use to better inform our
19 policies.

20 To give you a bit of an overview of what
21 we're going to discuss over the course of the next
22 day and a half.

1 First we're going to have just a brief
2 background by myself on the issues leading up to the
3 need for why we're having this public meeting at
4 this time, a general overview of the order and
5 content of the presentations that you're going to
6 hear over the course of the next day and a half, and
7 then get a perspective as to what FSIS hopes to
8 accomplish with this public meeting.

9 Regarding the background, last year was a
10 year in which we identified an increase in the
11 number of adverse events and that has continued
12 through to this year. We hosted a public meeting in
13 April of this past year in which we discussed the
14 results of a checklist that was in part a result of
15 needing to know more about the control procedures in
16 place by the industry that we regulated. We did
17 that checklist last fall and reported the outcome in
18 April.

19 In addition, in April, we identified a
20 number of things that we were considering in terms
21 of putting on the table issues that we thought might
22 need to be addressed in order to get greater

1 controls for *E. coli* O157:H7, and in particular, we
2 identified that there was considerable inconsistency
3 in the controls in place by industry as well as
4 those procedures in place by the Agency.

5 In addition, there was an increase in the
6 percent positive results for FSIS test of trim and
7 of ground beef. We started the trim program last
8 year. We didn't do any of the ground beef program
9 for a number of years, really since 1994, and the
10 Agency has found that the increase of positive rate
11 is on the rise again in an adverse way and as of
12 this week, our percent positive rate for our ground
13 beef program is double that for which we had it this
14 time of last year.

15 All this leads us to believe that the
16 signals that we have are percent positive rate in
17 trim and in ground beef, are indicating that
18 contamination, getting through the slaughter and
19 dressing operations is on the rise. As a
20 consequence, getting through that particular
21 operation, as well as getting through the trim, and
22 then into ground beef.

1 We also identified that there was evidence
2 of primal cuts being used specifically for ground
3 beef operations and that the bench trim derived from
4 those products for the most part were not being
5 addressed in control programs by industry. And so
6 this served as a source in terms of raw materials
7 that may, in fact, be contributing to poorer control
8 for O157:H7.

9 And then finally, sampling and testing are
10 increasingly being used as components of an
11 effective HACCP system, and *E. coli* O157:H7 has
12 always been identified by the Agency as one of the
13 supplemental controls that needed to be in place by
14 industry but what we found and what we are finding
15 is that for many establishments, the *E. coli* O157:H7
16 tests are in some cases the only controls that are
17 in place in terms of informing their system.

18 Improperly designed sampling and testing
19 programs therefore jeopardize the effectiveness of
20 HACCP systems, and there is an increase in
21 likelihood that the public health will be negatively
22 impacted if, in fact, these control programs are not

1 improved.

2 As a consequence, we took the information
3 that we gained from last year's experience from the
4 checklist and information that we had gleaned from
5 our own program and developed a draft compliance
6 guideline on sampling and testing. The intention of
7 that guideline was to provide some framework as to
8 how we thought a properly designed sampling and
9 program should be put together for 0157:H7 with a
10 particular focus in trim. This would be product for
11 which we would do an excision test as opposed to
12 pulling a composite test, much like we would do for
13 ground beef, but other components that involve trim
14 would include head meat and cheek meat which would
15 not be included necessarily in an excision program.

16 In any case, the compliance guideline had a
17 special focus on the N-60 testing program that was
18 in use by industry for which the Agency has, as
19 well, adopted in its own testing program, and then
20 we identified a framework for identifying when too
21 many positives are too many in terms of indicating
22 that negative results might, in fact, be false

1 negatives and that product would be released even
2 though it tests negative that might have a higher
3 likelihood of testing positive if re-tested or found
4 and used later in the system.

5 And so we invited comment on that
6 particular compliance guideline which issued in
7 August. We reopened the comment period on it in
8 September and it runs through, comments on that
9 particular document through November 17th. And so
10 this meeting is intended to as well gather
11 information that can supplement the information we
12 would use to inform that document, perhaps as
13 drafting it as a final or reissuing it as a draft
14 depending on the types of comments that we get.

15 In any case, I think that it would serve as
16 a useful guidance to industry as well as to the FSIS
17 employees.

18 In addition to that one particular guidance
19 on N-60 testing, we issued a smaller document that
20 condensed down the information with a specific focus
21 to provide sampling frequencies for small and very
22 small plants which was derived from the larger

1 program.

2 Today, as well, the Agency did post another
3 compliance guideline for N-60 labeling, and so you
4 should be able to go to the website and find that
5 criteria. It was posted just before the start of
6 this meeting.

7 In terms of the overall presentations that
8 we have available over the course of the next day
9 and a half, we're going to first hear perspective on
10 the FSIS N-60 sampling and testing program. This
11 will give you an idea as to how we've designed our
12 program, issues related to the laboratory
13 considerations and things as we go forward into the
14 future as to what we are looking at in terms of
15 enhancing and improving our program.

16 We'll have a second presentation on a
17 perspective from industry N-60 procedures and
18 effective feedback systems. This would be from the
19 perspective of a user of beef trim making ground
20 beef with helpful guidance as to what should and
21 could be in place to develop and effective program.

22 That would follow with a perspective on

1 laboratory methods and consequences of
2 inconsistencies and non-uniformity in N-60 sampling
3 and testing as well as laboratory specific issues.
4 And so we hope to hear issues from experience
5 gleaned from industry in terms of a laboratory and
6 what they receive in the laboratory and then
7 considerations that they have in terms of reporting
8 back results.

9 That then would be following a perspective
10 on consumer expectations regarding N-60 sampling and
11 testing. So that we can get on the table what the
12 consumers expect, what they believe that they
13 understood the programs to be really from all sides.

14 And then we will have a public comment
15 period where we can, as well, when feasible, provide
16 some clarification to any issues that arise for
17 which it would be helpful to get more information,
18 and if we have the answers, we'll share them at that
19 time.

20 I do want to identify that for those of you
21 here today, we are attempting to have a telephone
22 call in so that the public can as well call in and

1 ask questions. There will be coffee out in the
2 lobby throughout the afternoon, and there is no
3 formal break that we're going to have. So I just
4 invite you to get up and go out and get a drink as
5 you need it, but we're not intending to have formal
6 breaks. We intend to just make the presentations,
7 follow them up with questions, and then provide
8 clarity as we can.

9 Tomorrow morning then we'll start up again
10 early with a perspective on what we have in terms of
11 some solutions to get at some of the issues and then
12 get feedback on that. That would involve the
13 presentation on the FSIS training to address issues
14 about our N-60 sampling and testing program. I
15 think we'll probably see a video on that as well as
16 get a perspective from industry on the available
17 best practices for the beef industry with a specific
18 focus on N-60 sampling and testing.

19 And then finally, we have an overview of
20 the FSIS guidelines on sampling and testing of trim.
21 This really would be an overview of the compliance
22 guideline that was issued that got at the very

1 specific focus on trim, on N-60 testing, on high
2 event days, and the criteria that was derived around
3 that.

4 Then in the afternoon, we'll have an
5 overview of the draft criteria for the N-60 labeling
6 in lieu of certificates of analyses. The Agency has
7 been presented on numerous occasions, evidence that
8 small and very small plants in particular are having
9 difficulty getting certificates of analyses and this
10 was intended to be one solution to the get at the
11 issue of getting more information to the industry
12 that actually uses trim from suppliers in the
13 production of ground beef.

14 And then we'll have an industry perspective
15 on the lessons learned from the *E. coli* O157:H7
16 outbreaks from last year as well as into this year.

17 And then we'll follow that up with an
18 invitation to provide comment and input on other
19 O157:H7 related issues. Anything that we missed on
20 O157:H7 and then we will certainly open that up to
21 any other issues that you think we should put on the
22 table.

1 It is the Agency's intention to ensure that
2 we have more technical meetings to address concerns
3 by stakeholders. And so if, in fact, we identify
4 other issues to be brought forward, our intention is
5 to have public meetings similar to this one in order
6 to address the issues. And then we'll have a wrap
7 up after that.

8 What we hope to accomplish then is to get
9 stakeholder input on issues related to O157:H7
10 control, have constructive input on enhancing the
11 utility of the guidelines on sampling and testing as
12 well as on the N-60 label draft claim that we are
13 making available as of today, and to get more
14 consistent and uniform application of sampling and
15 testing by both FSIS and the industry.

16 And then finally, as we all want to do, is
17 to improve public health protection associated with
18 *E. coli* in raw beef. Thank you.

19 MR. ALMANZA: I don't know how you do that
20 with that right there.

21 The first presenter will be Dr. Jose Emilio
22 Esteban. He's a Science Advisor for Laboratory

1 Services and Research in the Office of Public
2 Science, Food Safety and Inspection Service at USDA.
3 Part of his responsibilities include assuring that
4 decisions made at the laboratories are
5 scientifically sound. He's been with the Agency for
6 six years, previously as Director of the Western
7 Laboratory, most recently in his current role as a
8 Science Advisor.

9 His academic accomplishments include doctor
10 in veterinary medicine, a Ph.D. in epidemiology and
11 two master's degrees, one in preventative medicine
12 and the other in business. Dr. Esteban.

13 DR. ESTEBAN: Thank you, Mr. Almanza.
14 Thank you all for giving me a few minutes of your
15 time to discuss issues that address laboratory
16 methods and sampling. This has been an area that I
17 have been working for a long time. Even before I
18 came to this Agency, I was working with CDC and
19 focused very much so on sampling issues. So this is
20 close to my heart here.

21 Okay. So this presentation today is going
22 to address three basic areas. One of the things

1 particular to the specific method we want for *E.*
2 *coli* O157:H7, changes that we've done or
3 modifications that have recently happened to the
4 sample collection, and the last part of it will be
5 talking about the sample processing.

6 I'm going to describe here basically the
7 results. I'm starting with the result -- During
8 calendar year '07, MT03 is an examination we have
9 for *E. coli* O157:H7 within the Agency. We went
10 about 12,000 samples that calendar year, and we had
11 about .24 percent of the samples that were positive.
12 During calendar year '08, up until September 14th,
13 we have close to analyzed 8400 samples and almost
14 doubled the rate of *E. coli* positives.

15 Now, while it might appear that it is a
16 significant difference, if you were to be very
17 strict statistically, there is still not a
18 significant difference because at those low levels
19 of prevalence, the variation is enormous. One
20 sample more, one sample less, changed that
21 percentage dramatically. But nevertheless, it is an
22 obvious increase in positive prevalence.

1 So in trying to address what may have
2 caused this, the only thing that we have changed in
3 the last few years have been the median, the method,
4 the way we collect our samples. We went from a
5 complete random or approximately a random program to
6 a risk-based sampling program. And the other thing
7 that could have changed is, in fact, a true change
8 in the pathogen prevalence. So I'm going to look at
9 each one of those, or at least the first two in
10 detail and see what we get.

11 Okay. The lab method is the same one
12 basically that we've ran for several years. There's
13 MLG Chapter 5. We publish it all the time. We have
14 very consistently. It includes a screen stage, a
15 confirmation stage, and a quantification stage. And
16 the only thing that we have changed recently in the
17 screen is over the last probably four years or so,
18 we changed from a lateral flow device, a quick
19 screen method, to a BAX or PCR approach.

20 As far as the confirmation, we really
21 haven't changed any of that. It's been basically
22 biological confirmation and genetic confirmation.

1 The quantification we started doing
2 recently, and that's to get an approximation to the
3 level of contamination that each particular sample
4 may have had.

5 On the outside table, there was a flowchart
6 with a method. Hopefully a lot of you -- that's
7 very detailed. I'm not going to go through the
8 details that the method has but basically it's a
9 five-day method, five to seven-day method depending
10 on how far you take it. The sample is collected.
11 About two pounds of sample is collected at the
12 slaughter plant. We receive it at the lab at which
13 time we select 325-grams, divide it into 5 subs of
14 65 grams each. We incubate that in enriched media
15 overnight. The next day we do the PCR screen. If
16 this screen is positive, we report it as a potential
17 positive result. We again re-streak that sample,
18 re-incubate selected media. The next day we pick
19 typical colonies and if that is positive, then we
20 report it as presumptive. And so for the last
21 level, that's when we have -- those colonies are
22 typical. We go forward with that. We do gene

1 typing. We do -- and biochemical confirmation. So
2 by day five or four, we've got an actually confirmed
3 genetically that there is a positive O157:H7.
4 There's really no possibility that it will be a
5 false positive.

6 And again, all the details are very, very
7 clearly in that flow chart.

8 So one of the things that we changed
9 starting in January of this year was our enrichment
10 media. We changed our enrichment because we wanted
11 to have a little bit more flexibility because the
12 number of samples we're processing, sometimes in our
13 three labs, and for those of you who don't know, the
14 Agency has three field services lab, one in
15 California, in Alameda, one in the Midwest in St.
16 Louis, Missouri, and one on the east coast in
17 Athens, Georgia.

18 We receive either one or two shipments a
19 day by FedEx of samples. In order for us to offer
20 the same service that we currently do which is
21 possibly solve within 48 hours, positive or negative
22 results within 48 hours. We needed to try to reduce

1 incubation time that we're getting. So they chose
2 to go to a media called TSB. Before you were using
3 media called mEC, modified *E. coli* media, and that
4 needed to incubate about 20 to 24 hours. The new
5 media which, by the way, is the same media that they
6 use in Canada and they use in Europe, TSB, and that
7 allowed us to have flexibility to incubate between
8 15 and 22 hours.

9 So we designed then a study to document
10 before we made the change that, in fact, those two
11 media were comparable but yet look at the incubation
12 time. Okay. And for that we have a very detailed
13 process control. It's a multiple page protocol that
14 we go through before we actually do the final study
15 and the data I'm presenting here is basically the
16 last page of that study where we compared the
17 performance of these two medias as regards to
18 incubation time, and -- and I know the top of that
19 slide is a little bit blurry but the first column is
20 the substrate. The second column is the actual CFU
21 that we inoculated those samples with. The third
22 column is the targeted inoculum level. It was

1 pretty much zero for CFU or 20 CFU, and the last
2 three columns on the right-hand side of the slide
3 present the percent confirmed positive samples.

4 So what we're trying to compare in this
5 study design is basically whether the media called
6 the same number of positives was positive or
7 negative by changing the incubation time, by
8 changing the type of media. So you have all the
9 media. Potentially we have run through the method,
10 swab the first, sausage which is summer sausage,
11 fermented sausage, beef trim, ground beef and beef
12 patties.

13 As you can see for swab and for sausage,
14 the two medias perform pretty much the same way
15 regardless of the incubation time. On beef trim,
16 TSB which are the two middle columns if you will,
17 there was no significant difference in how they
18 performed, whether they were incubated at 15 hours
19 or 22 hours, which is really the target for our
20 study. We wanted to make sure that we could
21 incubate a shorter time and get the same result.
22 And the last column is the mEC at 24 hours, and you

1 can see that media that we were testing, which was
2 TSB, performed at least as well as or better than
3 the mEC and that was the target of this study.

4 If I can go back one, this data you saw
5 before is based on five sample sets sent to three
6 different labs at two inoculation levels, doing it
7 in triplicate. So there was a lot of samples behind
8 that table to get to those numbers.

9 So what this tells us basically is that the
10 media perform at equivalent.

11 Okay. So the next thing we wanted to look
12 at what was whether we had a significant difference
13 in the sampling results based on how we were
14 collecting the samples. Remember, we changed from a
15 quasi-random sampling method of collecting samples
16 to a risk-based sampling protocol.

17 And what we've done here is summarize the
18 whole experience over the last few years since we've
19 changed to a risk-based sampling method. The dark,
20 on the vertical axis, you have the number of
21 positive samples, and on the horizontal axis is the
22 type of plant by category, 1 through 4. You can see

1 the dark columns are what -- in looking at the risk-
2 based sampling methodology, the dark columns is what
3 we would have expected to see as passive samples
4 given the new sampling protocol, and you can see in
5 category 3 and category 4, the observed is higher
6 than the expected which means it was not because of
7 the sampling protocol that we're getting more
8 positives because the expected -- we actually were
9 seeing.

10 Okay. So what has changed? The sample
11 selection methodology, if the risk-based sampling
12 algorithm does not contribute to the increase that
13 we're seeing, if enrichment media have no
14 statistical contribution to the increase that we're
15 seeing, and at least the study that we designed, the
16 purpose was not to define whether we have a better
17 recovery but whether the media was performing the
18 same.

19 So if the way we collect samples is not
20 different and the way we analyze samples is not
21 different, then the only thing that is left is that
22 maybe there is an increase in prevalence and we at

1 the Agency don't collect daily data in a quantity
2 you in industry do, to document that this is, in
3 fact, what you're seeing. So I don't have that data
4 available to me. So I cannot say it's actually
5 increasing pathogen prevalence.

6 All right. So we address issues regarding
7 the media itself and we'll look at examples.

8 Now, as far as sample processing, as I
9 mentioned before, we are trying to follow industry's
10 lead here in doing an N-60 sampling protocol, and
11 again the purpose of our sampling the ones that FSIS
12 does is to determine whether the HACCP system is
13 working. So we follow the N-60 protocol, but we
14 have their limitation, which their method calls for
15 use to analyze 5 - 65 gram samples which is about
16 325-grams of tissue.

17 This is actual data that we received from
18 the lab, and it includes all the samples that we
19 received from April to September of this year. What
20 you see on the vertical axis again is the frequency
21 of samples. The horizontal is the number of pieces.
22 The target here is 60, N-60, which we receive 60

1 samples in a submission. You can see it's pretty
2 much a bell-shaped curve other than the last column,
3 which there was too many pieces to count that we got
4 back from the field, but for the most part, it
5 follows the bell-shaped curve around 60, which we
6 would expect.

7 The other thing that is not considered in a
8 lot of those sampling protocols is the type of trim
9 that we collect the sample from. As you can see in
10 this chart, and I apologize. The horizontal axis is
11 labeled estimated percent fat. It's actually
12 proportion. So, for example, the highest column
13 there, the first one, is 10 percent fat is 90
14 percent meat or looks like meat. So again it
15 declines so that the vast majority of samples have
16 90 percent, the 90/10 trim, and the next column will
17 be 80/20 and next one 70/30, and so on and so forth.
18 So most of the samples have some fat but the
19 majority of them have little fat on them.

20 This is some actual pictures of what we
21 receive, and the guidance we have right now for the
22 N-60 protocol is the inspector should collect pieces

1 that are 4 inches by 2 inches by 1/8 of an inch
2 thick. And for the most part, they are trying
3 really hard to get us that. The problem with that
4 is that in doing their job correctly, we're getting
5 60 pieces that weigh 2 pounds, but we're only able
6 to analyze 325-grams. So we have conflicting thing
7 here. If we analyzed all 60 pieces, we analyze 325-
8 grams.

9 So one of the issues that we have to
10 consider here is the sample is collected, is mushed,
11 combined into this bag, is sent to the lab where
12 it's bounced like a football in the FedEx truck for
13 two days or a day, we get the sample in the lab and
14 we take everything out of that bag and cut pieces
15 into 65 gram samples. So even though we're not
16 sampling all 60 pieces, we have a pretty
17 representative sample of what the 60 pieces that
18 were submitted to the lab were. But we cannot
19 possibly, with the way we're collecting our samples
20 right now in the field, meet both objectives, 325-
21 grams and 60 pieces.

22 And I'm not familiar with how industry is

1 actually is doing this. Maybe we'll hear that
2 later.

3 So because we acknowledge there's some
4 limitations how we're doing sample collection and
5 processing, there is a couple of things that I want
6 to show you that are work in progress. One is, and
7 I don't know if some of you go back that long, but
8 we used to collect ground beef samples and ask the
9 inspectors to collect two pounds of sample. When we
10 started sending in the HACCP weighings, it actually
11 allowed them to collect exactly the amount that we
12 need for analysis. We are trying to find an
13 analogous system here where we give them a container
14 that fits the 60 pieces that weighs 325 to 365 grams
15 so that the inspector has a visual guide of what he
16 or she needs to collect, trying to standardize the
17 sample collection, so that when we get to the
18 laboratory, it's more consistent throughout. So
19 we're evaluating different containers for this.

20 The other thing that is a big limitation is
21 the tools the inspectors have right now to collect
22 the samples, and we're asking our inspectors to

1 collect literally with clippers and knife slices
2 that are one-eighth of an inch thick. It's really,
3 really difficult to do them. It takes them, you
4 roughly 40 minutes to an hour to be collecting all
5 these samples. You cannot expect the inspectors to
6 do this all the time. So we're trying to look at
7 different cutting tools that will allow us to
8 collect a more standardized, uniform, appropriate
9 sample size.

10 So those two pieces of work are currently
11 in progress.

12 The last one, and I think this one is going
13 to be quite interesting because I have no idea what
14 the result is going to be. We're trying to document
15 that there is no significant loss in recovery in
16 analyzing the entire 325-grams as a sample rather
17 than dividing it into 5 subs of 65 grams each. What
18 that would mean for the labs is that it will be an
19 automatic increase in throughput. We'll be
20 analyzing one sample rather than five subs for each
21 sample. So paperwork, processing, reporting,
22 everything will be substantially improved for us.

1 Again, the only difference that we might
2 find there is that there may be some issues with
3 increased sensitivity because we are analyzing the
4 entire sample now, and I don't know what the result
5 would be like, but we'll keep you informed.

6 Those are the three things that I wanted to
7 talk about today, sample collection, method changes
8 and sample processing, and I'm really eager to hear
9 any feedback or questions you may have.

10 MR. ALMANZA: Thank you. We may want you
11 to do a few questions.

12 DR. ESTEBAN: Sure. Please. Dan, do you
13 want to moderate?

14 DR. ENGELJOHN: Can you just ask her to --

15 DR. ESTEBAN: Sure.

16 DR. ENGELJOHN: We need a microphone and
17 identify your name and association. Sheila's coming
18 with a microphone.

19 MS. NESTOR: I'm Felicia Nestor with Food
20 and Water Watch. I missed the beginning of your
21 presentation. So perhaps you answered this. The
22 categories 1 through 4 on the plants, did you, did

1 you tell us what those categories are?

2 DR. ESTEBAN: No.

3 MS. NESTOR: Could you explain? Are they
4 the volume categories that are on the recent
5 sampling, you know, over 250,000?

6 DR. ESTEBAN: Do we have the table? Let me
7 become familiar with this table here. Category 4 is
8 less than 1,000 pounds. Category 3 is 1,000 to
9 50,000. Category 2 is 50,000 to 250,000. Category
10 1 is more than 250,000.

11 MS. NESTOR: Okay.

12 UNIDENTIFIED SPEAKER: Can you repeat that
13 please?

14 DR. ESTEBAN: Yes. Category 1 greater than
15 250,000. Category 2, more than 50,000 up to 250.
16 Category 3 is from 1,000 to 50,000, and Category 4
17 is less than 1,000.

18 MS. NESTOR: Just a quick follow up. Am I
19 correct, do I remember correctly that you had the
20 highest rate of unexpected results in Category 3?

21 DR. ESTEBAN: I believe so, yes. 3 and 4.

22 MS. NESTOR: Oh, 4. Okay.

1 DR. WARREN-SERNA: Wendy Warren-Serna, Food
2 Safety Net Services. A question for you on your
3 inoculation study. What were the samples sizes,
4 analytical sample sizes that you inoculated in terms
5 of the beef trim and ground beef? Was it 4 CFUs in
6 a 65 gram sample or 4 in a 325?

7 DR. ESTEBAN: We inoculated -- we prepared
8 a dilution that was a percentage of 4 or 20 CFU and
9 they inoculated that into one sample and then subbed
10 it out.

11 DR. WARREN-SERNA: So that would be in a
12 the context of a 65 gram sample.

13 DR. ESTEBAN: 325-gram sample.

14 DR. WARREN-SERNA: So 4 in a 325-gram.

15 DR. ESTEBAN: Or 20.

16 DR. WARREN-SERNA: Or 20.

17 MR. DANIELSON: I better spit my gum out
18 here. Old judging team trick. Thank you for the
19 information. I will share with you I guess some
20 anecdotal information so that -- from the industry
21 or at least from -- I'm Dean Danielson with Tyson
22 Foods.

1 We do a little bit of testing in this
2 method over the years. I believe just last month my
3 lab manager told me that we have exceeded our 1
4 millionth sample since we started this process in
5 2002. So we've got a little bit of experience under
6 us in method development and in sampling
7 development.

8 I can't remember last year if in the
9 October meeting or sometime when the USDA new method
10 was published, but in our evaluation of when that
11 was published, my laboratory micro expert told me
12 you should expect a 2X or more increase in USDA
13 positives based upon this method increase and that's
14 based upon our years of methodology evaluation,
15 enrichments methods and the things that were
16 strictly put into play in the new methods.

17 So we are not shocked or surprised at all.
18 In fact, we fully expected it to be a little bit
19 higher than what perhaps you are showing. And
20 whether I said that publicly or amongst others in
21 industry meetings, we have professed that several
22 times and feel that the numbers are about what they

1 should be.

2 I will share with you that in our trim
3 testing program this year, our trim incident rate
4 '08 versus '07 is down about 25 to 30 percent from
5 '07. We did not see continuing increases, and so we
6 see a downward trend. We believe '07 was an anomaly
7 of a year. If you look over several years, year
8 after year after year, the annual rates change.
9 They ebb and they flow. Obviously seasonally and
10 geographically as well, but our trim data is down 25
11 to 30 percent.

12 I'm aware of finished product grind data
13 from a large grinder in '08 versus '07, 50,000
14 samples analyzed in '08, and their finished grind
15 numbers are down substantially from '07 in a
16 methodology that hasn't changed. So that's
17 anecdotal information that I share.

18 I am troubled with the not analyzing the
19 whole sample collected. We would submit that that
20 is something that needs to be looked at. In fact,
21 we're chastised or we've been told through FSIS
22 reviews that you've got to analyze the whole sample,

1 and I find that it's not being done here, and I
2 would, you know, I urge you to look at that.

3 DR. ENGELJOHN: Thank you.

4 MS. SMITH-DeWAAL: Caroline Smith-DeWaal
5 with the Center for Science in the Public Interest.

6 Dr. Esteban, did you -- do you have any
7 statistical backing for the N-60 as your number of
8 samples? Did you test N-80 or N-100? I'm just not
9 perhaps familiar with the statistical backing as I
10 need to be, and I'd like to hear from you. Thank
11 you.

12 DR. ESTEBAN: Yes. We followed the N-60
13 because that seemed to be the industry standard.
14 The statistical foundation of the N-60 is part of
15 the case 15 in the ICMSF table. And the only flaw I
16 see with the N-60, and it's not a flaw. It's a
17 simple description of a statistical -- of where the
18 N-60 came from, is that it assumes a 5 percent
19 prevalence and if the prevalence were lower, of
20 course, the end would have to go up, and so that's
21 basically the information for the statistical
22 background.

1 Statistics are a tool, okay. So if you
2 want to -- your numbers, it'll whatever you want.

3 MS. SMITH-DeWAAL: I just have a follow up
4 thought. It was my understanding that the prevalence
5 that N-60 is based on is a 5 percent positive which
6 I mean we don't think we're -- we hope we're nowhere
7 near that. So has USDA looked at a number that
8 would provide a higher confidence level given the
9 prevalence that you think you may find in trim?

10 DR. ESTEBAN: At this point we have not,
11 but I'll take that into consideration.

12 DR. BERNARD: Dr. Esteban, thank you for
13 your presentation first of all. Dean Bernard,
14 Keystone Foods.

15 Focusing on this slide, there was an
16 earlier question about it, but if you just look at
17 the categories, I'm not sure that it gives us the
18 complete picture here. It certainly makes Category
19 4 look somewhat suspect, but I'm wondering if the
20 sample sets here are balanced, if you were to look
21 at this in terms of percent positives by sample,
22 what this data would look like. Do you have that

1 information?

2 DR. ESTEBAN: I don't have it with me, but
3 we did look into it and adjusted it by sample size
4 within each category, and it still appeared that the
5 expected rate was below what we were observing for
6 those two categories. So after adjusting for number
7 of samples, the sampling proportion within that
8 category, there is simply -- and again, let me
9 emphasize this. Well, two things first. Never
10 leave your slide out because somebody will find
11 something to look into it. (Laughter.)

12 And number two, to answer your question,
13 remember we're talking about very, very small
14 numbers here, and so a change in one or two up or
15 down. In this case, you know, you go from 10 to 15
16 or if you compare Category 3 with Category 4, you
17 know, we look at percentage on small numbers. Huge
18 changes. They're not significant. Okay. Here the
19 difference is that it's pretty consistent that the
20 expected is below the observed, which seems to
21 suggest that it was not the way we collected the
22 samples that was causing the effect, but rather

1 something extraneous. I'm not saying that the
2 combination of changing to TSB, changing the
3 sampling algorithm and something in prevalence, the
4 combination of those three things interacting may be
5 the end result we're seeing, but statistically we
6 can't point to either the media or to the sampling
7 format.

8 MS. JOHNSON: Excuse me, Dr. Engeljohn.
9 Did you want to take one or two more briefly and
10 then move on? One more.

11 DR. MASTERS: Barb Masters, Olsson, Frank
12 and Weeda. You can go to the next slide. I'll let
13 you move on. One more slide. On that particular
14 slide, you're looking at the percentage, like 90/10
15 and 80/20. Have you looked at those particular fat
16 contents?

17 DR. ESTEBAN: Which one? That one.

18 DR. MASTERS: That one.

19 DR. ESTEBAN: Oh.

20 DR. MASTERS: Have you looked at the
21 particular fat contents and then tried to determine
22 what percent positives you got in any particular

1 category to see if you had any particular percentage
2 of positives, for example, you might expect to see
3 more positives in a particular category of product,
4 and have you looked across those to see if you got
5 more positives in a particular category of fat to
6 see if that may have had an impact on, since you've
7 got obviously more lean product into the laboratory,
8 and have you looked at that and determined if that
9 impacted on your sample that you received and then
10 did you cut that -- were you able to take that back
11 to see where those samples came from, from the size
12 of plants and that sort of thing? Have you done any
13 more data sort on that?

14 DR. ESTEBAN: Good question, and actually I
15 don't have the data with me, but I can tell you that
16 the more fat the sample has, the worse our method
17 performs. Okay. So a sample that is 50/50, we
18 rarely, if ever, find *E. coli* on it, O157:H7 anyway,
19 whereas with very lean or very, very muscle intense
20 trim, the likelihood is that we will find more
21 positives. Now, I don't have the statistical
22 analysis done, but it's a work in progress.

1 MR. ALMANZA: Thank you.

2 (Applause.)

3 MR. ALMANZA: We'll have a chance for more
4 questions. I think we should move on though, and as
5 I expected, we're going to have a lot of good
6 comments, and certainly a lot of good questions.

7 So with that, we're going to move onto the
8 next presenter, which is Tim Biela. I've known Tim
9 from back when I was a District Manager in Dallas.
10 He's the Senior Vice President of Operations and
11 Chief Food Safety Officer for American Food Service.
12 He's got a bachelor's degree of science and biology
13 and a master's degree in engineering, quality
14 assurance, and is directly involved in improving the
15 safety of ground beef industrywide. He is active in
16 several industry organizations and chairs the
17 processing sector for the Beef Industry Food Safety
18 Council. Tim.

19 MR. BIELA: I know the focus of today's
20 meeting is about testing, and I want to caution
21 everybody about, you know, a premise that we all
22 understand as scientists, and that is that you can't

1 test your way to safety. We have a good system
2 that's out there today called HACCP, which is a
3 systematic approach towards food safety. It doesn't
4 rely on end product testing to basically have an
5 effective system of producing safe food, and I want
6 to try to cover some of this in prerequisite
7 programs, approved supplier programs, and
8 certificates of analysis.

9 And I work for American Food Service
10 Corporation. We produce about 7 million pounds of
11 ground beef every week to give you an idea, and I've
12 been testing I think longer than most people. So I
13 do understand the necessity to test as a
14 verification activity for the process controls that
15 I have out there to produce safe products. About
16 100 million pounds or 120 million pounds of that
17 product goes to retail. So it goes, you know, into
18 consumers' homes, not to commercial establishments,
19 where I believe there's better controls associated
20 with, you know, the CCPs.

21 Al was the District Manager for many years,
22 and I hope I made his job pretty easy by not

1 creating a lot of opportunities for failures. You
2 know, going back to 1995, you know, the USDA pointed
3 out that, good sanitation is a fundamental
4 requirement of federal meat and poultry inspection
5 laws and yet poor sanitation practices, and I want
6 to key on this, because I think it's one of the
7 focus areas that we've got to go back and pay
8 attention to, are the most frequent deficiencies
9 found, not just in meat and poultry plants, but in
10 food plants in general, and they create the risk for
11 unsafe production of food products. There's a
12 direct link between insanitary practices and the
13 likelihood of product contamination with pathogenic
14 bacteria.

15 This was right out of the preamble to the
16 HACCP regulations. So I gave them the credit for
17 that by giving them an approach.

18 The HACCP system is considered as the right
19 approach, the best approach for creating safe foods,
20 and it's about preventing contamination, not
21 detecting contamination. You cannot test
22 your way to food safety, and again, this is a guy

1 that's been testing longer than most people in the
2 industry. When people wouldn't test trim, I tested
3 it myself. I took a lot of criticisms for that.
4 I've took a lot of criticisms, and I'm going to talk
5 about testing in the right perspective, but not the
6 approach that's going today, which is to test and
7 test and test and test and retest, which really
8 doesn't make good scientific sense.

9 You know, we've got to be accountable, not
10 the Agency, but we as the industry have to be
11 accountable for meeting the standards that we've
12 outlined in our HACCP programs. These are the food
13 safety programs that we've got to utilize.

14 Regulatory oversight, I believe there's
15 plenty of regulatory oversight out there. You know,
16 the Agency is supposed to be evaluating the HACCP
17 systems, the systematic approaches to develop safe
18 foods in every plant that produces products. And
19 then they have systems in place to verify it.

20 One of the most recent notices said don't
21 do any of the inspection activities. Go focus on
22 taking a test. I said earlier, don't do that.

1 Don't take your eye off the process controls that
2 create safe food to do verification testing because
3 again you're going to miss the opportunity. I would
4 have had many more positive events, I think, if I
5 didn't use a systematic approach towards process
6 control, and you can do that by looking at the
7 documentation and the practices that are occurring
8 in those critical areas that create risks.

9 I heard the conversation earlier about the
10 dressing procedures and the failures. We know where
11 contamination occurs. We know that the
12 interventions that have been researched can have an
13 effective reduction of these harmful bacteria. And
14 then through verification testing and validation of
15 this HACCP approach, I think you can create safe
16 products. And the Government has the ability to
17 take appropriate actions when the industry doesn't
18 do it.

19 I haven't studied quality for 25 years. I
20 could tell you this Plan-Do-Check-Act, this is about
21 identifying improvement opportunities, identifying
22 who your key customers are. Remember HACCP is a

1 systematic approach, and it doesn't come from, you
2 know, out in the blue. It really comes from a
3 system of process control and improvement that is
4 continuous. Plan-Do-Check-Act. We've got a system
5 in place. You plan the system based on what you're
6 trying to produce, look at who your customers are,
7 create effective process verification activities,
8 and you can produce safe products, and I've been at
9 this for over 15 years now, producing raw ground
10 products for consumers, and I'm thankful to say that
11 as far as I know, I don't believe our products have
12 ever made anybody ill. I'd like to be able to say
13 that for the continuation of my career, but I'm
14 going to focus on the HACCP system I have in place
15 rather than testing because, again, I'll have a
16 portion that is verification testing, but I won't
17 focus on that as the key component.

18 When we engage in process improvement, we
19 seek to learn things that cause things to happen and
20 then use that knowledge to reduce variation. If we
21 know that there is an increase in variation, then we
22 can also from that assume that there's been a

1 decrease in process control. It's pretty obvious.
2 So I would suggest that the Agency focus on the
3 process controls that we all have in place. All I
4 hear about is the inconsistencies, and I hate to
5 tell you, because I've been looking at human
6 behavior for a long time as a part of quality, we're
7 going to continue to have inconsistencies from plant
8 to plant to plant.

9 Best practices and the best practice
10 documents out there. Not everybody utilizes every
11 step. I would suggest if you use them, that you do
12 utilize all of the process controls that you can
13 apply effectively and then utilize the experts in
14 the industry to guide you that way, but you're going
15 to have people pick and choose, and there are people
16 that pick and choose, and sometimes they choose to
17 utilize raw materials that aren't sampled and tested
18 effectively, or don't go through facilities with
19 proper process controls and interventions. Let's
20 focus on what we need to do, and I'm going to try to
21 do that through the next few slides, talking about
22 supplier programs.

1 Removed activities have no value and
2 improve customer satisfaction and customer
3 satisfaction is fit for use, that's what it's
4 called. It's called safety as well.

5 There are a number, and as I said, the
6 focus for me is about HACCP programs first because I
7 think that's extremely important, not just in our
8 facilities but in the other facilities that we
9 purchase raw materials from. I do not slaughter
10 and/or fabricate animals. I buy boneless beef
11 products from USDA-inspected establishments.
12 However, I understand it's my responsibility because
13 I cannot improve its quality to understand what
14 they're doing and how they're doing it to produce
15 safe raw materials that come into our facility. I'm
16 going to do a lot of verification in that, and it's
17 not going to be based on all micro. There's a lot
18 of sampling and testing that I'll do to look for
19 unacceptable, indigenous inclusions, or I will look
20 at other information including cold chain
21 management. I do audits in those facilities. I
22 understand who my supplier is and who I'm buying

1 from, and I think that's critically important.

2 There is the part for control programs for
3 0157, and as I say, I do use testing as a way of
4 verifying or validating my system of controls,
5 including the microbiological prescreening
6 requirements that we all talk about, N-60.

7 When you create something that people won't
8 do, believe me, they'll modify it. I hear questions
9 about, well, what's most statistically important
10 here? The statistics don't fly in the face of this
11 because you can't predict when these occurrences
12 will happen on the high stand, in slaughter and
13 dressing, that will contribute these pathogenic
14 bacteria. It's not predictable. I wish it was and
15 give you my anecdotal information. Fifteen years of
16 doing testing, last year was a catastrophic year.
17 Thirty-seven finished product events for 0157. It's
18 the worst I've ever seen. Up to that point, the
19 worst I had ever seen was seven.

20 So I do know that some things change, but I
21 think part of what's changed is if we take our eye
22 off of process controls and we rely on the finished

1 product validation testing, then we forget about
2 what actually creates safe products, which is the
3 process control portion of this thing.

4 Processors like ourselves, and I said that,
5 I know I have a responsibility. I know I have a
6 responsibility to know who I'm buying raw materials
7 from, how those raw materials are being produced,
8 and then subsequently to be able to verify that they
9 are complying with as much as possible the practices
10 or policies, procedures that not only they define,
11 but that I would like to see them utilize. And I've
12 always tried to bring value to them when I've gone
13 to their facilities, not as an audit and I am a
14 sanitarian. So it's easy to walk in and say that's
15 wrong and that's wrong, but the other side of it is
16 to be able to say, have you ever approached it
17 differently, and that's what I'm going to try to get
18 all of you to do is approach this differently. Look
19 at it as a systematic approach towards creating safe
20 products.

21 Processors do have a responsibility, and we
22 do not have any other methods to control bacterial

1 hazards than looking at our suppliers. Therefore,
2 it is essential we develop a system that ensures
3 safe raw materials to be utilized for raw ground
4 products. It's important, and I do rely on N-60
5 screening because I think it's very appropriate and
6 I can tell you it's been very effective.

7 Going back 15 years, I haven't modified my
8 testing behaviors too much. I used N-25 when I
9 sampled and tested on my own, and it's not any
10 different than N-60. You can make it N-17/60. You
11 could make it combo by combo, and I don't think
12 you're going to improve the quality of the raw
13 materials that are coming at the system.

14 However, given all of that, I still believe
15 you need to have good consistent process
16 verification going on for individuals involved in
17 producing one of the higher risk products which is
18 raw ground.

19 Companies are responsible for outlining the
20 requirements, in other words, establishing those
21 process controls and verifying their controls, and
22 then that they're implemented, working as designed,

1 that's called validation.

2 We spend a lot of time before we ever buy
3 from somebody, and I've told even the smallest
4 processors, it's important, know who you're getting
5 it from and how they're actually producing it, and I
6 know I've been in most of the slaughter plants in
7 the United States, they'll let you in, they'll talk
8 to you, they'll tell you what they're doing, they'll
9 show you their HACCP program, they'll let you audit
10 their facilities. I think it's important and you
11 have got to define what your expectations are.

12 I don't care if you're the smallest person.
13 You're out there spending your dollars when you go
14 to the store. You expect to be a good buyer, right?
15 Well, that's what you should do when you process
16 meats is be a good buyer. Define what your
17 expectations are and write them down. Have them
18 acknowledge them.

19 And then perform consistent process
20 verification. When it comes in, is the trailer
21 sealed. Does it meet the temperature specifications
22 or standards that you've established? Is the

1 packaging intact? Is it covered properly? Is there
2 no signs of filth? A whole series of things that
3 you need to document. And most of these things are
4 outlined in our best practice documents but I think
5 they're very important.

6 We do a lot of testing, not specifically
7 for pathogens. I do a lot of profiling, aerobic
8 plate counts tell me about their ability to create
9 safer products through cold chain management. I use
10 coliform and *E. coli* as an indicator of good process
11 controls during dressing. I also test for others
12 but I look at all of these things and I put them
13 into an algorithm, if you want to look at it that
14 way, that tells me what, number one, the industry
15 can do by class of animal or class of facility and
16 who is the best and then I go basically spend my
17 money and buy what I can get to be the best.

18 I require, and this is very important, that
19 every raw material that's used for non-intact raw
20 ground products is sampled, tested, and found
21 negative prior to the time it comes into the
22 facilities. It's very important. You must. We've

1 heard a lot, and we do a lot of primal specific
2 products as well. Believe me, everything is tested.
3 So even guys that are creating, maybe using the
4 center of the muscle, and then they're using the
5 bench trim, still create a system of verification
6 activity that you've prescreened it. I think that's
7 extremely important. Raw ground beef, my analogy
8 for that is homogenized bacteria because we do
9 distribute it throughout the product. The CCPs
10 still cooking, but there is a lot of verification
11 and process control that we can put in to create
12 safe products.

13 These certificates of analysis, it's our
14 responsibility as the industry, and if it's not that
15 you don't have an expert, there's experts sitting
16 all over the place out here in this audience that
17 can basically guide you towards what that
18 certificate says, what was the analyte size that was
19 used for testing? What was the enrichment
20 procedure? What was the method, that it meets an
21 accreditable standard, and then it must be signed by
22 the laboratory so you know that, yes, people did

1 look at the results and they can stand behind what
2 actually happened.

3 Raw materials, I mentioned, I use a lot of
4 information to basically look at process controls
5 and believe me, I'm getting a lot closer after all
6 these years of putting all this information
7 together, to be able to say, when I believe that
8 plants are changing, they're changing their process
9 controls because I will see changes in these trend
10 data. So we track and trend constantly, and we
11 constantly feed it back to them. We define for them
12 what the expectations are, and then when we
13 document, when they're out of specification, we
14 actually communicate it to them because it's
15 extremely important.

16 Plan-Do-Check-Act is a feedback system.
17 That's what a feedback system does. When you define
18 your expectations for a supplier and they don't meet
19 it, do you communicate effectively? It's not for
20 somebody else to control your process. It's for you
21 and you should be communicating on a consistent
22 basis.

1 Require action plans, and I know that
2 sometimes it's a challenge, even for somebody like
3 me to be able to get them to pay attention because
4 there is a lot going on. They've got a lot of
5 focus.

6 Finished products, I do the same thing. I
7 look at it as a flow. Raw product into finished
8 product. If I maintain cold chain and I'm using the
9 best raw materials I can, I can track and trend the
10 same data and believe me, it tells me whether my
11 process is in control.

12 There are times, especially for retail, raw
13 ground products, that I do verification testing for
14 O157, but it's not testing my way to safety. You
15 can imagine every time we've gone through an event,
16 and I still do it with every event, we do root cause
17 analysis to try to determine what the contributing
18 factors are and eliminate those factors that create
19 risks for our system. That's what these positive
20 event results, whether it's on the other side as a
21 raw material processor or on the processor side,
22 will give you, but we do have to take responsibility

1 for basically validating that the process control
2 system, HACCP, works for us, and this is a way to
3 get it, not 0, because I can't test my way there.

4 You can sample and test all you want, but I
5 know that there are low levels that pass even
6 through my system, but I know that the systems that
7 we've put out there through best practice documents
8 are very effective. I've been doing it for 15
9 years. I put 1 million pounds literally every day
10 into retail, and I don't think that I've got people
11 chasing me. I could tell you otherwise. I think
12 I'd get the calls from the attorneys. So I'm either
13 lucky or it works. It's not perfect, but I think
14 there is a system that can be utilized.

15 So you can profile finished products, and I
16 think it's important, and when you do that, I even
17 create arbitrary numbers because they're not
18 mandatory regulatory standards. I create arbitrary
19 numbers that I look at and say, if it goes above
20 this, I won't put it out there as a raw ground
21 product. I'll only sell it to a processor that will
22 thermally process that, and this is not about 0157.

1 This is just about these other arbitrary numbers
2 that I think might create better risks because I
3 know I can't test my way to find pathogens all the
4 time.

5 Programs should be designed. You heard
6 this earlier. They should be very robust. They
7 should be scientifically sound, defensible,
8 validated for each individual location because a lot
9 of times what I get is let's just take and can a
10 program and put it somewhere. Well, it doesn't work
11 that way. You've got to go see what's going on in
12 that facility and you've got to design a program
13 that works there.

14 Our documents that we've put out there
15 through the Beef Industry Food Safety Council have
16 tried to create menus, but I think at times, and
17 we're trying very hard right now to put verification
18 validation data back into those so people know how
19 to do that because one of the things that everybody
20 continues to say is how do we actually do that. So
21 we're trying to put those back in there, but they
22 are very good documents and they create an

1 opportunity, basically as an outline, for how to
2 create safer products. The programs we have, have
3 to be verified and verifiable.

4 And then they have to be constantly
5 challenged. You don't just put a program together
6 and then lay it on the shelf and say that's it,
7 we're done. Every event we have, we research it
8 like it was the very first one because we want to
9 find out what's going on and we want to be able to
10 have that feedback and that root cause analysis into
11 the system to create safer products for consumers.

12 Remember, HACCP is based on prevention, not
13 detecting something at the end of the line, and I
14 think it's very important. So it should reduce, in
15 fact, whether -- we're talking this or any other
16 because again I study quality. So I know that if
17 you have process controls, you are less reliant on
18 finished product inspection to meet the standard
19 you've established. And in this case, it's for safe
20 products.

21 If, in fact, the concept is applied
22 correctly and actual verification validation are

1 used, you can, in fact, reduce the risks associated
2 with O157:H7 in beef products.

3 MS. NESTOR: Thank you. Felicia Nestor,
4 Food and Water Watch. Tim, it's really good to hear
5 you describe your program. This is the second time
6 I've heard you. You described it out in Chicago
7 also. And I wish you were in charge of the way FSIS
8 runs its program because, you know, the commitment
9 to tracing every positive back and finding out why
10 the process control system at the supplying plant
11 did not work is critical, especially when we hear
12 about the difficulties with sampling.

13 My one question for you though is, you
14 know, you say you've been into a number of slaughter
15 plants, and you not only get a COA, but you verify
16 and the slaughter plants will let you in. I
17 wouldn't doubt that they let you in, but there are,
18 according to my latest calculations from what I got
19 from FSIS, there are 379 plants that do over 1,000
20 pounds of ground beef a day. There are 940 that do
21 less than 1,000 pounds of ground beef a day, and
22 looking at USDA's recall data, some of those plants

1 look like they might make 40 pounds a day or 150 or
2 200 pounds a day. So they don't even get up to
3 1,000 pounds.

4 So in terms of expecting these small
5 companies to be responsible for the quality of
6 product coming into their plant, you know, they
7 don't have a travel budget. They don't have any
8 market power because they're not purchasing anything
9 significant from the large suppliers. So what's
10 your idea about that? How can they be as proactive
11 as you are given the facts?

12 MR. BIELA: Yeah, I have the same concerns
13 over the years. I know there's a difference between
14 smaller companies. When I started for the company I
15 work for, we were smaller. I'll say that. We've
16 grown. I think maybe a little bit of that is maybe
17 because we are doing some good things. I'd like to
18 think we don't sell it in the marketplace, so to
19 speak.

20 So, believe me, there's no value added to
21 our system for the \$3 million I spent on, you know,
22 positive events last year. That didn't include my

1 testing budget. That's just the cost of the
2 products.

3 But, you know, the food industry in general
4 has tried to figure out appropriate ways to be able
5 to gather information, this audit information about
6 who's doing what, and how they actually rate as
7 compared to others. And, you know, I don't know if
8 maybe the Global Food Safety Initiative, some of the
9 things that are up and coming and moving as we speak
10 today may, in fact, give companies an opportunity to
11 see something posted on a website that let's them
12 know.

13 I'll give you the secondary approach. If I
14 didn't have control, I'd make sure I was testing
15 every bit of my finished product. I mean that's --
16 see, because I like to think that you're always in
17 control until you give up control, and where I don't
18 have that budget, then I'd be looking at something
19 different because knowing what the risks are
20 associated with raw ground and, you know, the one
21 thing I don't want people to say is, gee, I didn't
22 know raw ground beef was dangerous. I've lived with

1 it for the past 17 years. It could be. I don't
2 want it to be. I wish it could be safer, and I wish
3 I had all the answers as to what you're asking.

4 As you know, I try to make a lot of these
5 presentations and offer myself up to the smaller
6 processors to be able to call and my guidance would
7 be if you can't get out there, and you don't know
8 where your raw materials are coming from, at least
9 perform finished product testing for 0157. It won't
10 completely again eliminate everything but it could
11 reduce the risk. I would also just make sure that I
12 verify my cold chain management, the condition of
13 cartons, all of those kinds of things because I
14 think that can have an impact on reducing some of
15 these smaller events that we see where there's a 90
16 pound recall and those kinds of things that I think
17 we all, you know, kind of step back and say, why do
18 these things happen?

19 MS. JOHNSON: We have one back here.

20 MS. SMITH-DeWAAL: Thanks. Caroline Smith-
21 DeWaal with Center for Science in the Public
22 Interest. I want to raise the same question with

1 you, Mr. Biela, that I did with Dr. Esteban.

2 Is N-60 the right number of samples? You
3 are indicating, and maybe your suppliers are using
4 that approach plus something else, but you're
5 indicating a high level of confidence in the
6 products that you're purchasing to go into ground
7 beef. How is N-60 providing that if, in fact, the
8 statisticians tell us that the confidence level
9 should be lower than it is?

10 MR. BIELA: Well, I'll give you as much
11 information as I have. Going back, and I'm going to
12 have to go back in history a little bit, back when I
13 started testing not just raw materials but finished
14 products, nobody tested raw materials. And I used a
15 five combo subplot and five select pieces, surface
16 material, from that created a N-25 for that five
17 combo subplot and, you know, I'd be happy to share my
18 data with your group. I mean, for the last 16
19 years, we've offered that information as that we
20 haven't seen any reduction within N-60, and what I
21 do see is exactly what we saw in the slides that
22 were provided, that the method gets beat up pretty

1 badly because we don't get surface material. We get
2 a lot of internal muscle tissue. If you start
3 analyzing internal muscle tissue, it reduces the
4 confidence even further.

5 My concern about going to even single
6 combos and those kinds of things is if you make it
7 so difficult that they can't get it done, we're
8 hearing the Agency say, gee, we'll push activities,
9 inspection activities off to get a good sample. We
10 looked at some of the samples that were up there,
11 and it's challenging, and I'm not criticizing them
12 because I see the samples that go from the packers
13 into the laboratories myself. We get them a lot of
14 times for companies that don't have access to
15 certified laboratory in their location where we'll
16 run them in our own laboratory.

17 The only thing I can say is I haven't seen
18 any reduction or increase in the number of positive
19 events. Last year I said that. Last year was
20 unique. I don't know what happened last year. It
21 was like we all took our eye off the ball. Thirty-
22 seven positive events for us as a company was

1 astounding. I mean that's, you know, when you're
2 dealing with that, that's almost one a week. I got
3 to where I flinched when the phone rang. It was
4 that bad.

5 This year, we're back down I think -- to
6 Dean's comments, we're back down to where it's more
7 normal. I've only had six events. That's across
8 five plants scattered all over the United States.
9 It's much better. I haven't seen the high levels of
10 contamination even when I've had events. So I just
11 -- again, we can't test our way into that rather
12 than when we do validation testing, if there's a
13 failure, it really is going back and trying to
14 figure out what's going on as a process control
15 failure. And it does directly relate to appropriate
16 slaughter/dressing procedures. We know that's where
17 the contamination occurs.

18 So, you know, I hesitate because I know
19 what you're saying and, you know, is 5 percent or 95
20 percent confidence interval effective? I feel very
21 good that it's being applied on a more consistent
22 basis today than it has been in the past several

1 years, and my hope is if we continue to educate
2 people on that, we pick one standard, it'll continue
3 to reduce that, and, of course, then I would also
4 carry that through with if you're putting raw ground
5 products into retail, design those products for
6 safety and then do a certain amount of verification
7 testing on that as well because I'm afraid even with
8 the systems that are in place on trim, that there
9 will be some that passes through there that are
10 large enough to cause public health issues and I'd
11 like to see people incorporate a validation step at
12 the end that the other part is working effectively.

13 MS. KOWALCYK: Barbara Kowalcyk, Center for
14 Foodborne Illness, Research and Prevention.

15 I wanted to echo Felicia's comment and say
16 that I was very impressed with your presentation,
17 the process that you're implementing at your
18 facilities, as I'm sure other companies are. I am a
19 statistician by training and spent 10 years working
20 as a statistician, and I'm very familiar with
21 statistical process control, and this is more of a
22 comment than a question, but as I'm sure you're

1 aware, Edward Deming is one of the fathers of
2 statistical process control, and he actually spent a
3 good bit of his early career at the USDA.

4 In the 1950s, 1960s, he went to Japan, and
5 then by the 1970s, the Japanese have these wonderful
6 products and American companies had rejected his
7 philosophies and couldn't understand why the
8 Japanese were surpassing us.

9 So in the 1980s, they embraced Deming's
10 management principles, one of which is you cannot
11 test or inspect safety in products or quality into
12 products. Again, the Americans kind of missed the
13 boat. I happened to be in college at the time and
14 did an internship in a company, a large company that
15 had Deming's management principles plastered all
16 over the place, but they got rid of the statistics
17 because it was too hard.

18 When I first came to Food Safety in 2001,
19 my reaction is HACCP is based on statistical process
20 control, and what happened is everybody embraced
21 Deming's management principles and threw away the
22 statistics because they were too hard, and I think

1 that the reason we have not seen the improvements
2 from HACCP that we had hoped for is because the
3 statistical process control piece of it has been
4 missing in too many plants, not all plants but in
5 too many plants, and this is a very important issue
6 that the Agency has to deal with, and we have to
7 provide the small plants, we have to encourage all
8 the plants to move to a statistical process control,
9 and you're going to have two types of
10 microbiological testing that will allow you to do
11 this.

12 One is your in process sampling which will
13 address your process control issues, and the other
14 one is going to be your end product testing which is
15 going to provide your verification and you need both
16 of them and they need to be as your -- I believe one
17 of your last slides stated, it needs to be a robust
18 sampling plan and I am not one to -- as a
19 statistician, I can tell you, you are absolutely
20 right. Every plant should have its own sampling
21 plan because it will be dependent on the variables
22 in that plant. There's not a one size fits all

1 sampling plan.

2 But we can do a lot better, and the one
3 thing that I think has been missing in a lot of the
4 conversations that I'm seeing, and I think that
5 these conversations are really great, and a lot of
6 the documents that have been coming out recently
7 from FSIS, I'm very encouraged, but it's the issue
8 that Caroline's brought up twice now is, what is the
9 power of your sampling plan to actually detect
10 whether your process is out of control, to actually
11 detect whether or not you've detected contaminated
12 lots?

13 And that's a really important way for the
14 public to evaluate the effectiveness of a sampling
15 plan in a process control system. And so that's one
16 piece that I haven't heard much being talked about,
17 that really I think for the benefit of those who are
18 not as familiar with statistical quality control,
19 you really need to look at that power, and that's
20 going to be dependent, N-60 apply -- you could take
21 N-60 and apply it 10 different ways and get
22 different power levels and basically your powers

1 reflect your confidence.

2 So, you know, I'm reluctant to say, well,
3 let's do it exactly this way in every plant because
4 I don't think that that's going to be effective, but
5 we need to really be focusing on making sure that
6 plants have a high level of confidence, that their
7 process is in control and that they're detecting
8 contaminated products.

9 MR. BIELA: I'd just like to make a brief
10 comment, and then we'll let that be the last
11 question, but you're absolutely right. One of the
12 challenges that we have is when we deal with this
13 event associated with pathogens, this particular
14 one, it's not predictable. It's very difficult to
15 design anything that's got confidence. What we do
16 know is this. If you sample consistently across
17 time, then you will detect events, and that's really
18 what it's all about because we do that -- that's
19 what the idea is behind N-60 is you're filling these
20 combo bins, take samples at distinct points across
21 that. So you've got a representation of the
22 population because that's what we're trying to do is

1 to predict something in a population.

2 Pathogen testing has its limits, and so we
3 use other data as well. You know, so we may not be
4 able to enhance that because statistics say pretty
5 much what we want them to. We may not get it past
6 95. I feel like if we apply effectively, and then
7 for those products that are going into the retail
8 marketplace and going to consumers' homes where
9 there's less control at times over the temperature
10 verification activities -- I'm hoping commercial
11 establishments use the food code and cook to proper
12 temperatures and those kinds of things, but where
13 there's potential for outgrowth because of the
14 controls at retail or improper cooking, I would say
15 that people should consistently test, and sampling
16 is the first part of the equation.

17 So, you know, without that, then we've got
18 to dig into what's sensitivity and specificity on
19 the laboratory side before you can actually
20 calculate anything because we can all talk about
21 what these confidence intervals give us, and then I
22 can change everything by just walking into the

1 laboratory.

2 Okay. Thank you all.

3 (Applause.)

4 MR. ALMANZA: Thank you, Tim, and, yes, you
5 did make my life a lot easier in Dallas.

6 The next presenter is Dr. Wendy Warren-
7 Serna. She's currently the Vice President of
8 Technical Services of Food Safety Net Services, a
9 network of ISO 17025 accredited laboratories,
10 offering a comprehensive scope of microbiological
11 chemical auditing and consulting services.
12 Dr. Warren-Serna has a B.S. degree from Oregon State
13 University in microbiology and a Ph.D. from the
14 University of Texas Health Science Center in San
15 Antonio in microbiology with an emphasis in
16 molecular immunology.

17 Dr. Warren-Serna in her role at Food Safety
18 Net Services has spent nearly eight years working
19 with the meat and poultry industries and offered
20 effective testing strategies and solutions, and
21 she's got to be the coolest person in here because
22 she sat right underneath the air conditioner on

1 purpose to avoid getting warm. So thank you.

2 DR. WARREN-SERNA: Well, good afternoon.
3 My role here today is to offer some insights and
4 hopefully provoke some thoughts on laboratory
5 testing, testing methodologies. But I wanted to
6 start with a very simplistic overview about the big
7 picture here.

8 So what we really need to do, and this is
9 obviously a very tall order, is to come up with an
10 integrated use of effective sampling strategies that
11 are compliant with industry standards, and I think
12 Tim had a very good point with regard to
13 consistency.

14 Proper sample preparation and handling
15 techniques, validated and accurately applied test
16 methods, and informed interpretation and application
17 of test data. So I think each of these components,
18 albeit very simplistically illustrated here, are
19 very important in doing a good job.

20 I'm going to speak very briefly on the
21 analytical sample, and the reason why is because
22 there are several individuals who are talking about

1 sampling today, but I did want to make a couple of
2 comments about assessment of the sample in the
3 laboratory setting.

4 So when we receive samples, we are very
5 interested in the physical status of the sample, and
6 I'm speaking directly about the N-60 collected
7 sample. Particularly we look at the composition of
8 the sample because there is some merit in surface
9 association with that sample. So, for example, the
10 sample would have surface associated fat.

11 Now, the caveats there are sometimes it's
12 not very clear what is surface and what's internal
13 fat. And we also have to recognize the fact that
14 these samples go through a lot of commingling.
15 Nonetheless, the surface of the carcass is, of
16 course, the first place that would be vulnerable to
17 contamination by fecal material or dust particles or
18 water particles that are carrying *E. coli* O157:H7.

19 We're also very interested in looking at
20 piece count and weight compliance. So to address an
21 earlier question with regard to what is the industry
22 doing in terms of collecting a N-60 sample, well,

1 the industry is doing a very good job collecting 60
2 pieces. We know that in the laboratory setting
3 because we can easily identify those folks that have
4 really paid a lot of attention, put a lot of
5 consistency and trained their staff in terms of how
6 to collect an N-60 that will fit into the analytical
7 sample that we utilize in the laboratory.

8 Now, the industry over the years has grown
9 comfortable with using a 375-gram sample. A little
10 bit different approach than what FSIS is doing, and
11 it really had an economic basis in terms of coming
12 up with a 375-gram sample. The FDA has also
13 utilized this technique in terms of a dry composite.
14 So you could actually compile in the analyses that
15 were performed several years up to 15, 25-gram
16 samples, which at the time that was a popular sample
17 size. You could combine up to 15, 25-gram samples
18 for a 375-gram sample of analysis.

19 So there was a lot of emphasis placed on
20 that sample size, more sample, more opportunity to
21 find the organism, and we've done a great job as an
22 industry figuring out how to get all of those 60

1 pieces into a 375-gram sample. Not to say everybody
2 does it 100 percent of the time and that there
3 aren't opportunities to improve techniques, but for
4 the most part, we do a good job. So I do know it's
5 possible.

6 Test method considerations, that's really
7 something I want to focus on today. So one question
8 I get a lot is the question is my test method
9 equivalent to or as sensitive as the USDA FSIS
10 method, and this becomes a challenging question to
11 answer because right now in our industry, we haven't
12 really stacked the cards in our favor per se to
13 measure tests against each other. And I'm going to
14 go through a few of my thoughts in terms of why that
15 is, but I would just ask you to ponder the question,
16 how would you determine if the method that you're
17 using is equal to or as sensitive as the USDA FSIS
18 method?

19 So when we get different methods that have
20 different sensitivities or different performance
21 characteristics, they could be sending different
22 messages. And that adds to the variability of what

1 we're doing in industry.

2 I was speaking recently with a family
3 friend who is a physician, and we were talking about
4 a therapy that was going to be applied to one of our
5 family members, and she looked at me and she said,
6 well, you know, we really don't know if this going
7 to work or not, and she said, but why do you think
8 we call it practice medicine? Because a lot of
9 times there's some practice that goes into it.

10 The truth is, there's a lot of practice in
11 microbiology, and while we try to abide to
12 standards, there is some practicing. What I would
13 like to do is see this practicing stay within a
14 certain lane or within certain gates so that we can
15 trust the data, make messages out of the data as
16 industry to see how we're doing.

17 So there are many drivers when it comes to
18 method selection. A few of them might be turnaround
19 time. How long is it going to take me to get my
20 test results? Costs certainly is a factor. The
21 target, how is the target detected? So is this a
22 protein-based test or genetic-based test, and the

1 perception on whether one of those might be better
2 or more sensitive than the other.

3 Comparison of available test methods really
4 does require our reliance on validation data. So I
5 don't know about you, but if I'm the one who's
6 charged with having to pick a method, I want to see
7 what sort of validation data do we have? Even when
8 I'm asked to use a test method for a food matrix
9 that may not be down the beaten path, I look at the
10 validation data and say is this a fair choice to use
11 this test on a particular test matrix that it might
12 not have been validated for? So I would certainly
13 look for in this validation a definition of the
14 performance criteria and validation. How was this
15 validation study designed?

16 So we're looking for some key things. I'm
17 going to talk in a little how do we come up with
18 performance criteria. What should these performance
19 criteria be to set us up for success? Validation
20 study design, we're talking about statistics of
21 sampling, but there's also a very important role of
22 statistics in determining the validity of a test.

1 So we want to make sure that the validation study
2 design was statistically significant.

3 Validation reports are ideally authored by
4 a third party relative to the test kit manufacturer,
5 and they're available in a complete and original
6 format. So if you're looking to see how a test
7 performed and what sort of validation was behind it,
8 you should be allowed to inspect to the validation
9 report and be able to scrutinize the design and also
10 these statistical significance. You should also be
11 able to see that the test method is being applied in
12 the laboratory is, in fact, the method that's
13 included in the validation.

14 Basic principles, again a heavy reliance on
15 basic principles of the scientific code of ethics,
16 you can actually download this from the ASM, at
17 asm.org, but true alliance on code of ethics
18 surrounding method design and application in the
19 laboratory.

20 Laboratory and test methods needs to be
21 transparent. Now it's true, test kit manufacturers
22 have oftentimes proprietary targets that they

1 utilize. That's how they make a business. That's
2 how they succeed. You can still do this in a very
3 sensitive manner to the proprietary information.

4 The test method needs to be replicable. So
5 robust and repeatable across multiple laboratories
6 across the industry, and there needs to be a proper
7 balance of science and economics. This is a very
8 challenging one for those of us who make a business
9 out of science but also for those who have to
10 include science in their business. So what sort of
11 choices, what sort of structure are we putting
12 together to make sure that we've properly balanced
13 science with economics because we can design the
14 most statically valid sampling and testing plan but
15 the truth is, we'll probably put a company out of
16 business. Okay. Is that what we want? Probably
17 not.

18 We can also make the best economic choice
19 for the company, but we may be completely lacking on
20 the science. That doesn't benefit the industry
21 either.

22 So it seems like there should be a

1 validation agency that's responsible or overseeing
2 validation of test methods. Well, in the years that
3 I've been in the food testing arena, particularly
4 focused on beef testing, I've seen an evolution away
5 from what once used to be and that was the use of
6 AOAC as a validation tool.

7 Particularly I'm referring to the AOAC
8 official methods of analysis, which is a robust,
9 very statistically significant validation procedure
10 that test methods could go through to determine if
11 they perform according to the criteria that were
12 stated in the original proposal. This was a
13 multiple laboratory validation. So you get that
14 reproducibility, that robustness, but it's also very
15 lengthy and it's also very expensive, and what we've
16 seen is that the industry has allowed or been
17 receptive to a very much abbreviated version of this
18 validation. And that's called an AOACRI. That is a
19 1 laboratory trial, 20 samples, not very
20 statistically sound in my opinion, validation of a
21 test method, and that's really where we have to rely
22 more on field testing and use in multiple

1 laboratories to gather performance data on a test
2 method.

3 There's actually more recently been a
4 processor specific requirement on test methodologies
5 that is more robust than the AOACRI. Specifically
6 this method requirement requires 3 trials of 25
7 samples each for a total of 75, and those
8 statisticians in the room, which I am not one, can
9 appreciate why 75 data points would be more powerful
10 than 20.

11 I would contend that in the absence of
12 oversight and requirements for test methodologies,
13 method validation does vary and so do the methods.
14 So this is a bit of a concern that I have because we
15 are drifting away from multi-lab validations. I
16 understand the driver's there, the economic drivers,
17 the timing driver's there, the business drivers.
18 AOACRI, is that a good compromise? I would question
19 that. So we are a bit in a custom validation
20 arrangement and very much reliant on independent
21 scientists making independent choices, and again I
22 think that is putting us at risk of having

1 variability in the validation requirements and
2 variability in the test methods.

3 Inconsistent methods can lead to
4 inconsistent results and expectations. So again if
5 we're having expectations of the data, are we
6 chasing the same range of information if we're using
7 different test methods?

8 Method consistency is driven by the
9 establishment of performance criteria. So how
10 should a method perform? Proper validation and
11 verification of consistent compliance with a method.
12 So not just validating it but also verifying that
13 the test method is being properly performed as its
14 being used.

15 Scientific consensus on the key elements of
16 method performance for *E. coli* O157 detection in
17 beef is important to properly define criteria, the
18 performance criteria and direct method validation.

19 So I brought an example with me of an
20 activity that happened recently. I believe it was
21 in May of this year. There was what we called a
22 think tank that occurred, and that was driven by the

1 Beef Industry Food Safety Council or BIFSCO.

2 So this approach, it can be a very good
3 approach, task force or committee approach to
4 outline method performance criteria. So what is
5 good for all? So one person really can't come up
6 with a one size fits all approach. You get lots of
7 very smart people in the same room, and we come up
8 with some really great ideas.

9 So the drawback sometimes can be that the
10 timelines are long when you put committees together,
11 you put working groups together. It can draw out
12 for weeks and months and years, and also who pays
13 for it? So again, going back to what we did in the
14 BIFSCO meeting, which I thought was very fruitful
15 and informative, is we had a multidisciplinary team
16 with key stakeholders in a room. So government,
17 academics, test kit manufacturers, laboratories,
18 industry, and we came up with some important
19 elements of method validation relative to industry
20 needs and in the interest of science.

21 It was deemed in terms of STEC which would
22 include *E. coli* 0157:H7 and non-0157:H7 that

1 produced Shiga Toxin. So Shiga Toxin *E. coli*. So
2 very relevant to our discussion today.

3 And when we came up with key validation
4 elements, and by the way, this is available on the
5 Internet, if you'd like to look at the summary from
6 this meeting, and I've included the website.
7 Hopefully you can see it on the bottom, but when I
8 looked at these validation elements, I found they
9 were interestingly similar to current *E. coli*
10 O157:H7 method inconsistencies. So I think there
11 might be a message there.

12 Product to enrichment ratio, a lot of
13 variability on this one. Type of product to be used
14 in the validation. We heard earlier that higher fat
15 means the method doesn't perform as well. So we
16 need to look in terms of fat content, ground beef
17 versus trim. I would argue that different levels of
18 background microflora would make tests work
19 differently.

20 The analytical sample unit size, so weight
21 of the sample, what should it be? Because there's
22 no doubt that putting more samples together has a

1 dilution effect, and it can affect your ability to
2 recover a target. So does the media ratio. These
3 are all very dynamic components of a method
4 validation.

5 Pre-warming of media and a product
6 temperature and how that impacts the overall
7 enrichment. So these are key elements. When we're
8 wanting our test to performance faster, what effect
9 does product temperature, incubation temperature
10 have on our ability to replicate the target to the
11 required levels to detect it in our detection
12 system?

13 The type of enrichment media. What should
14 we be using? We've heard some indication that
15 enrichment media change overall sensitivity or your
16 probability of detection in these test methods. And
17 the effect of the initial inoculum dose on
18 sensitivity. The industry's really been pushing
19 hard on lowering that initial inoculum level in the
20 test sample where you see some amazing differences
21 in the efficiency of the test methods that are
22 available to us in terms of recovery and sensitivity

1 specifically here would relate to the probability of
2 detection of the organism.

3 The truth is, going back to the practice
4 comment, practice of microbiology, recovery of *E.*
5 *coli* O157:H7 from beef requires careful compliance
6 with validated methods. There's an equal importance
7 of sampling, sample prep, enrichment, post-
8 enrichment handling as applicable and detection. So
9 sample prep and enrichment activities must yield the
10 proper number of cells for delivery into the
11 detection system.

12 Activities must be prioritized to optimize
13 the probability of detection, and we certainly don't
14 have time to go through all the micro components
15 that are important but just a few comments I think
16 that are very important in these areas. Enrichment,
17 we have to provide the best opportunity for growth.
18 Basic needs including nutrient time and temperature.
19 So we want the optimal selectivity of our target and
20 efficiency or ability to replicate those cells in
21 the shortest time possible.

22 Product impact, we need to consider that as

1 we're enriching the composition and again the
2 competing microflora that might inhibit your ability
3 to grow the target.

4 Environmental impact. We have to consider
5 that all of these interventions and product handling
6 conditions affect our ability to recover the
7 organism. For example, an acid treatment or a
8 freezing treatment that might be applied to a
9 product is going to injure the cells in such a way
10 that we might have to further coerce them and really
11 engage them into a replication cycle. Maybe we have
12 to lengthen our incubation time.

13 Post-enrichment handling. Should you --
14 the point here is not reducing your probability of
15 detection. Validation within a specific detection
16 system is a must. So you must validate any post-
17 enrichment sample handling procedures. For example,
18 in a wet composite or wet pooling arrangement, which
19 we have learned about in the recent guidance
20 document, storage of enrichment during the detection
21 phase of testing is critical, especially if it may
22 be subjected to further testing. The results can

1 vary considerably especially if the organism is near
2 the limit of detection of the assay. So again if
3 you are enriching a sample and handling that sample
4 enrichment in some way, performing the test method
5 and then you expect to come back to that enrichment
6 and perform further testing, sometimes this was
7 referred to in the guidance document as retesting,
8 don't think that the organisms are in a sit stay
9 position if you have a dog. They're not. They're
10 doing things. They're interacting with each other.
11 So dynamic activities are occurring in this
12 enrichment and it needs to be taken into account in
13 the validation data.

14 Detection, so it's very important to have a
15 complete understanding of the detection targets.
16 Even if it's proprietary, you need to understand the
17 nature of the detection targets. So is it multiple
18 genes from a general enrichment, an individual
19 protein, and individual protein and individual gene,
20 et cetera. So you have to understand this in a
21 complete format so that you can truly measure the
22 pros and cons of a specific detection system, and by

1 that, you can make a very well defined and informed
2 decision about the test method you're using.

3 Knowledge of the threshold level of cells
4 required for delivery to the detection system for a
5 consistent positive result, if the organism is
6 present, is key. So that the probability of
7 detection can be properly calculated and, in
8 particular, if post-enrichment handling occurs and
9 further testing is possible.

10 Laboratory considerations. ISO 17025
11 accreditation is a good way to support a
12 laboratory's quality system. The reality is, it's
13 not a thorough auditing process by these agencies in
14 terms of technical technique. You are somewhat at
15 the mercy of your auditor in terms of how much
16 technical auditing you are allowed in this process.
17 So it really does rely on the quality and the depth
18 of the laboratory staff that are employed at a
19 particular laboratory to self-police the technical
20 aspects of the laboratory.

21 Ethical structure and influence of
22 management of a laboratory is very critical. A

1 laboratory should, in fact, welcome auditing,
2 transparency, peer review of methods employed at the
3 laboratory. So if you have questions or concerns
4 about the methods that are being used, you should be
5 able to review it all in intensive detail.

6 Conflicts of interest should be clearly
7 communicated so that third party guidance can be
8 employed as needed to insure proper balance of
9 science and economics. Any of the hardcore
10 scientists in the room understand that it's very
11 important when you're balancing a science with a
12 business discussion, and there is a clear conflict
13 of interest, you need to make sure that there is
14 third party oversight to insure a proper decision is
15 made for your specific needs.

16 So some concluding thought, test method
17 consistency can be achieved by establishing expected
18 performance criteria including the probability of
19 detection of *E. coli* O157:H7 at a specified level in
20 the test sample, such that methods can be validated
21 for compliance and in the context of a reference
22 method.

1 In the absence of a method validation body,
2 an established industry accepted performance
3 criteria, test methods will continue to be
4 inconsistent.

5 In the absence of technical policing of
6 laboratories, test methods may be improperly
7 performed and/or applied, which to Tim's point is
8 you can set up all this sampling design, all of this
9 process control but the truth is, if it gets to the
10 laboratory and the laboratory doesn't know what
11 they're doing or they are improperly applying
12 methods, it's a bit futile.

13 Thank you for your time.

14 (Applause.)

15 DR. ENGELJOHN: Are there any questions?
16 In the back.

17 MS. CHENG: Thank you. My name is Yuen
18 Cheng (ph.). I'm from the Grocery Manufacturers
19 Association. My question is in the testing
20 laboratory, the commercial testing laboratory, how
21 often is the FSIS method is being used? And is it
22 considered the reference method for testing for

1 0157? And what are some of the primary
2 considerations in your decision of using or not
3 using, you know, the FSIS method? Thank you.

4 MS. WARREN-SERNA: So the FSIS method is
5 used certainly if a customer asks us to specifically
6 follow it. With our knowledge in terms of
7 performance characteristics of various commercially
8 available method, we can also serve as a technical
9 guide for our customers in weighing the pros and
10 cons.

11 The truth is, with the FSIS method, we know
12 specifically what the targets are, what it's looking
13 for, what the scientific caveats might be in terms
14 of various targets to help guide them through making
15 a good choice in which method they should follow.

16 Certainly we can look at the information
17 that's available to us in terms of what inoculum
18 levels are used in validation data, which is why I
19 asked the question I did, to get a better idea of
20 what sort of efficiency does this method have in
21 terms of probability of detection of a contaminant
22 at a specified level.

1 So it's not a very straightforward answer,
2 and it's most definitely not a one size fits all.
3 So I could not represent the base, the industry in
4 toto if you will, in terms of why they would or
5 would not choose to perform a certain method.

6 Now, certainly, if they're wanting to
7 determine if the organism is being detected at an
8 equivalent level to what FSIS is testing for, then
9 you would want to follow a similar method.

10 MS. SMITH-DeWAAL: Caroline Smith-DeWaal
11 again from Center for Science in the Public
12 Interest. In terms of the variability of the lab
13 results and methodology, I mean kind of everything
14 from the inputs to the outputs, is there any benefit
15 to requiring accreditation or the use of only
16 accredited labs to help address that variability?

17 MS. WARREN-SERNA: What I would say again
18 to the comments I made in my presentation is that
19 accreditation of what falls under calibration
20 laboratories, through the ISO 17025 standard, is a
21 good idea. It is a good way to assure the quality
22 system of a laboratory. It's certainly not all-

1 inclusive in terms of technical applications of test
2 methods and data. So again that goes back to who's
3 running the laboratory? Is it a microbiologist, a
4 scientist who can make informed decisions about what
5 test methods should or should not be used to advise
6 an individual, this is a good idea or this is a poor
7 risk management decision?

8 So again, you know, the ISO standard is a
9 great idea to accredit quality systems. I would say
10 that the nature and the depth and the quality of the
11 staff of the laboratory in making scientific
12 microbiological decisions is more important.

13 (Applause.)

14 MR. ALMANZA: Thank you, Wendy. Our next
15 presenter is Felicia Nestor. She's currently a
16 senior policy analyst with Food and Water Watch and
17 worked for nearly a decade as Food Safety Director
18 at the Government Accountability Project.
19 Ms. Nestor has had extensive contact with FSIS
20 inspectors, learning how FSIS policies are
21 implemented in the field. She also issued several
22 reports based on analysis of FSIS microbiological

1 testing.

2 (Pause.)

3 DR. ENGELJOHN: We have some technical
4 difficulties at the moment. I would just suggest
5 perhaps that if you need to take a restroom break,
6 now would be a good time to do so.

7 (Pause.)

8 MR. ALMANZA: We're going to get started.

9 MS. NESTOR: Good afternoon, everybody.
10 Sorry for that technical difficulty. I actually
11 have two presentations I'm going to make. The first
12 is a presentation of the consensus that's been
13 reached by a number of groups, and they're listed
14 there: Center for Science in the Public Interest,
15 Consumer Federation of America, Food and Water
16 Watch, Safe Tables Our Priority, and United Food and
17 Commercial Workers Union. After that, I'm going to
18 make a presentation about Food and Water Watch's
19 position, which is not a matter of consensus.

20 Okay. So as a group, the consumers believe
21 in these general principles, that a primary goal of
22 meat and poultry inspection is to protect public

1 health by reducing foodborne pathogens in meat and
2 poultry products. It's the government's role to set
3 public health standards and assure that the products
4 resulting from industry process control programs
5 meet those standards. A strong microbiological
6 testing program is essential to determine whether
7 those standards are being met.

8 Both the government and individual
9 companies must perform regular sampling of meat and
10 poultry products to verify company process controls
11 are working as intended. All sampling should be
12 consistent with the protocol established by FSIS.

13 The objectives of microbiological testing
14 must be clearly identified. FSIS must identify its
15 public health goals and the specific objectives of
16 the microbiological testing programs it conducts and
17 oversees, identify the particular sampling plan or
18 plans it is considering, identify possible sampling
19 options, for example, stratified sampling or purge
20 sampling. We've heard about those, but we have not
21 been given much information about them, and the
22 public health benefits possible with each option.

1 Finally, the microbiological testing must
2 identify techniques to improve the effectiveness of
3 sampling.

4 Currently, neither FSIS nor companies are
5 sampling sufficiently to protect public health.
6 Increased government and industry sampling should
7 occur in the context of the development by FSIS of a
8 comprehensive program designed to trace
9 contamination back to its source, and the
10 requirement that FSIS inspectors review sampling
11 results regularly.

12 FSIS should increase its own level of
13 sampling in both slaughter and processing plants.
14 Specific goals for increased sampling should be
15 identified and reasonable timelines should be set.
16 FSIS should periodically report on its progress in
17 achieving these goals.

18 FSIS should require companies to increase
19 their sampling frequency. FSIS should recommend
20 some sampling standards that are statistically valid
21 for the specific purposes for which they will be
22 used. Companies can develop alternative sampling

1 regimes if they can demonstrate that they are equal
2 to or more effective than the one recommended by
3 FSIS.

4 FSIS should make available sufficient
5 resources and technical assistance to smaller plants
6 to help them develop adequate sampling plans. We
7 couldn't really make a determination of what smaller
8 plants meant. It certainly doesn't mean only the
9 very small plants or all small plants, that that's
10 something that should be discussed.

11 Periodically FSIS should review its overall
12 sampling program to determine whether his performing
13 the necessary functions and after seeking public
14 input changed the program as necessary.

15 FSIS should report aggregated or individual
16 plant testing results to the public on a routine
17 basis but not less frequently than biannually.

18 The adequacy of each plant's sampling plan
19 must be evaluated and certified or approved by an
20 independent third party such as ANSII. Sampling
21 plans must be implemented correctly and there need
22 to be mechanisms for verifying this.

1 FSIS must identify standardized procedures
2 for taking the sample, ensure that inspectors are
3 trained to carry out sampling procedures correctly
4 and routinely verify that industry employees are
5 collecting samples correctly, instruct inspectors to
6 collect a list of suppliers for any lot of product
7 that it samples at the time of sampling, instruct
8 inspectors to request and examine each plant's most
9 current sampling results, each plant must keep
10 records on the source or sources of material for
11 each lot that it samples, provide the most recent
12 sampling results to FSIS inspectors immediately upon
13 receipt of the results, notify the FSIS inspector or
14 local officials if the plant receives notice of a
15 positive result when the inspector is not in the
16 plant, provide FSIS with a list of the source
17 suppliers to any lot from which FSIS collects a
18 sample at the time FSIS takes the sample.

19 FSIS should clearly define the actions it
20 will take based on the results of microbiological
21 testing. Trace back is an essential element of
22 effective process control. When a positive is found

1 in the processing plant, trace back to the supplier
2 is critical and must be done as quickly as possible
3 so that other potentially contaminated products in
4 distribution can be identified.

5 FSIS must hold a public meeting to discuss
6 issues associated with sampling.

7 Finally, we recognize that what we are
8 recommending involves additional costs. However, we
9 believe that what we've outlined here has a public
10 value that is worth an investment of public funds.
11 FSIS should provide the public with a progress
12 report in how the Agency is addressing these issues
13 within six months.

14 The consumer groups also have a consensus
15 document that we've released, and it's available.
16 It has more detail than what was in this PowerPoint.

17 And now I'm going to discuss Food and Water
18 Watch's position if I can figure out exactly how to
19 -- no. And there we go. Okay.

20 Again, I want to say this is Food and Water
21 Watch's position. I have not discussed it
22 extensively with other consumer groups, and it's not

1 a matter of Safe Food Coalition or any other
2 consumer group consensus.

3 My comments are going to focus on FSIS
4 because consumers really don't have influence over
5 industry. Customers have influence over industry,
6 but we are recognized by FSIS as a stakeholder, and
7 we assume that we have some influence over FSIS.

8 I'm going to be talking a lot about data
9 from the past, but I'm not doing that in order to
10 rehash the past. I'm identifying trends that I see
11 still influencing the Agency's policies at this time
12 that I think might be part of the problem and really
13 need to be reviewed.

14 The reason I'm focusing on trace back and
15 FSIS actions at source plants is it doesn't look
16 like we're close to finalizing what kind of sampling
17 should be done, who should do it, when it should be
18 done, and work all the bugs out of the system but
19 trace back and increased actions for process control
20 by FSIS are things that can occur immediately and I
21 think will provide, you know, some benefit, public
22 health benefit in the near term.

1 Okay. The perspective of Food and Water
2 Watch is that consumers deserve effective government
3 oversight of the food supply. We also are concerned
4 about increasing consumer desire for locally
5 produced meat. Many people are concerned because of
6 the massive recalls by large multinational
7 conglomerates, and they feel that the food may be
8 safer in local markets or farmers' markets.
9 Consumers are also increasingly concerned about
10 environment and sustainability, and for that reason
11 as well, they want locally produced meat.

12 So far, FSIS' *E. coli* testing policies have
13 harmed both of those goals. FSIS has consistently
14 focused its enforcement at the end of the line at
15 grinders and very small plants. More than 40
16 percent of the very small grinders that were
17 producing ground beef in 2003 have stopped. FSIS
18 has also avoided identification of plants that could
19 have been the source of the problem particularly the
20 large slaughter plants.

21 As a result, we believe that FSIS policies
22 have prolonged unnecessary danger for consumers and

1 created undue hardships for many smaller plants that
2 received contaminated supplies for making ground
3 beef yet had good process control systems
4 themselves.

5 If you look at *E. coli* testing data, from
6 1998 through 2007, you can see up to 70 percent of
7 the tests were taken at the very small plants which
8 FSIS estimates to produce 1 percent of the product,
9 and the large plants which the large slaughter
10 plants make approximately 80 or more percent of the
11 product, and they have gotten about 1 percent of the
12 testing. It's increased recently, and we're
13 encouraged to say that in 2008, the Agency actually
14 has it up to 6 percent, but it probably should be
15 more.

16 Okay. This is a hypothetical diagram of
17 the beef production system with a few notes. The
18 yellow circle is the slaughter plant, and there are
19 approximately 35 large slaughter plants that produce
20 more than 80 percent of the beef. The slaughter
21 plants then sell numerous types of products, coarse
22 ground trim, carcasses to other plants, and one lot

1 produced by a central slaughter plant can get
2 divided up so that it is going to hundreds, if not
3 more, very small grinders. And the little circle
4 there is, you know, FSIS has taken most if its
5 samples at the very tiny grinders that make less
6 than one percent of the product. It might have been
7 a good idea if FSIS then traced those positives back
8 to the slaughter plant and required some cleanup,
9 but it appears that that has been a very rare event.

10 I'm not sure what's going to happen here.
11 It's doing it one by one. I'm going to be giving a
12 copy of this to FSIS, so I'm not going to go through
13 all of these, but I'll just say that FSIS has
14 publicly committed to trace back on a number of
15 occasions, and I can tell you that consumer groups
16 are under the impression that it is FSIS' goal to
17 identify as much contaminated product as possible
18 when FSIS finds a positive. And it's my
19 understanding that that is not a goal of FSIS.
20 FSIS' current trace back policies have specified
21 actions, and one of them is not to quickly go back
22 to the source slaughter plant and then trace forward

1 to all plants that might have received some of the
2 same lot of contaminated product.

3 The Agency has not been transparent about
4 its use of trace back, which is why I think so many
5 of us are confused about what actually happens when
6 FSIS finds a positive, but the evidence that I've
7 been able to get through FOIA and the recall website
8 suggests that it's been pretty rare.

9 Since 1998, from 1998 through the end of
10 2007, FSIS test data showed that FSIS found *E. coli*
11 contamination in over 200 plants. Around 80 percent
12 of these plants were only processing plants. They
13 did no slaughter themselves and only reprocessed
14 product they got from other FSIS slaughter plants.

15 It is our position that FSIS has the
16 responsibility to trace back to the source of the
17 problem when either FSIS or plant testing indicates
18 that the FSIS inspection program has failed to
19 prevent contamination from leaving a plant. There's
20 a lot of focus on what industry is responsible for,
21 what companies must do, but we believe that FSIS is
22 in these plants every day, FSIS puts the seal on the

1 product, FSIS is responsible for all of these
2 plants, and it's incumbent upon FSIS when there's
3 evidence that contamination is getting out these
4 slaughter plants, to go back to the slaughter plants
5 and find out what the problem is.

6 I tried to find out how many times FSIS has
7 traced back since 1998. The recall database shows
8 that there were 11 recalls based specifically on
9 FSIS trace back after FSIS found a positive in
10 another plant. So that's 11 out of 207 positives.

11 The test data that I've gotten from them
12 only shows three plants that were tested as part of
13 a trace back investigation. Now, I don't know if
14 that's the limit of it or not. There's a
15 possibility that FSIS didn't code earlier or, you
16 know, didn't have its coding up to speed, but that's
17 what the data I received through Freedom of
18 Information Act shows.

19 Okay. When FSIS conducts a recall after
20 illness, that is a trace back investigation. And
21 this chart shows the amount of product recalled
22 based on particular causes. The top line is

1 illness. That's 58 million pounds. There were 38
2 recalls after someone got sick. You can see that
3 the bottom, FSIS testing, there were 48 recalls
4 after FSIS found a positive in a plant, and you can
5 see really how little contaminated product was
6 identified and removed from commerce after those
7 positives.

8 In contrast, if you look at FSIS trace back
9 recalls, there were only 11 of those, and there was
10 much more contaminated product removed.

11 FSIS not only has failed to trace back, but
12 there are other ways in which it's sort of taken its
13 eye off the ball at the large slaughter plants. I'm
14 sure everyone's familiar with the testing
15 exemptions. I analyzed how many tests were actually
16 done under those. Most large slaughter plants went
17 three or four years without one FSIS test. Some
18 went five years without one test. Some were tested
19 one year, skipped for two years. So it was very,
20 very sporadic and minimal testing at most large
21 slaughter plants.

22 The large slaughter plants failed nine

1 *Salmonella* sets. There were five recalls because of
2 other indicators of *E. coli* positives, and FSIS
3 continued to believe in the interventions until the
4 ConAgra recall caused a real public scandal.

5 There were also failed FSIS tests at
6 closely associated processing plants. We know from
7 the OIG report that FSIS ignored the numerous
8 failure of company tests at ConAgra, and presumably
9 other large plants, and that there were repeated
10 fecal NRs which were an indication of lack of
11 process control, and there doesn't seem to have been
12 much done about it.

13 FSIS' risk-based *E. coli* test proposal
14 continues to recommend less testing at plants that
15 use interventions. Now, I don't know whether
16 this -- I've heard that this part of the test
17 proposal has not been implemented yet, but if it is
18 implemented, we'll have very serious concerns about
19 that.

20 Since 2004, FSIS has allowed plants to use
21 a sampling scheme that was not well-founded and
22 effectively created a regulatory standard other than

1 zero tolerance for *E. coli* O157:H7 without public
2 input or knowledge. We weren't notified of this,
3 and it was only last year based largely on
4 information that I got from inspectors that we
5 really started looking at the N-60 sampling and what
6 the result of positive tests was.

7 Also after 2004, FSIS tested only pretested
8 product at the plants that were testing. Therefore,
9 it didn't have a good idea of what levels of
10 contamination were coming off the slaughter floor,
11 and certainly FSIS must have known that small
12 processors were using the primals and bench trim
13 from other products coming off the slaughter floor.

14 Inspectors in those plants were not
15 instructed to scrutinize how the plants were using
16 the sampling, despite the fact that the testing was
17 a fundamental part of the plant's HACCP program and
18 the inspectors therefore would have had jurisdiction
19 over it. And FSIS kept no records of how many
20 thousands of pounds were diverted to cooking between
21 2004 and 2007. So this is a problem in other areas
22 of FSIS oversight, but a lot of these records are

1 kept just in the plant or just in the district
2 office, but certainly out of the Washington, D.C.
3 headquarters.

4 There are a number of ways that inspectors
5 lack control at the large slaughter establishments.
6 Inspectors at high-speed plants have said repeatedly
7 that they don't have time to do an adequate check
8 for fecal contamination at the final rail, and the
9 fecal NRs from the coolers and the processing floors
10 confirm that fecal is getting off the slaughter
11 floor.

12 In contrast, a very small plant that has a
13 fixed point, that carcass cannot leave the floor
14 until the inspector has had a chance to look at it
15 and look for fecal on the whole carcass.

16 You know, we're talking about process
17 control and experimentation. It seems to me that a
18 good experiment to do would be to find out whether
19 inspectors and employees can actually spot fecal
20 contamination at line speeds going that fast. You
21 know, it's one thing to say that you are looking to
22 improve a process but then refusing to ignore lots

1 of evidence that there's a problem.

2 Inspectors also complain about a new
3 limiting definition of fecal contamination which
4 requires texture or granularity, a number of other
5 things. It has to be the right color and, you know,
6 once, once the fecal contamination goes through the
7 interventions, there's a good chance that the hay
8 and the grains just may have been rinsed off, but
9 it's not necessarily the case that the contamination
10 is no longer active or dangerous.

11 Another limitation on inspectors is that
12 the line inspectors who are looking at every carcass
13 are not authorized to identify fecal. They have to
14 call the IIC to confirm that it is fecal, and they
15 cannot write a NR. Only the IIC can write a NR for
16 fecal, and very often in plants where you have
17 inspector shortages, the IIC is on the line and the
18 IIC is not allowed to write a NR for fecal
19 contamination that he sees while he is acting as an
20 inspector.

21 You know, in the new policies, FSIS is
22 recommending that small plants audit their

1 suppliers, and that if they get a positive, that the
2 plant notify the supplier and I guess give them some
3 tough talk or something. But given what I mentioned
4 before, you know, the minimal amount of product that
5 they are buying, they don't really have the
6 authority or market power to make any impact. We
7 also know small plants have been threatened with
8 blacklisting if they test.

9 In this situation, it says the sale of
10 unadulterated food is a matter of private contract,
11 and we don't believe that at all. FSIS has a
12 responsibility to make sure that adulterated product
13 is not leaving plants, especially routinely or on a
14 repeated basis when there's been evidence of product
15 at a slaughter plant.

16 So our recommendation is that FSIS must get
17 more involved by strengthening its trace back
18 program and increasing scrutiny and oversight at
19 slaughter plants, particularly the large plants at
20 which FSIS has decreased oversight since the
21 beginning of HACCP. Thanks.

22 (Applause.)

1 MR. ALMANZA: Questions?

2 MS. NESTOR: It looks like I said
3 everything I needed to say.

4 DR. MASTERS: Barb Masters, Olsson, Frank
5 and Weeda. Ms. Nestor, you indicated that your
6 combined document, the consensus document, there was
7 a more detailed that was available. Where is that
8 document available?

9 MS. NESTOR: Oh, I think it's probably
10 outside. Oh, Chris has them.

11 DR. MASTERS: Okay. Great. Thank you very
12 much.

13 UNIDENTIFIED SPEAKER: Thank you. Felicia,
14 thank you for your presentation. There was an item
15 I believe on your first set of slides from the
16 consensus document, and this is a comment, and maybe
17 my industry colleagues would like to chime in here.
18 There's a continuing, I see coming back, this
19 concept of sampling purge which we did some work
20 with some years ago. We found it to be very
21 undependable.

22 MS. NESTOR: Undependable?

1 UNIDENTIFIED SPEAKER: Right. It's not
2 always present in the combo even at the point where
3 we are which is somewhat down the line, and it
4 certainly isn't present in combos at slaughter,
5 which is where most of the sampling that you're
6 talking about is going to be taking place. There's
7 a lot of things that contribute to whether you have
8 it or not, and we're not going to go into that now,
9 but it certainly in our experience is an
10 undependable sample matrix. Thanks.

11 MS. HATCH: Michelle Hatch with Greater
12 Omaha. One thing that I would like to mention and
13 actually in FSIS' defense here is the fact that,
14 first of all, I just want to comment that the
15 information that is FOIA-able I think has been taken
16 and skewed. Information even put in newspapers can
17 be skewed. So I think that needs to be reviewed a
18 little better.

19 The other thing I want to say is that in
20 looking at things from a microbiological standpoint,
21 which is definitely my background, when you go to
22 homogenize anything, you definitely are taking that

1 and multiplying that bacteria over a surface area,
2 and so there are other places to test that, which is
3 why they do test that on an end sample to get that,
4 and it's not that testing is not being done at a
5 slaughter plant because it is being done at a
6 slaughter plant, and I think that that needs to be
7 noted.

8 MS. NESTOR: Yeah, the slides I put up were
9 analysis of the testing between '98 and 2002, at the
10 large slaughter plants when there was the exemption.
11 When ConAgra hit, dramatically, all of a sudden
12 everybody's being tested, and I can show you the
13 chart. It's a very dramatic difference.

14 MR. BURNS: Hi, Frank Burns with DuPont
15 Qualicon. I have a question. You mentioned
16 blacklisting. Is that -- I'm assuming you're
17 talking about when a grinder is told if they test
18 incoming trim from a slaughter plant, that they will
19 no longer be supplied by that company?

20 MS. NESTOR: Yes.

21 MR. BURNS: And is it your understanding
22 that that's widespread?

1 MS. NESTOR: It's my understanding that
2 it's not rare.

3 MR. BURNS: Okay. Thank you.

4 MS. NESTOR: And part of it is what I've
5 heard from small slaughter plants. The other part
6 of it is what I've heard from large industry, and I
7 think, you know, there is an arguable basis for
8 that. If a large slaughter plant produces a lot and
9 wants to know that it can release that safely into
10 the public and it's done testing itself, it wants to
11 know what its liability is. So I'm not saying that
12 there's, you know, that it's not rational. It's
13 rational behavior, but it's just not good for the
14 public and, you know, FSIS with its testing, that's
15 why FSIS with its testing should be doing more trace
16 back, and whenever any small plants find a positive,
17 I think FSIS needs to get involved with the trace
18 back and not just put it on the tiny plant.

19 MR. BURNS: Thank you.

20 MR. DANIELSON: Thank you, Felicia. Dean
21 Danielson with Tyson.

22 I'd like to, a couple of things here. On

1 your slide that you showed 38 million pounds that
2 was illness related --

3 MS. NESTOR: 58.

4 MR. DANIELSON: -- 58 contaminated product,
5 I think the FSIS trace back was 3.8 million,
6 something.

7 MS. NESTOR: Yeah, something like that,
8 yeah.

9 MR. DANIELSON: -- from FSIS and then -- of
10 contaminated product, and FSIS testing was 194,000
11 pounds.

12 MS. NESTOR: Right. Potentially
13 contaminated. I mean that's the product that FSIS
14 identified.

15 MR. DANIELSON: Associated product. You
16 didn't say potentially contaminated. That was not
17 all contaminated. That 38 million pounds, I mean
18 there's some big recalls in there that went over
19 numerous days, and it was an arms around, mainly
20 because there was a lack of records and
21 documentation. So it wasn't all contaminated
22 product --

1 MS. NESTOR: Right.

2 MR. DANIELSON: -- that was entered or that
3 was captured, and the differential is not -- when,
4 you know, it's associated product. So that
5 differential to me becomes a little bit less
6 alarming from that context.

7 Clarification for me. Fecal you said is a
8 new definition includes texture. It's my
9 recollection that that definition has been in place
10 since zero tolerance came into play in 1994.

11 MS. NESTOR: No, I think it was later than
12 that.

13 MR. DANIELSON: 1993, and that's been a
14 component in my recollection of the definition of
15 fecal applied at the plants and utilized since the
16 very start. If I'm wrong on that, then somebody --
17 you guys can correct me up there. And more fecal
18 getting into the coolers, I don't know what that
19 timeframe is. I can assure you from today versus 10
20 years ago, versus 15 years ago, these carcasses are
21 immaculately clean compared to what they were in the
22 eighties and the early nineties, when I started in

1 this business. They are like night and day
2 difference, and I just wanted to share that from a
3 timeframe standpoint. Thank you.

4 MS. NESTOR: I would like to see data on
5 that. I mean I would like FSIS to provide the fecal
6 NRs. I mean I've always advocated that FSIS needs
7 to collect more of this data, and as far as the
8 definition changing in 1993, I think it may be one
9 of those situations where some policies were in
10 force some places and not others because it was, I
11 would say, towards the end of the nineties that
12 inspectors were still complaining that they had just
13 been informed that they were no longer allowed to
14 identify it as fecal unless it had grains.

15 MR. McCULLEN: Brian McCullen (ph.),
16 National Beef. And, you know, it's always an eye
17 opener to hear different viewpoints when we come to
18 these meetings, and as an industry person, we don't
19 always hear the consumer groups like we probably
20 should, but I do have to ask just a couple of
21 questions.

22 One is you said four percent of small

1 grinders since 2003 has stopped grinding. Where did
2 you get that number?

3 MS. NESTOR: I have FSIS' *E. coli* testing
4 data, and they identified every plant that was
5 tested in 2003, and then every plant that was tested
6 in 2007 for *E. coli*. And so by state we have
7 identified the plants that are no longer -- the very
8 small plants that are no longer grinding beef under
9 FSIS inspection. Now, perhaps they're grinding it
10 under retail. The most recent information I got
11 from the Agency shows that just since 2007, I think
12 it is 60 plants that make less than 1,000 pounds
13 have stopped grinding. I'm not sure. It's either
14 40 or 60. There's a difference in number.

15 MR. McCULLEN: Well, I appreciate that
16 clarification. I just want to caution. It's easy
17 to make references and assumptions that people have
18 stopped grinding because of bad things going on.
19 There's a lot of other reasons for it, and the data
20 or the presentation that was given, there is a lot
21 of innuendoes there that I hope that when you
22 provide the data, the paperwork for everybody to

1 look at, they support some of the claims that you
2 made up there, basically state them as fact, and
3 then I'd like to see the backup data that supports
4 everything you've said.

5 MS. NESTOR: Sure. My understanding is not
6 about plants stopping grinding, the very small
7 plants. It's not based solely on the data. I've
8 just worked on a report on the disappearance of
9 small slaughterhouses and processing facilities
10 around the country and have had occasion to talk to
11 a good number of very small plants. And they've
12 talked about how difficult it has been to be held
13 responsible for contamination coming into their
14 plants, and that the FSIS expectations, while they
15 may be appropriate and very doable by large
16 processors, are much less so for the smaller plants.

17 MS. JOHNSON: Mr. Almanza, how many more
18 questions do you want to take before we get to open
19 comment? We have four people signed up.

20 MR. ALMANZA: We'll take one more question.

21 MS. JOHNSON: One more question before we
22 go to open comment. Okay.

1 MS. SMITH-DeWAAL: Felicia, thanks.
2 Ms. Nestor, thanks so much for your comments
3 earlier, and I do just want to draw back attention
4 to the consensus points. It's critically important
5 as the Agency moves forward that you do, in fact,
6 and many of us feel, and I think the consensus
7 document reflects that, the need to get more and
8 better testing in, and we will continue to challenge
9 you to make it as good as it can be, but don't
10 question at all that we want more testing in your
11 program to validate it. I certainly don't think
12 this is the best time to be debating visual
13 inspection criteria because visual inspection is
14 part of the program. It's been part of the program
15 since 1906, but we need to improve on that. So I
16 really do. I think Felicia's made some excellent
17 points, but I really want to make sure the Agency
18 goes back and focuses really on the issue of the
19 sampling. Thank you.

20 (Applause.)

21 MR. ALMANZA: Thank you, Felicia, and thank
22 you for warning me out in the hall not to take this

1 personal. (Laughter.) Maybe that's why it's so
2 warm with this flack jacket on.

3 But all kidding aside, one of the things
4 that surprised me is the reference to the slaughter
5 inspectors because one of the things that I've done
6 as a District Manager and Deputy District Manager
7 and as the Administrator is I walked up there on the
8 rail every single time, and every single plant that
9 I go to, I have not had one single inspector tell me
10 I have a problem with fecal material or detecting
11 ingesta, and that's so foreign to me because they
12 have eight feet to inspect. I stand up there next
13 to them. I inspect with them, and none of them have
14 ever had any problems with that. So it kind of
15 caught me by surprise. I do make it a point to go
16 out there and put my whites on, and I'll go out on
17 the kill floor with them to perform post-mortem
18 inspection duties with them, and I do hear some
19 comments about things that they don't feel
20 comfortable, that they can't write NRs and, of
21 course, we have a response for them, but to be able
22 to go out there and stand there with them and

1 perform post-mortem inspection duties with them,
2 ante-mortem inspection duties, and to live what they
3 live, I'm just not hearing those comments, and I
4 just wanted to make that point.

5 The first person that signed up is Gina
6 Bellinger (ph.) from Food Safety Net.

7 MS. BELLINGER: I'm good.

8 MR. ALMANZA: You're good. Okay. The
9 second person is Sherrie Jenkins for Food Safety
10 Net.

11 MS. JENKINS: I was going to talk tomorrow.

12 MR. ALMANZA: You're going to wait and talk
13 tomorrow.

14 MS. JENKINS: Tomorrow.

15 MR. ALMANZA: Okay. And then, Felicia,
16 you're third.

17 MS. NESTOR: No, I didn't sign up.

18 MR. ALMANZA: Somebody signed you up.
19 (Laughter.) Maybe they thought you didn't have
20 enough time. And then Barbara Kowalcyk.

21 MS. KOWALCYK: Do you want me to stand?

22 MR. ALMANZA: However you're most

1 comfortable.

2 MS. KOWALCYK: Okay. Barbara Kowalcyk,
3 Center for Foodborne Illness, Research and
4 Prevention. And the first comment I wanted to make
5 is I really appreciate the Agency putting together
6 this meeting and responding to a lot of issues that
7 I, as well as many others, have brought up about
8 sampling in microbiological testing. And as we
9 heard earlier today, HACCP has largely been
10 discussed as a preventative type program or type
11 system, but from a statistical standpoint, HACCP
12 really would be more appropriately described as a
13 means for minimizing the variability of a system.
14 And as I said earlier, my biological testing is a
15 critical component both for process control and
16 verification testing.

17 That said, microbiological testing cannot
18 replace effective prevention strategies and process
19 control which are key to controlling microbiological
20 contamination. Any microbiological testing must
21 address the following five points, some of which
22 overlap what Felicia presented earlier.

1 The first is the objectives of
2 microbiological testing which must be driven by
3 public health goals and should be clearly
4 identified. I won't go through the CDC stats, but
5 as we all know, foodborne illness is a serious
6 public health issue that affects too many American
7 families each year.

8 The second point is a robust sampling plan
9 that is designed to meet the objectives, the
10 microbiological testing objectives, with a high
11 degree of confidence must be developed. This is
12 critical to the generalizability and
13 interpretability of the results. And it's key to
14 any effective microbiological testing program.
15 Since it is not possible to conduct 100 percent
16 testing, one must use a sample to draw inferences
17 about the entire population. A robust sampling plan
18 will, one, ensure that the samples collected are
19 representative of the entire population; two,
20 minimizes bias; three, addresses potential
21 statistical problems such as confounding,
22 collinearity and error actions; and, four, ensures

1 that the sample size is sufficient to provide the
2 desired level of confidence.

3 Further, it is important that the sampling
4 plan address the fact that foodborne pathogens are
5 heterogeneously distributed throughout food products
6 and there is significant variability and prevalence
7 rates over time. Due to the complexity of designing
8 such a sampling plan, it is highly recommended that
9 a statistician or someone with equivalent training
10 is involved in the development of the sampling plan.

11 Of course, developing and implementing such
12 a robust sampling plan will require FSIS and
13 industry to invest significant additional resources
14 compared to that that is currently being expended.

15 CFI recognizes that some plants may not
16 have the necessary resources to develop such robust
17 sampling plans, and as a result, we recommend that
18 FSIS provide those plants with the necessary
19 technical assistance to develop robust sampling
20 plans.

21 In the compliance document, which I'm sure
22 we'll be talking about tomorrow, it was suggested

1 that small and very small plants use extension
2 specialists for this purpose. However, I do not
3 think that that's sufficient unless, of course, you
4 provide additional money for extension specialists.
5 Specifically, FSIS needs to provide statistical
6 consulting services in some form or another to the
7 very small and small plants or basically any plant
8 that can't afford it.

9 Third, my third point is the adequacy of
10 the sampling plan should be evaluated and certified
11 or approved by an independent third party.
12 Basically we heard this already before.

13 One, you need to have representative
14 samples. These sampling plans must be implemented
15 correctly, but more importantly, you can make
16 statistics say whatever you want it to say. As a
17 statistician, I've heard too many times statistics
18 being called black magic, and it's true. If you dig
19 deep enough, you will find the answer that you want,
20 but that doesn't mean that it really represents
21 what's going on in the plant or it really affects
22 the interpretability and generalizability of the

1 results.

2 So my fourth point is that FSIS needs to
3 establish mechanisms for verifying that industry and
4 government sampling plans are implemented correctly.
5 And FSIS and industry, as I said earlier, must
6 specify the power of the results to achieve the
7 testing program objectives. This will allow the
8 public to evaluate the reliability of the results.

9 This also goes hand-in-hand with analyzing
10 the data using proper statistical methods and having
11 inferences drawn from that data be based on
12 statistical theory. For example, as many of you
13 know, I've been highly critical of the way that the
14 FSIS verification testing data has been used over
15 the past several years, and that program is
16 specifically designed to test whether a specific
17 plant is meeting the HACCP performance standards at
18 a specific point in time. It is not designed to
19 make year-to-year comparisons, which I frequently
20 see the data being used to do. So we need to make
21 sure that not only once you have the robust sampling
22 plan put in place, that you actually interpret the

1 data from that plan appropriately.

2 And finally as Felicia said earlier, the
3 results of the microbiological testing program
4 should trigger some actions which should be clearly
5 defined by FSIS and as well as the circumstances
6 surrounding those actions.

7 Again, to conclude, I want to thank FSIS
8 for holding this meeting and for the compliance
9 documents that you recently published. I think that
10 this is an important step in the right direction.
11 Of course, the devil is always in the details, which
12 I'm sure we'll get to tomorrow, but this is an
13 important step. As I said earlier, we need to
14 basically put the statistics back into statistical
15 process control. Thank you.

16 MR. ALMANZA: Thank you. Next is Dean
17 Danielson, Tyson Foods.

18 MR. DANIELSON: I need a place to put my
19 notes here. There's been a lot of discussion about
20 the history of N-60, the basis of it, where it came
21 from, when it came from. So I thought important for
22 this meeting and this group of people for me to

1 share some historical perspective on it and the
2 basis and nature of it since I'm the one that
3 created it at least at Tyson. So if you bear with
4 me a few minutes, I think it's important that we
5 touch on some of these things.

6 The basis of N-60 testing came about
7 actually in the winter of 2002. I've heard 2004
8 thrown around. It was the winter of 2002. It was
9 designed at that point after the reassessment that
10 came out, requirement, in the fall of 2002 as a
11 result of some serious events to the industry that
12 previous summer.

13 So as a result of the reassessment
14 activity, and the new challenge presented to us, as
15 O157:H7 is reasonably likely to occur, one of the
16 tactics or one of the strategies we put in place at
17 that point was doing testing of 100 percent of the
18 trimmings from a beef carcass destined for raw
19 ground beef, whether that be ship trim or internal
20 grinds.

21 So that came about in the winter of 2002,
22 became fully implemented by us in 2003, and we had a

1 first full year's dataset in 2003.

2 Now, I'm going to get into some of the
3 statistical basis here in just a second, but
4 interestingly enough, that first full year, 2002,
5 when we weren't doing N-60, we were doing some other
6 things, N-25, some core grinding, core drilling
7 things, that first full year that we put N-60 into
8 place without a whole lot of other changes, the
9 incident rate, the findings, the sensitivity jump, I
10 can give you numbers. I've got all that data. It
11 jumped monumentally.

12 It clearly brought to us the foresight.
13 Prior to 2002, as an industry, our methods were not
14 very good, laboratory methods were not very good.
15 We weren't sampling robustly across the industry or
16 the -- we didn't know how to find O157:H7. We've
17 learned a lot in the last four or five years. We've
18 gone through those learning processes, and we came
19 to a great awakening in 2003, with an incident rate
20 that was quite a bit higher than anybody thought.
21 You know, we used to think point 1, I think in '94,
22 when we, I say we, made it an adulterant. It was

1 made an adulterant. The prevalence rate was
2 believed what? .1 percent, something. It was very,
3 very low, and that was all based upon industry and
4 academic methods that really couldn't find it. We
5 had not a clue how much or where or how widespread
6 it was. So learnings have increased dramatically
7 over the last six, seven years and even more
8 dramatically over the past two to three years. So
9 in 2003, we got the first set of data.

10 Now, I want to walk through some of the
11 elements that went into how N-60 was created.
12 Obviously you all are aware of the ACMF (ph.) Case
13 30, Case 15, that defines the most serious level of
14 sampling out there from that particular table, and
15 that's an obvious place to start, and it tells you
16 that it's an N-60, and there's criteria around it
17 for 95 percent confidence, and it makes an
18 assumption of a 5 percent prevalence rate in the
19 population being sampled, all right.

20 So, back in 2002, we really didn't know a
21 great deal more than that. We didn't know how much
22 was around and out there. However, in searching and

1 supporting the process, we reached some conclusions
2 on a 5 percent prevalence rate in the basic
3 statistical assumption that all statistical programs
4 need, that the prevalence rate of the population was
5 5 percent. I didn't say the incident rate of the
6 trim, or otherwise, I would have picked .1 percent
7 of the ground beef, what we knew at those days.

8 In the preamble of the Directive 10,010
9 back whatever year, that must have been 2002, the
10 preamble specifically shows a table and states that
11 trimmings from cows and bulls have a low prevalence
12 rate of greater than between 5 and 30 percent.
13 That's assuming that there's 1 CFU per gram, or no,
14 excuse me, at least 1 CFU in a combo of meat.
15 That's a range of 5 to 30 percent that was in the
16 preamble. It also said steer and heifer trimmings
17 had a range of 20 to 60 percent, at least of combos
18 with at least one cell in that combo. So there's a
19 number that we observed and rationalized it into the
20 development of the prevalence rate that goes into
21 the statistical conclusion supporting a 95 percent
22 confidence level of a testing program.

1 Additionally, we researched the literature
2 and an article published from the Clay Center
3 Research Station in 2002, I believe, shows the post-
4 intervention carcass to be 5.7 percent in this
5 particular study. That 5 percent number of the
6 prevalence rate of the N-60 program is and has been
7 represented and is transparently represented to
8 represent the post-intervention carcass. The
9 prevalence rate of the post-intervention carcass is
10 how we've always presented, always designed it.

11 So it's not the incident rate of the trim.
12 It's not whether we have good methods or bad
13 methods. It's academic research. It's what we took
14 out of the preamble.

15 Additional information then that we further
16 gathered through looking and assessing binomial
17 distributions and comparing the actual data we got
18 from validation studies of N-25 comparative
19 samplings to core drill samplings to N-60 surface
20 slice samplings, and applications within the
21 binomial.

22 And another key element that we used to

1 support this statistical assumption, and it is an
2 assumption. You may disagree with what the
3 assumption is, but it is a valid assumption to put
4 into the confidence interval development, is we used
5 the Poisson distribution. The Poisson distribution
6 shows us that a contamination, a very low
7 contamination level of 4 CFU per thousand
8 centimeters squared, the detection probability is 95
9 percent with an N-60 sampling plan.

10 So there is a statistical basis for N-60.
11 It's multi-tiered. You make assumptions and you go
12 with them, or if they're not valid, they're changed.

13 So in 2003, once we had a full set of data,
14 we implemented this program and we did it across the
15 board. In 2004, we said, okay, now what -- how do
16 we validate this, and part of that validation
17 process was a pretty in depth third party review
18 that we invited some noted independent reviewers in,
19 Dr. Ann Marie, Dr. Mohamed Kumari, Dr. Randy
20 Huffman, all three in like a two, two and a half day
21 conference. We went through every element of what
22 N-60 was, the sampling, the testing, the statistics,

1 the data and from that presentation, that
2 independent review, we came out of that with an
3 awareness of that group and an acknowledgment from
4 the people that we recognize in the third party
5 review, that the basis of the decisions and the
6 actions we took were sound in the way that we were
7 interpreting and applying them.

8 I point you to another study. I've seen
9 some criticism that there is no published data out
10 there. I'll share this with you. There's a study
11 published in the Journal of Food Protection in '04
12 by Murphy and Seward, and the summary statement is
13 from their study of industry data, at a 95 percent
14 confidence level, a sample size of 52 is recommended
15 for a process that has an *E. coli* occurrence rate of
16 less than 1 percent. That's a published peer
17 reviewed paper. So I'd point that out to you.

18 Then along in 2005 I guess, it became more
19 and more important to us, and you've seen references
20 to total N-60 versus N-60. N-60 is just 60 samples,
21 boom, boom. This whole program of *E. coli*
22 assessment, we've heard it from the lab methods,

1 we've heard it from the sampling, how do you do the
2 thin slice samples, analyzing the samples. It's a
3 total program, and we've learned a lot over the last
4 few years about the totality of that program,
5 whether it's FSIS inspectors doing it or people
6 we're buying meat from or selling meat from. It's a
7 total program, and all elements, a three-legged
8 stool, have to be in place. If you're going to have
9 the robustness and sensitivity of the testing
10 program, again the process control that we're
11 talking about.

12 *E. coli* testing in a slaughter plant has
13 two functions. One, it's a verification of the
14 process. We call it a process beacon. When we have
15 hot event days or multiple days, it tells us that we
16 have a system or a process, a control that needs to
17 be assessed and taken care of and take product
18 actions and do corrective actions necessary. It's a
19 verification of the process. It's also an
20 accept/reject of the trim that we manufacture. So
21 it has two functions. The 95 percent confidence,
22 it's not 100 percent. We don't get it all. We know

1 that. We understand that. It would be nice if we
2 could, but we don't. So I just thought I'd share
3 with you some history so that everybody in the room
4 understands it as we talk about it for what it's
5 worth.

6 MR. ALMANZA: Thank you, Dean.

7 DR. ENGELJOHN: Thank you, Dean.

8 (Applause.)

9 MR. ALMANZA: Felicia, you want to --

10 MS. NESTOR: Yes. I just want to bring it
11 back again to FSIS, and we hear now that the
12 industry didn't really know how to sample and didn't
13 know what it was doing, but in 1998, when FSIS told
14 us that the large plants were not going to have
15 to -- or that FSIS was not going to be testing them,
16 it was because FSIS was working on the best science,
17 and this was a scientific program and everything
18 was, you know, everything was known.

19 And so, you know, again I mean FSIS needs
20 to be clear with the public what it knows and the
21 limitations, you know, how confident it is in the
22 assertions that it's making because I mean, really

1 to hear now that we didn't know is pretty surprising
2 after seeing the testing data at all of the large
3 slaughter plants for five years.

4 MR. ALMANZA: Thank you. Barbara.

5 MS. KOWALCYK: Barbara Kowalcyk, CFI. I
6 just wanted to follow up on a couple of things.

7 I'd love to see the Journal of Food
8 Protection references that you referred to, but --
9 and I have no doubt that maybe the initial
10 prevalence level, assuming the initial prevalence
11 level of 5 percent may or may not be appropriate,
12 and we can debate that.

13 It is true that in statistics you have to
14 make assumptions, but I want to bring up about
15 statistical process control and what Tim discussed
16 earlier, the whole plan, do, check, and act. All
17 right. The whole idea of statistical process
18 control is you track your data and you continually
19 improve the process until you have a very tight
20 narrow region of variability around a target.

21 Now, obviously here the target is zero, and
22 I would love to say that we'll someday get to zero

1 contamination, but I fully realize as a scientist
2 that that would not happen. But we want to improve
3 the process, and one you do that is by plan, do,
4 check, and act. So if we set the prevalence rate
5 right now under the assumption at 5 percent, and
6 say, yes, N-60 is appropriate for a prevalence rate
7 of 5 percent, what happens when that prevalence rate
8 goes down and as we improve the process? Will that
9 assumption then be adjusted?

10 In the past, that has not happened. The
11 whole idea about HACCP, and I'm specifically talking
12 about the microbiological baseline studies is the
13 whole idea is you're going to set these performance
14 standards, and then Agency was going to continually
15 redo those studies until and keep bringing those
16 performance standards down, and while the Agency
17 has, and I do commend them doing more baseline
18 studies, most of the original ones have not been
19 repeated, and we are still dealing with performance
20 standards that are over 10 years old.

21 And so I think one of the concerns that,
22 I'm not going to speak for all consumer groups, but

1 one of the concerns that my group has is that if we
2 agree to an assumption of 5 percent, and maybe it
3 was appropriate in 2002, I'd like to see if it's
4 appropriate now, if as industry improves the process
5 and reduces the prevalence on trim post-
6 intervention, are we then going to go back and
7 readjust the number of samples and re-look at
8 sampling plans to make sure that they're actually
9 detecting what we think it out there?

10 So I have not seen that plan, do, check,
11 and act part being played out within FSIS and within
12 the public policies, and that's a very critical part
13 to making HACCP really work.

14 MR. ALMANZA: Thank you.

15 MS. KRANTZ: Yes, Kathleen Krantz with
16 Greater Omaha Packing. I think we've heard a lot of
17 data and history of where we were and where we are,
18 but I don't think we can lose sight of where we're
19 going, and I think as an industry, we've spent a lot
20 of money in protecting public health by food safety
21 interventions within our slaughter plants, within
22 our whole food processes, and I think with the

1 assistance of FSIS, in working through food safety
2 assessments and working through how can we do things
3 better, we must not lose sight of where we've been,
4 where we're going and how we're going to continue to
5 work together to improve the process, to get that
6 confidence level of the consumers.

7 As a matter of fact, we're all consumers.
8 We all have children, grandchildren. We're all
9 eating our own products.

10 So our goal is to continue to continually
11 improve the process, and I think that whether we're
12 on the FSIS side of things, the consumer side of
13 things, or the industry side of things, we must
14 continue to work together. Thank you.

15 MR. ALMANZA: Thank you. Anybody else?
16 Over here against the wall.

17 MR. BURNS: Frank Burns again from DuPont
18 Qualicon. As the incidence of O157 continues to go
19 down, it's useful to us as an indicator of process
20 control also goes down, because if it's too
21 infrequent, then you really don't get any feedback
22 on your process. And I was encouraged a lot by what

1 Tim Biela said about using a lot of other fecal
2 indicators, and at some point, if we continue to get
3 lower and lower levels, doing a lot more testing or
4 taking more samples is not always going to suffice
5 to measure our process control.

6 So I think, you know, thinking a little bit
7 beyond a single organism as an indicator of process
8 control might be a fruitful way to go.

9 MR. ALMANZA: Thank you. Anybody else?

10 (No response.)

11 MR. ALMANZA: Okay. Then we'll close out
12 the comment period. I do appreciate everybody's
13 participation. I think that as we anticipated,
14 these are painful meetings somewhat, but they're
15 necessary and -- well, for me, but they are
16 necessary, and I think that they will give us
17 additional information to be able to make decisions
18 on. The one thing that we have to be careful of is
19 that we have the right information and the right
20 data to be able to move forward, and I certainly
21 believe that. So thank you again, and we'll see you
22 all tomorrow.

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(Whereupon, the meeting was 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:

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
ADDRESSING SAMPLING AND TESTING
METHODOLOGIES, COMPLIANCE GUIDELINES
AND N-60 LABELING

Washington, D.C.

October 14, 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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