

UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

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SUBCOMMITTEE 2

ISSUE II: ACROSS ESTABLISHMENT PUBLIC HEALTH
RISK-BASED INSPECTION ALGORITHM

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February 5, 2008

1:15 p.m.

Key Bridge Marriott
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Iowa State University

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DR. SHELTON MURINDA
DR. BRIAN COVINGTON
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MS. FELICIA NESTOR
MR. CHARLES LEE
MS. PAT BUCK
MR. JOHN RICE
MR. BOB McKEE

I-N-D-E-X

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

2 (1:15 p.m.)

3 DR. DICKSON: Everything you say from here
4 on out is on the record.

5 Mr. Tynan has suggested that we go ahead
6 and get started. What I want to do here, a couple of
7 basic things. I'm going to go around the table and
8 let the Subcommittee introduce themselves.

9 First off, I'm Jim Dickson from Iowa State
10 University. To lay some ground rules here, as much
11 as possible without impeding the discussion, because
12 this is on record, it would greatly help the
13 transcript if you would state your name before you
14 make a comment, not only for those here but for those
15 around the room as well, if you would be kind enough
16 to introduce yourselves, so that we can get this
17 captured on the record. Okay. Kibbe.

18 MS. CONTI: Good afternoon. My name is
19 Kibbe Conti, coming from South Dakota, Northern
20 Plains Nutrition Consulting.

21 DR. GRONDAHL: I'm Andrea Grondahl, and I
22 work with our State Meat Inspection Program under the

1 North Dakota Department of Agriculture.

2 MR. KOWALCYK: Michael Kowalcyk from
3 Cincinnati, Ohio. I'm a consumer advocate with the
4 Center for Foodborne Illness Resource, Research and
5 Prevention.

6 DR. MURINDA: Shelton Murinda, Cal Polytech
7 Pomona, just outside LA. I teach -- I'm a
8 microbiologist. I also teach a course of meat
9 processing.

10 DR. HENRY: Craig Henry, Grocery
11 Manufacturers Association. I'm the Senior Vice
12 President/Chief Operating Officer for Scientific and
13 Regulatory Affairs based here in D.C.

14 MR. COVINGTON: Brian Covington, Keystone
15 Foods, Corporate Food Safety in QA.

16 DR. HARRIS: I'm Joe Harris, and I work for
17 Southwest Meat Association, headquartered down in
18 Bryan, Texas.

19 DR. DICKSON: Again, I'm Jim Dickson from
20 Iowa State University.

21 Before we get started, I'd like to read our
22 charge as far as what we are to accomplish and to

1 point out that we are reporting at 4:00 this
2 afternoon. So ready or not, we are reporting at 4:00
3 this afternoon, which gives us about 2 1/2 hours from
4 right now.

5 MR. PAINTER: Excuse me.

6 DR. DICKSON: Yes, sir.

7 MR. PAINTER: Could I ask a question
8 please?

9 DR. DICKSON: Yes, sir.

10 MR. PAINTER: Is it acceptable, although
11 that Mr. Bryce and I are not voting members of the
12 Committee, since we're sitting at the table, is it
13 acceptable for us to have a place at the table and a
14 voice?

15 DR. DICKSON: Certainly.

16 MR. PAINTER: Thank you.

17 DR. DICKSON: And again, I'll have you
18 gentlemen introduce yourselves.

19 MR. PAINTER: Yes, my name is Stan Painter.
20 I'm the Chair for the National Joint Council of Food
21 Inspection Locals.

22 DR. BRATCHER: Chris Bratcher, past

1 President, National Association of Federal
2 Veterinarians.

3 MR. McKEE: I'm Bob McKee. I'm the ATSP
4 representative.

5 DR. DICKSON: Okay.

6 MR. PAINTER: I'm sorry. I didn't mean to
7 open up a can of worms.

8 DR. DICKSON: Again, the main thing is the
9 Subcommittee has to report at 4:00. We are
10 interested in comments from the rest of you in the
11 room but again, the Subcommittee does have a job to
12 accomplish within the next 2 1/2 hours. So if I
13 shorten your comments, it's not because we're not
14 interested. It's because we've got to get this done.

15 Our charge today is on Public Health Risk-
16 Based Inspection. FSIS would like our comments on
17 the inclusion of noncompliance reports and other
18 criteria in its proposed public health risk-based
19 algorithm.

20 Specifically, the Committee should consider
21 the following questions in its discussion.

22 The first one, and we'll take these one at

1 a time. So I'd like to take this, what data analysis
2 in addition to those that have been done by FSIS,
3 would the Committee view as helpful to the Agency in
4 assessing the utility of the inclusion of inspection
5 observations, including those recorded as NRs, in its
6 public health risk-based inspection algorithm?

7 So just to reframe that question a little
8 bit, this is in addition to what FSIS has already
9 done, not to say that we can't comment on what
10 they've already done, but the focus of that first
11 question is what would we like to see in addition to
12 what has already been done?

13 Okay. Thoughts or comments from the
14 Subcommittee. Dr. Harris.

15 DR. HARRIS: This is Joe Harris. One thing
16 that I think would be from the NR perspective, the
17 analysis that we saw presented today was fairly
18 broad. It appeared to be across all product
19 categories, and I know they probably -- the Agency,
20 I'm assuming, considered all product categories but I
21 do think it would be interesting to see that a little
22 more finely tuned and maybe look at specific process

1 categories to see if that relationship is the same
2 for every processing category.

3 For example, one of the things that they
4 presented on to us this morning on NRs was if one has
5 a NR within the last seven days, then what's the
6 increased likelihood that there will be a positive
7 *Salmonella* finding in the next 14 -- I don't remember
8 the exact phrasing on that. My question was, well,
9 that would be somewhat dependent on what product
10 we're talking about, you know, just because I
11 received a NR and if I'm making a ready-to-eat
12 product, it should not necessarily increase my
13 likelihood of having a positive *Salmonella* finding.
14 Conversely, if I'm getting, you know, NRs related to
15 a raw product, you know, intervention at slaughter,
16 that would very likely greatly increase my likelihood
17 of finding *Salmonella*. So I would like to see that
18 fine tuned a little more.

19 DR. DICKSON: And I appreciate -- Jim
20 Dickson here. I appreciate that. This is slide 12
21 of Dr. Travis' first presentation, yes, across
22 establishment ranking concept. This is slide 12

1 showing the results of the Carnegie Mellon study of
2 comparing NRs with the probability of a positive
3 *Salmonella* within the next two weeks.

4 Other comments or follow up to what Joe had
5 said?

6 MR. KOWALCYK: This is Michael Kowalcyk. I
7 think to add to what Joe was saying, I think it would
8 also be important that we understand better how those
9 categories of NRs distribute and what they've seen
10 out in the field. In other words, what percentage of
11 total NRs is going to set time period represent FSIS
12 to find food safety related NRs versus, you know,
13 what percentage of total NRs is that? And then
14 again, stratifying the data across different types of
15 product groups may be another useful way of looking
16 at it, and we might find that in some categories, all
17 NRs may be highly predictive. We don't know. All
18 the categories are lumped together in one group.

19 So again, sharing more information about
20 how the study was done, would aid this Committee as
21 well as the overall Committee in making any
22 recommendations.

1 DR. BRATCHER: Chris Bratcher with NAFV. A
2 couple of things came up to me today when I was
3 looking and listening to some of their prompts. Some
4 facilities may have a number of HACCP plans, and a
5 good example would be fully cooked O3G plan and then
6 it goes into a product that has raw components like
7 an entrée, potpie, something else like that, and when
8 it comes out, it's an O3H. So there are certain
9 parts in a lot of plants that don't get considered
10 and so you either have prerequisite programs or they
11 have a HACCP plan or they have some other way of
12 controlling temperature, lethality, basically
13 Appendix A and Appendix B, and then it doesn't even
14 matter because the product that they're producing is
15 not a fully cooked product.

16 So we need a way to address some of those
17 things because those could go into a factor of what
18 kind of product they have and what kind of health
19 basis they would have, and it might not be caught in
20 the system we've got in place now.

21 DR. DICKSON: Again, Jim Dickson from Iowa
22 State. They mention that this was part of Appendix

1 E. You know, I don't suppose you read Appendix E in
2 enough detail to really know that, but has anybody
3 really gone through Appendix E in sufficient detail
4 to comment on that?

5 DR. HARRIS: Those of you looking for
6 Appendix E, it's the last section behind Tab 5.

7 DR. DICKSON: Right.

8 DR. HARRIS: And to answer your question,
9 no, I haven't studied that in detail.

10 DR. DICKSON: Yeah, Appendix E looks like
11 about 65 pages in my book, and to be honest with you,
12 I haven't read it in all detail. I think the point
13 that we're making here, and I'm not trying to speak
14 for the group, is that this single graph, slide 2 in
15 Dr. Travis' presentation, may not be representative
16 of all product categories and all species. So is
17 that a fair statement to make?

18 Other comments on the use of NRs?

19 MR. COVINGTON: This is Brian Covington. I
20 guess, you know, we stayed pretty broad in the
21 presentations today. So there's a lot more
22 information that we as a Committee and, you know, out

1 in the field would need to look at but -- and one of
2 those is what are those prompts. They identified a
3 single NR or multiple NRs. Is that going to be any
4 of the 66 regulatory citations that were quoted in
5 the technical report? And then also what questions
6 does that lead to because to follow on Michael's, and
7 take it a step further, if you just broke down the
8 O1B02s, not all of those are created equal for preop,
9 depending on where they are in the process and where
10 they're found, if you take a slaughter debone
11 facility, and you have a preop NR issued in debone, I
12 don't think that has a very good correlation to you
13 getting a *Salmonella* positive on a bird rinse coming
14 out of the chiller. It gets back to the three times
15 more likely. So I think a more in-depth analysis of
16 how these NRs are going to be broken down within the
17 process categories as well is needed before we can
18 effectively analyze how it goes into this algorithm.

19 DR. DICKSON: Again, Jim Dickson here. I
20 think that -- can anybody speak with any degree of
21 confidence on what USDA's health related NRs are?
22 Has anybody seen a list of what those are?

1 DR. HARRIS: There was a list out on that
2 table and I picked one up. I don't know where I
3 stuck it, but I do have one.

4 DR. DICKSON: Okay.

5 DR. HARRIS: Ranking of noncompliance
6 records based on public health significance.

7 DR. DICKSON: Okay.

8 DR. HENRY: And that's 66 -- this is Craig
9 Henry, 66 citations out of the regs, and that's what
10 they're basing it on.

11 DR. DICKSON: Okay.

12 DR. HENRY: So I think again when you look
13 at this, it's an interesting observation. The
14 analysis and believe me, I have not had a chance, nor
15 do I think many other people, to dig into the
16 Carnegie Mellon results, but it's interesting that
17 those results stand on their own value which says
18 those NRs as analyzed could be correlated with
19 potential for a *Salmonella* positive. Okay. Great.
20 Well, that's not applicable to all products which
21 we've established. What we're really trying to get
22 down to which we've talked about in generality here,

1 the applicability of NRs to public health
2 significance which means, you know, more than just
3 *Salmonella* in itself. We come back and look at, you
4 know, how are they correlated with those plants that
5 ended up with a serious enforcement action, such as a
6 recall, you know, I don't know that we have that
7 nailed down correctly here, especially since, of
8 course, the Agency has made it very clear that the
9 intent is to get an appropriate analysis of all the
10 data they have and using the citation becomes a very
11 easy way to have the computer spit out whether
12 there's correlation or not, and no matter how you do
13 it, anyone that's dealt with NRs for any period of
14 time, there is a great deal of interpretation that
15 has to go with a NR one way or the other. Not all of
16 them are clear cut, black and white, with a direct
17 public health significance.

18 So I think that analysis, and they speak to
19 this being peer reviewed, and I think the question
20 there becomes peer reviewed in what light, for what
21 purpose? Just to say did Carnegie Mellon do the
22 right job? Or are we properly analyzing NRs for the

1 appropriate application to public health significance
2 overall.

3 DR. DICKSON: Is there a recommendation or
4 a comment that we could put in the report to that
5 effect?

6 MR. SMITH: Bill Smith with the Food Safety
7 and Inspection Service.

8 Just try and clarify, I don't want to get
9 into the use of the Carnegie Mellon as a -- for what
10 it wasn't intended. What that was intended to do was
11 to establish that NRs -- there could be a scientific
12 basis to use a NR, not that that was going to go
13 across all nine processed, but that you can from a
14 scientific standpoint say NRs can be used in the
15 determination. That's really what that study was
16 about. It was not to say that *Salmonella* is in each
17 of the nine processes.

18 So I just wanted to make that very clear
19 because in the past there was no science behind the
20 NR, and so this is to say, yes, there is a scientific
21 basis to use NRs. It was not to be applied across
22 all nine categories as -- just using that slide 12.

1 DR. CATLIN: And there's a lot more
2 analyses in Appendix E looking at the NRs and what
3 they are related to when we look at those analyses.

4 COURT REPORTER: Will you identify
5 yourself?

6 DR. CATLIN: Michelle Catlin, FSIS.

7 DR. DICKSON: Jim Dickson here. So to
8 summarize this, Bill, would you say that the purpose
9 of that study was to demonstrate the predictive value
10 of this class of NRs for probable or possible
11 *Salmonella* contamination?

12 MR. SMITH: Michelle would probably know
13 better --

14 DR. DICKSON: Michelle, would you like to
15 comment on that?

16 DR. CATLIN: This is Dr. Michelle Catlin
17 again. The purpose of it was to -- there was a lot
18 of criticism before that the NRs weren't really
19 demonstrating anything, we couldn't link them up to
20 anything. It was not all that useful information.

21 So we asked ourselves, is there a way to
22 look and see if there's an association between having

1 a NR and having something that might be more directly
2 linked to public health outcomes, and we went to --
3 to do that.

4 If you look at Appendix E, you'll also see
5 some examination with *Lm* and *E. coli* but when you get
6 to those other end point, the positives on *E. coli*
7 O157 or the positives on *Lm*, the number of positives
8 is so small that statistically you just start losing
9 all power to be able to detect anything. So we
10 looked at -- so we focused on the *Salmonella* more
11 because you have enough data there to look and see
12 whether or not there's any associations. Not to say
13 whether or not it was causal. We don't try to make
14 any causal implications with that. Just to look and
15 see if it predicts or is more likely -- means that
16 you are more likely to have *Salmonella*.

17 DR. DICKSON: Michael.

18 MR. KOWALCYK: This is Michael Kowalcyk. I
19 think to follow upon this, on the surface, this study
20 seems to demonstrate that there is a strong
21 association to a NR leading a positive *Salmonella*
22 result. Now I think everybody has made good points

1 until looking at it across product types and whatnot.
2 One thing that can be done is looking at where those
3 *Salmonella* positives exist, how is that associated
4 with an event such as a recall and something like
5 that, and it kind of leads to the question, what are
6 the public health consequences to a positive
7 *Salmonella* result?

8 So this study seems to indicate that NRs
9 aren't arbitrary in that they are indicative of
10 something out of control. The interpretation of how
11 that NR is addressed is probably where a lot of the
12 sticking points are but I think this is a reasonable
13 place to start.

14 My question is, in looking at again the
15 total NRs that occur during let's say a month or a
16 quarter, what percentage of NRs does this represent?
17 And then -- because then that might lead to having
18 another problem as far as data if it's a very small
19 fraction of NRs that are truly public health related
20 while all NRs are showing some association with a
21 positive *Salmonella* result.

22 DR. DICKSON: Okay. Chris.

1 DR. BRATCHER: Chris Bratcher, NAFV.
2 Routinely as a front-line supervisor, I look at the
3 O1s, O3s and O6s, and I look for a trend or a spike
4 in any of those areas, and it's not so much that I'm
5 looking for a *Salmonella* problem or anything like
6 that. I'm looking at the overall operation of that
7 plant in process control, and if there appears to be
8 a loss of process control in any one area, it's cause
9 for me and my inspection team in that plant to see if
10 there's something going on, to see if something's
11 changed, the HACCP plan, the SSOP, employees,
12 whatever, and it's better to catch those things
13 before it gets out of control than to catch it after
14 we have a recall or a positive finding of *Listeria* or
15 something like that.

16 So I think it's very predictive and from my
17 experience, if you're not following those things from
18 the plant standpoint, or from the inspection
19 standpoint, you're going to miss an opportunity to
20 correct something before it happens.

21 MR. PAINTER: Stan Painter with the
22 National Joint Council. Two issues that I would like

1 to see addressed with the NRs is the Agency took a
2 stand a number of years ago to put multiple NRs under
3 one number, and if the plant chooses to appeal a NR,
4 then, you know, you may have six issues that are tied
5 to one NR and five of them may not be an issue but
6 one is an issue, and you have everything tied up
7 based on the appeal because you appealed the NR. You
8 don't appeal a specific portion of that. I would
9 like to see it broke back down into, you know, each
10 occurrence would stand alone.

11 And the other issue is the response from
12 the plant, you know, it's how many times do we
13 accept, retrain the team member, and that's a pretty
14 generic response especially when it comes to a place
15 of human error or something that a person done, it's
16 we'll retrain the team. Thank you.

17 DR. DICKSON: Jim Dickson here. If I can
18 ask you gentlemen here, it says inspection
19 observations including NRs. Are there other
20 inspection observations that could be included in
21 this system that are not currently being captured
22 other than NRs? Is there something that your

1 inspectors are doing that is not currently being
2 captured in the system? That might be important.
3 That might be an issue.

4 DR. BRATCHER: Chris Bratcher. Probably
5 the most important thing is that the NRs should
6 reflect the condition of the plant, and I guess the
7 problem is, you can have a very good plant and no NRs
8 or you can have a very good inspector and have a lot
9 of NRs and it still be a very good plant. So there's
10 an objective part of that that you never can capture
11 if you're using just empirical data to make that
12 reference. And so there has to be some exceptions to
13 this, and I don't know if that's after the FSA or
14 before the FSA. I would think that the front-line
15 supervisor should have some input into whether it
16 needs to have an FSA in a plant.

17 I'll give you another example. If you have
18 15 acres under roof, and a person writes NRs on preop
19 sanitation, that may not be all that indicative of
20 the conditions of that facility because a person
21 could look enough, any day and find something that
22 was wrong, and they could write one every time they

1 did preop but it would be a matter of my judgment as
2 to whether that's indicative of a problem in that
3 plant.

4 MR. McKEE: This is Bob McKee, ATSP. And I
5 guess I'd take an opposing view. I really like the
6 opportunity to have that food safety assessment done
7 for cause if those NRs indicate it. So it's going to
8 take some of the objectivity out of how things are
9 done in the plant, if you bring in that third set of
10 eyes after the front-line supervisor and the
11 inspector, they could come in and verify whether or
12 not, in fact, all the right things are being done in
13 that plant. So I'm real comfortable with the FSA
14 concept.

15 DR. DICKSON: Jim Dickson here again. Any
16 thoughts in general on how to reduce the human
17 variation, maybe that's the best way to say it, the
18 establishment-to-establishment or inspector-to-
19 inspector variation? Any thoughts at all on how to
20 deal with that?

21 MS. NESTOR: Are you opening it up to
22 public comments or no?

1 DR. DICKSON: I'll ask for it. I want to
2 go around the table first to see if anybody's got any
3 comments, and then I'll come to you.

4 MS. NESTOR: Okay.

5 DR. DICKSON: Thoughts in general here?

6 MR. COVINGTON: Jim, this is Brian
7 Covington. I can speak to that a little bit because
8 I have multiple plants that operate under the same
9 process category, and that's one of the things that
10 we try to do is figure out, you know, how we can
11 standardize but we do see differences. In looking at
12 the ISP procedures that are performed each month, we
13 can see differences in each of the plants and it's
14 very difficult. I mean it's just like us. It's hard
15 for us to gain consistency day-to-day in our
16 operations and, you know, you're always going to have
17 some of that human variable on our side, the
18 inspector side, whatever it may be, and that's going
19 to be very difficult to standardize.

20 MR. PAINTER: Stan Painter with the
21 National Joint Council. You know, in the field, I
22 see and I work as a relief inspector and I go to a

1 number of different locations, and for a plant that
2 has a more specific HACCP plan or a more specific
3 SSOP plan, it's easier to determine and it's easier
4 to identify something versus if you just have
5 something, a generic statement, we will operate under
6 sanitary conditions, you know, then, you know, that
7 is very subjective, you know, and it's hard to be, if
8 you're looking for specifics, you know, for the
9 inspector to identify, you know, you identify
10 something and that inspector determines it's not
11 under sanitary condition. And, you know, being more
12 specific would be helpful.

13 DR. DICKSON: Okay. Well --

14 DR. BRATCHER: Chris Bratcher. One of the
15 things, believe it or not, that's helped with some of
16 that in my circuit is the team inspection concept,
17 because we put the -- and we knew we had variations
18 from one inspector to the other but when we put those
19 together as a group, and they had weekly meetings
20 they have to discuss, with -- usually with me being
21 present, some of the issues that have come up in the
22 plants in how they're going to handle it, it works as

1 a tool to correlate those people so that they're all
2 thinking the same way, and some people are adding
3 comments or adding things that should be checked or
4 looked at. Other people are saying, well, we've done
5 that, and that's not the case. So team inspection
6 has helped some at least in one instance.

7 The other thing is a span of control for
8 the front-line supervisor has been identified for
9 several years now, that it's too large or too great,
10 and if we had more time to do more correlations and
11 more things like that, I think we could tighten it a
12 little bit and get a better cross section of people
13 doing the same thing for the same reasons.

14 DR. DICKSON: And you had a comment?

15 MS. NESTOR: Sure. Felicia Nestor, Food
16 and Water Watch. I've been talking to inspectors for
17 about 13 years, and one of the most common questions
18 I ask them is do the NRs in the plant reflect plant
19 conditions, and the number one answer that they give
20 when they say no is because they don't have time to
21 write NRs. If you have a guy on patrol, especially
22 one who is doubled up, and has a number of bad plants,

1 they may think that they are protecting public health
2 better if they go onto the next plant and try to put
3 their finger in the dike there rather than taking the
4 hour that it takes to write the NR, consulting the
5 plant's HACCP plan and all that. And so I keep
6 recommending that the Agency reinstitute its coding
7 so that inspectors, when they perform the inspection
8 task, they can write I didn't perform this inspection
9 task because I didn't have the time. Just with a one
10 letter code. You know, the inspectors don't have to
11 write NRs but they do have to report whether they did
12 a task, and just with your circuit, you find that,
13 you know, 30 percent of the inspection tasks are not
14 being done because the people don't have that time.
15 That might explain why a plant has no NRs and others
16 do.

17 DR. DICKSON: Thank you. Any follow-up
18 comments?

19 MR. PAINTER: This is Stan Painter with the
20 National Joint Council. And going back to what
21 Felicia was saying in time and the ability to do what
22 you need to do, in the opinion of the Union, the

1 downfall came back in 2003 with what was called MAW,
2 and that was the method of assigning work, and we're
3 still trying to figure out how that thing is applied
4 and how it's looked at as far as being able to visit
5 an establishment, you know, when you're driving 80
6 something miles, you know, that's certainly not
7 getting the job done and protecting the public, and
8 in the name of working under the guidelines of the
9 method of assigning work.

10 DR. DICKSON: Jim Dickson here.
11 Dr. Grondahl, did you have any comments and I would
12 guess most of your state inspected plants are small
13 and very small, anything unique to that environment
14 that you might want to add to this discussion here?

15 DR. GRONDAHL: This is Andrea Grondahl. I
16 don't know if I have anything to add to that but one
17 thing I've been thinking about as far as the
18 standardization of inspectors and how to tie that
19 together in my mind is really through the food safety
20 assessments. Part of what the EIAO does prior to the
21 food safety assessment is looks at all data prior to
22 going into the plant to make their assessment. And

1 if they're looking at that data, they can see, okay
2 these, you know, this is what's been written for NRs,
3 these are the NRs, and then when they go in the
4 plant, they should be getting a good feel if, you
5 know, if the inspector is finding on the compliances
6 that they should.

7 So, you know, in thinking about this first
8 question, what data analysis and I know the FSAs are
9 being considered but I think they need to be, you
10 know, and I don't know if that's part of the answer,
11 but I think that's definitely part of the
12 standardization for inspectors.

13 DR. DICKSON: Okay. Any other discussion
14 from -- yeah, I'm sorry.

15 MR. COVINGTON: Brian Covington. One of
16 the things I would like to see is in the for cause
17 and directed procedures after a NR is written, the
18 vulnerable points in any process, it's been
19 determined a list of questions that the inspector is
20 to go ask and get yes/no answers. Has there been any
21 dry runs on those questions? What is the analysis
22 and are those questions and the answers that come

1 from those questions, in fact, indicative of process
2 control which is what they're geared to go at and
3 then in turn relating to the public health
4 significance of the process?

5 You know, it's -- we would love to gather
6 the data in a very nice, neat package with yes/no
7 answers, but a lot of times in some of these
8 processing establishments, these food safety systems
9 are very complex and it may be very difficult to ask
10 the right questions and get a yes or no answer
11 because I think we went through that with Nona 6507
12 in trying to fill out the checklist and a lot of the
13 answers didn't fit the box.

14 DR. DICKSON: Okay. I believe in this, Jim
15 Dickson here, implementation schedule, that they have
16 sort of a timeline for implementation, and if I'm
17 correct, Carol --

18 DR. MACZKA: Yes.

19 DR. DICKSON: -- that this includes some of
20 this sort of testing and evaluation process. Is that
21 -- I think that's included in here.

22 DR. MACZKA: Not to really test the NRs.

1 That hasn't been worked in yet, but in terms of
2 generating those questions and Ilene can answer this
3 also but, you know, we did pull together a group of
4 Agency folk, many of them have been inspectors in
5 plants, and so we used those people to generate those
6 questions. However, there is no plan to actually, at
7 this point, actually test the NRs with individuals.

8 DR. DICKSON: Stan?

9 MR. PAINTER: Stan Painter with the
10 National Joint Council. I just want to say that, you
11 know, based on something that was said, it looks like
12 we're, in my opinion, going back to where we were a
13 number of years ago with the decision tree, which
14 created a lot of controversy, you know, you had a lot
15 of inspectors spending time, you know, trying to
16 explain to the plants and the plants had concerns
17 over, you know, how they got from a major to a
18 critical issue, and then supervisors as well spent a
19 lot of time dealing with those issues. And, you
20 know, I don't -- we don't need anything in the field
21 in my opinion that's going to create a bunch of
22 arguments, you know, and yes or no, you know. And

1 we've been told as inspectors over the years that
2 HACCP has a lot of gray areas, and now we're into yes
3 or no. So what happened to the gray areas? And, is
4 this yes or no thing going to create a bunch of
5 controversy where there shouldn't be.

6 DR. DICKSON: Okay. Other comments on the
7 first question, what data analysis? And I apologize
8 to all of you behind me here, but any general
9 comments? What we'll do at the end of this, after we
10 go through all four of these questions, we'll look
11 for some summary points, too, that one of you who
12 volunteer to make the presentation. Craig, I think
13 you said you wanted to do it.

14 All right. Any other comments on question
15 1?

16 (No response.)

17 DR. DICKSON: The second question, for the
18 purpose of illustration, a thirty day time window was
19 used for calculating NR rates in the proposed
20 algorithm. What time window would the Committee
21 propose for calculating NR rates and/or what criteria
22 should be considered in establishing the time window?

1 DR. GRONDAHL: Andrea Grondahl. Going back
2 to Joe's comment he made initially for question
3 number 1, in that NRs or the correlation should be
4 more closely looked at as far as the *Salmonella*
5 positives and the correlation with NRs and the
6 predictive analysis, in looking across the different
7 categories, I think that should be tied into number
8 2, to determine that window, that time window.

9 DR. HARRIS: Joe Harris. And I don't have
10 a lot of insight on whether or not the 30 days is too
11 long or too short. I think that is highly dependent
12 on the establishment, the process involved. I know
13 for some establishments, if we do a 30-day look back,
14 that's going to be quite a few NRs to consider.
15 Other establishments, there won't be any NRs in that
16 last 30 days. And so you're going to have every
17 extreme, and I don't know if 30 days is the right
18 number, but I guess I don't have a better number to
19 suggest frankly.

20 DR. DICKSON: Okay.

21 DR. MURINDA: I think 30 days is a very
22 short window for considering that, for example,

1 microorganisms that contaminate animal or animal
2 feed. The -- no changes that have been in those
3 microorganisms. So we need to consider decisions
4 first before we can settle down to how many days, I
5 think.

6 DR. DICKSON: Mike.

7 MR. KOWALCYK: Michael Kowalcyk. I'm
8 referring to Appendix E on page 22, Table E-4. This
9 gets to a question that came up earlier about
10 relationship to food safety recall. It brings to
11 mind a question as to why the category that FSIS
12 selected is not in this table. So it's missing some
13 data. So I'd like to see how that would fall out.
14 All NRs and industry proposed NRs, if you look at the
15 statistics around it, and I can walk you real quick,
16 they have a 95 percent confidence interval, if that
17 confidence interval contains 1 in between the lower
18 and upper number, there's no significance,
19 significant difference in that study. It looks like
20 there is for the industry proposed NRs 28 days. It
21 is not quite significant but it's a .1 which may
22 indicate a couple of things because 14 days is highly

1 significant.

2 Now I would like to learn more about the
3 process when a NR is written, how quickly are steps
4 taken, not only within the inspection team as well as
5 within the plant, because it seems like if we're
6 looking at advising the Agency on how they're going
7 to allocate resources, it seems like there's a very
8 short window when a health related NR is apparent.
9 It gets people's attention. It needs to be
10 addressed, and it seems like that's occurring in that
11 very narrow time window. It correlates highly with
12 some adverse event, either a positive reading or in
13 this case, a food safety recall. Again, I would like
14 to see the category for the FSIS selected and see
15 what those statistics are, but it seems like, and the
16 data isn't showing this, but are there actions and
17 can the Agency show this Committee actions that
18 typically occur when food safety related NRs are
19 written, that there are certain sets of interventions
20 that occur, and if that is part of this proposed
21 system. Because it seems like something is happening
22 that the further out you go, the less significant it

1 gets, and again, we've discussed issues with
2 questions about how the study is, and frankly I'm not
3 very comfortable with this Subcommittee coming to the
4 full Committee with anything really definitive
5 because, I mean speaking for myself, I haven't read,
6 I mean I would have to read through this a couple of
7 times to really get into it and -- but it seems like
8 that 28 day, 1 month timeframe, it seems like
9 something is occurring. I can't put my finger on it
10 though.

11 DR. DICKSON: One follow up to that,
12 Michael. Jim Dickson here. Table E-5 on page E-24,
13 I think has that FSIS data in detail. Again,
14 continuing on, Jim Dickson here, the comment I had on
15 this about the timeframe is that in looking at their
16 conceptual approach, and again this is slide 5 out of
17 Dr. Travis' first presentation, and again we've all
18 seen this conceptual approach, the first part of that
19 approach relates to volume. You look at
20 establishment volume compared to national volume, and
21 I'm wondering if it's not more appropriate to tie in
22 the timeframe to production volume rather than 7

1 days, 14 days, 30 days, whatever, because an
2 establishment, a large establishment, you know, it
3 might be appropriate to look at it over a 7 days
4 period but like Joe said, in a smaller establishment
5 or a very small establishment, they might not have
6 any NRs in a 30 day time window. So I'm wondering if
7 it's more appropriate to tie this into production
8 volume as compared to 7 days, 14 days, 30 days,
9 something like that. Yes, sir.

10 MR. LEE: We have plants that are --
11 Charles Lee with Cargill. Processing plants, huge,
12 small, I can tell you that it has absolutely zero to
13 do with how many NRs you get. So to try to tell you
14 volume is going to be a predictor, I can't see it.
15 We've got a plant that gets 20 NRs a week. So they
16 get 20 NRs a week. We've got a plant that gets 1 a
17 month because that's just how they operate between
18 the USDA and the plants, that works. So it might
19 make more sense to look at an individual plant and
20 say, well, what's one's role for this plant, or maybe
21 even this district, I'm not sure, and if they're
22 operating under normal parameters, then fine and we

1 may be looking at a three month window. I'm with
2 Joe's point, I don't know how far we go back.

3 DR. DICKSON: Right.

4 MR. LEE: But volume by itself just doesn't
5 get it because it's just so variable by plant, part
6 of the country to part of the country.

7 DR. DICKSON: Okay. Thoughts on that,
8 follow up comments, anything anybody would like to
9 add to that? And I'm not trying to put words in your
10 mouth, if I understand it correctly, a timeframe is
11 probably more important than production volume.

12 MR. LEE: I think so, and I think that also
13 what's normal for that plant. I mean if over a
14 three-month period they normally get five NRs, and
15 all of a sudden they've gotten eight, there may be
16 good in three-month windows if you start seeing
17 trends.

18 DR. DICKSON: And again, comments from you
19 gentlemen here, anything that -- Stan.

20 MR. PAINTER: Yeah, Stan Painter with the
21 National Joint Council. The 30-day time window is
22 extremely short. You know, personally I wouldn't

1 consider anything less than a year, and, you know,
2 I've been in plants that were huge and that, you
3 know, you go through those plants and, you know, you
4 -- a product contact and, you know, your fully cooked
5 product and everything was acceptable, and then you
6 go down the road, and there was a plant about the
7 size of a small mobile home and, you know, it just,
8 it just isn't the same, you know, and a lot of it,
9 it's according to the commitment and the
10 understanding by the plant of the HACCP process and
11 how it should work.

12 DR. DICKSON: Okay.

13 DR. MURINDA: Shelton Murinda. I'm still
14 in agreement with Stan with regard to an extended
15 timeframe for those initial analyses. After you get
16 that new data initially, you might find that there is
17 a certain timeframe that's adequate for that
18 particular establishment which could be 30 days or
19 even less.

20 DR. DICKSON: So if we -- Jim Dickson here.
21 If we are to go back to them with a comment or
22 comments or recommendations on this one, if I'm

1 summarizing what I'm hearing, because of the
2 variation that we see from establishment to
3 establishment, FSIS probably needs to evaluate this
4 on at least a regional basis. Does that sound
5 reasonable? And then the immediate question that
6 comes up is if you've got a plant in Pennsylvania and
7 a plant in Arizona and the time windows are
8 different, how do you deal with that argument?

9 Thoughts or comments? I see people shaking
10 their heads.

11 MR. COVINGTON: Brian Covington. If you're
12 going to -- if we're going to go down that route,
13 we've also got to include the seasonality because
14 different problems for those of us with plants in the
15 deep south where it's 95 and above in the summer, you
16 know, condensation is a much larger issue, and you
17 have different issues that pop up throughout the year
18 that may be in certain parts of the country. So I
19 think it's also not just regionality but seasonality
20 because weather will have an influence on a lot of
21 the factors affecting the process.

22 DR. DICKSON: Back to the original

1 question. What time window would the Committee
2 propose or what criteria should be considered in
3 establishing the time window?

4 DR. MURINDA: Shelton Murinda. The
5 timeframe has been answered. It's talking about
6 seasonality which is taking the whole -- summer or
7 winter, spring, whatever, and I think we are all in
8 agreement -- that we need to extend the timeframe way
9 beyond 30. That would incorporate the differences in
10 seasons. I don't know whether we can -- regional
11 differences in climate, like this time of the year,
12 we are in winter, but in California we are in summer.
13 There's those differences that need to be
14 incorporated into the algorithm.

15 DR. DICKSON: Okay. Brian.

16 MR. COVINGTON: Brian Covington. Let me
17 just clarify if I may. I'm not advocating a year.
18 I'm probably like Joe. I don't know what the
19 appropriate timeframe is but all I'm suggesting is
20 that every month of every -- of the year we have
21 weather changes that affect the activities of every
22 plant and somehow, I don't know how you divide that

1 timeframe up, but that factor has to be included in
2 this window.

3 DR. BRATCHER: Well, you also have to have
4 seasonal products. Chris Bratcher, NAFV. You have
5 seasonal products, too, which are impacted
6 tremendously as well. Maybe what you need is some
7 kind of a proportional where you have a 30-day window
8 in comparison with yearly data and previous monthly
9 data. So if you look at it, you're looking at this
10 month versus a year ago this month, as well as for
11 the whole year, and then you do some kind of
12 proportional comparison to those. That's the only
13 way I know that you could do it.

14 DR. HENRY: This is Craig Henry, GMA. Just
15 going back, and I think we're certainly chasing this
16 around the barn again, there's so many things that
17 are going to happen when they start running the PHIS
18 system. We've got more unknowns than we have knowns
19 right now in my opinion. First off, at least in the
20 slide set it says the algorithm is going to be run
21 monthly, and if we're going to use this as a triage
22 for LO 1, 2 and 3, I think you're going to have to

1 just put a stake in the ground and there's got to be
2 some test calculations run. You've got to find out
3 what is the output from the system when it runs and
4 whether we pick 30 days or we pick 60 days or we pick
5 6 months, I guarantee you there's a variability
6 within all of those selections, depending upon the
7 plant, the product type, the time of the years, the
8 location in the country. There's just inherent
9 variability that's going to be there, and what's
10 going to suit some isn't going to suit others. So my
11 recommendation is let's get all the data gaps filled
12 in, and I think the Agency needs to run the
13 algorithm, run this system, because this is, you
14 know, it's not clear-cut. It's a triage tied to an
15 algorithm that is further subdivided down into the
16 level of inspection, too, and until you get to see
17 what the data is actually telling you, because why
18 are we running it?

19 The only reason the Agency's running it is
20 to decide where the inspector's resources are
21 supposed to go ultimately. Is that not right? I
22 mean we're really looking for major shift of people

1 between LO 1, LO 2 if you will, that's the FSAs that
2 are going to be done with LO 3. So until you run it,
3 I don't see how you can make a determination what the
4 impact of one selection of a NR or another is going
5 to be.

6 DR. DICKSON: The comment -- go ahead.

7 MR. SMITH: This is Bill Smith, FSIS.
8 We're not looking to have a major shift of in plant
9 inspection personnel. So if we didn't make that
10 clear this morning, we're making that clear now.
11 What we will do, what they do plan to change, is not
12 going to be two people here and a half a person
13 there.

14 DR. HENRY: Yeah, this is Craig Henry. Not
15 to cobble that up, but the point is, something's
16 going to change as a result of the calculation, be it
17 the number of tests run, be it where you send the
18 EIAOs. Something has to change based on the
19 frequency of the calculation, and right now because
20 of the way the NRs are figured into it, that's
21 another variable that we don't know. I think that
22 certainly until something else comes up, the

1 statistics from Carnegie Mellon stand as they are.
2 You take the 66 citations, you put them in the system
3 and you see how the plants fall, and then we go to
4 the next level of analysis.

5 DR. DICKSON: Comments over here.

6 DR. CATLIN: A couple of things to clarify.
7 Dr. Henry started to clarify --

8 DR. DICKSON: Michelle --

9 DR. CATLIN: Michelle Catlin, FSIS. You
10 know me. There are -- I don't want people getting
11 confused by the time window because there's first of
12 all how frequently you would run the algorithm which,
13 you know, you could run it monthly, you could run it
14 daily, and you have to look at how fast you can
15 actually responded to the algorithm that you're
16 getting. And then there's what time period that you
17 want to look back on. Do you want to look back for
18 the past 30 months, the past week, the past 6 months?
19 So that's sort of what the question is, but
20 regardless of how long that look back is, you can
21 still be running the algorithm on a given period.
22 And you actually alluded to that a little bit in your

1 response, Dr. Henry.

2 DR. HENRY: This is Craig Henry. Let me
3 ask a question in response to what Michelle just
4 said. Is there any reason why you would not vary
5 that depending on what you're getting? In other
6 words, you can run -- you can say it's 30 days.
7 Thirty days may not be the right window. For
8 example, let's say we got 20 plants that you look at
9 the 30-day window, and all of them on the average
10 only have 5 NRs. But if you went back and looked at
11 a 90-day window, all of a sudden you come up with 25
12 or 30 NRs. Is that not the better window to do the
13 analysis of where those plants should fall between LO
14 1, 2 and 3?

15 DR. MACZKA: I just want to say that we are
16 actually running --

17 DR. DICKSON: Please.

18 DR. MACZKA: This is Carol Maczka. We are
19 actually applying the algorithm to a set of data now,
20 and Dr. Curtis Travis said that. We don't have the
21 results yet but it will be applied. And your other
22 point is well taken which is that you should look

1 historically how plants match up to each other, how
2 they are relative to each other -- cut point to
3 change, depending on how the plants are -- with one
4 another.

5 DR. CATLIN: One more thing. Dr. Michelle
6 Catlin. If you look in the poultry slaughter, the
7 place I can find it quickest, on page 27, you do see
8 where we have started to run the algorithm based on
9 current data for those parameters, which is the
10 majority of the criteria that is listed. Based on
11 those parameters, to see how plants would fallout,
12 and one thing, if you look at -- for public health,
13 you'll see that they're on the fifth quintile. So
14 that would be -- you're getting rates of between 2.89
15 and 13.4 percent and are using a 30 days window. So
16 you can look at the data. Even with the data we have
17 currently, you can look and see how the distribution
18 fall out and things like that, and that, as Carol
19 mentioned, Curtis Travis is doing that, is doing more
20 of that for different types of plants.

21 DR. DICKSON: Stan, did you have a comment?

22 MR. PAINTER: Yes. Stan Painter with the

1 National Joint Council. You know, normally I would
2 not say that there would need to be a time window set
3 but I'm of the opinion in this case, if the group
4 don't decide to do a minimum and we come up with no
5 recommendation or the group doesn't come up with a
6 recommendation, then that's free reign to do
7 whatever, and I totally disagree with what Carol
8 Maczka just said, you have to, you know, you're
9 comparing one plant to the other. You know, you may
10 have one plant that's producing -- throwing whole
11 chickens in a combo to go somewhere else, and then at
12 that other location, they're actually deboning and
13 grinding and mixing and blending and cooking and
14 things of that nature. So I don't, I don't think
15 that we need to put everything into one basket.

16 DR. DICKSON: Do we have other comments on
17 this? We've thrown out a number of ideas here.
18 Other comments on the time window? We talked about
19 criteria, time. We talked about seasonality.
20 Dr. Henry said we just need to start somewhere.
21 Other thoughts or comments about this? Anything
22 anyone would like to add? I'm sorry. You folks, I

1 had my back to you. I apologize. Yes, ma'am.

2 MS. BUCK: This is Pat Buck from Center for
3 Foodborne Illness, Research and Prevention. As a
4 question, these windows, would they have anything to
5 do or is it part of the plan to have performance
6 standards and the amount of testing, would that play
7 a role in determining the size of the window that we
8 should be using?

9 DR. DICKSON: My understanding, Jim Dickson
10 here, is that this is simply -- the question that
11 we've been asked is what is the time window for
12 looking at noncompliance reports in the algorithm.
13 So this is a component of the overall algorithm, and
14 if I'm misstating anything, somebody from FSIS jump
15 in. So we're focused solely on this time window for
16 NRs.

17 MS. BUCK: Yeah, but I think there's many
18 variables to which time window you would pick, and I
19 would think one of the things that might be looked at
20 is the amount of microbial testing that was being
21 done and the type of product that was being produced
22 and the seasonality. So I think that this may be why

1 you want very desperately to have that time window to
2 establish. I think that maybe we need to, you know,
3 do more investigation as to what factors should be
4 considered in selecting a timeframe.

5 DR. DICKSON: This is Jim Dickson here.
6 Again, the conceptual approach while we're looking at
7 establishment public health risk ranking and again
8 this is slide 5 in Dr. Travis' presentation, across
9 establishment ranking concept. The public health
10 ranking contains a magnitude component which is the
11 volume in comparison to national volume. The public
12 health attribution which we talked about. This is
13 really the second part of the hazard. So we've got a
14 magnitude component, a hazard component. The NRs
15 come under the first part of that calculation of
16 hazard. Measurements over time, verification, health
17 based NRs, all of that gets lumped together in there,
18 and this is just, this is just one component of that,
19 of that --

20 MS. BUCK: I wasn't here this morning.

21 DR. DICKSON: That's fine. Thank you.

22 Dr. Maczka.

1 DR. MACZKA: Just one more thing maybe that
2 you might want to consider, instead of a timeframe,
3 you might want to consider like a number of
4 observations. That might be -- maybe sort of what
5 you were alluding to. Instead of looking at 30 days,
6 60 days, maybe how many, you know, a certain number
7 of observations.

8 DR. HENRY: This is Craig Henry, GMA. I
9 think almost we come back to the question 1 in part,
10 and this is a little bit about what Stan was saying.
11 Again, I'll have to go back to my recommendation you
12 put a stake in the ground and we'll say 30 days for
13 the sake of argument or 60. We can take a vote on
14 that, but I think it comes back to the gray zone,
15 Stan, because I mean let's look at this. You know,
16 the computer's going to do the calculation and
17 somebody at some office, Chris or somebody, is going
18 to get a report saying, guess what? Here's what it
19 just tells me I'm supposed to go do. Now I guarantee
20 we're all pretty good at second guessing any system,
21 and if it was me, I'm going to guess that Chris is
22 going to look at it, and he's going to say, okay,

1 this is what I'm supposed to do with my 40 plants,
2 and somewhere he's probably going to say, you know,
3 these five over here, they want me to go over and
4 leave them a LO 1 or LO 2, it doesn't make sense to
5 me. I mean there's got to be an analysis of some
6 other documentation, and I'm not sure what that is.
7 I don't know where the Agency is capturing that
8 information because right now it seems like it's kind
9 of push button allocation and resources wherever they
10 may be, you know, using the algorithm. I mean, we're
11 putting the data in. It's going to churn something
12 back out, but there does get to be an issue such as
13 do I have enough data points? Does this make sense,
14 et cetera, et cetera, relative to what we're doing?

15 DR. DICKSON: I'm not sure who was first.
16 Michael.

17 MR. KOWALCYK: Michael Kowalcyk. I think
18 Craig raises a good point, and I think it's related
19 to broader question of the whole algorithm itself,
20 and the verification of the algorithm, before this is
21 actually put into practice, I would strongly
22 encourage or actually recommend the Agency to do that

1 type of trial test to verify is the algorithm
2 predictive of risk, not ordering plants, but is it
3 truly predictive of risk, and determining what are
4 you trying to predict? Are you trying to predict a
5 positive test result if that's your end result, and
6 that needs to be clearly defined and I think we've
7 gone through a lot of meetings with the Agency in
8 this Committee trying to nail down exactly what that
9 dependent variable is. And I think until we get
10 there, I myself personally, I'm going to struggle
11 with making a recommendation that I think would stand
12 on its own merits, but I think as a Committee we
13 would struggle about how to direct the Agency with
14 having that. That's a pretty big piece of puzzle
15 missing.

16 To the point about the application of the
17 NRs, I think people made some very good points about
18 really trying to get an understanding, if this is
19 truly a representative sample of NRs and
20 representative sample of plants across a long time
21 period because there are things such as regional,
22 seasonal variations of what's being processed,

1 there's variation.

2 The age of a plant may correlate with the
3 type of NR that they get because of just the layout
4 of the plant. These are other questions that all
5 feed into what could lead to an adverse outcome, be
6 it a positive result.

7 So I would strongly recommend that the
8 Agency, in addition to the Carnegie Mellon study, to
9 continue to make sure that this is representative of
10 what is exactly happening out in the marketplace, and
11 if it's reflective of all the plants you would apply
12 this new system to, and then as the algorithm is
13 developed, then exactly what Craig said, before
14 anything happens, test it and see what the system
15 would recommend doing and compare that against what
16 management and the front-line personnel would do --
17 see what you are changing because this is probably
18 for another Committee meeting but resource neutral is
19 a term that comes up in several of the reports, and
20 it's been discussed about shifting people around but
21 then it said that, well, you're just going to shift
22 what people are doing in the plant.

1 Well, I can tell you that taking an
2 inspector who's doing something and putting them on
3 another task, be it downloading forms or updating
4 forms, there is an opportunity cost to that because
5 that same inspector, you're actually down resourcing
6 another part of a plant, and I compliment the Agency
7 on looking to allocate the resources more efficiently
8 but I think that cost sometimes is forgotten and if
9 it is to be resource neutral, we need to get a better
10 understanding as to how you would ultimately segment
11 the regulated facilities.

12 How many plants could you increase
13 inspection activity on? Is it 5 out of 100? Is it
14 20 out of 100? I'm not sure I know the answer to
15 that. So I think that's where a lot of us are
16 struggling here and seeing until something comes out
17 and then go through that process to understand what
18 changes you would recommend to your current
19 management system.

20 DR. DICKSON: Okay. Stan, did you have a
21 comment?

22 MR. PAINTER: I did. Stan Painter, with

1 the National Joint Council. If I understood
2 Dr. Maczka correctly, her proposal was or her
3 suggestion was, was the number of visits, and if that
4 was her suggestion, I'm not in favor of that either,
5 because as an inspector, I've been told, you know,
6 when I had seven or eight locations to visit, go
7 through the front door, wave at them as you go
8 through, and go out the back door. And that's --
9 that in my opinion is not adequate inspection. All
10 that's doing is saying, I've been there, I left a
11 footprint in the water as I went through the
12 building.

13 DR. DICKSON: Chris Bratcher.

14 DR. BRATCHER: I wouldn't let him get by
15 with that. But I think -- Chris Bratcher. I think
16 what we're saying here is there are too many
17 variables for this new tool for any of us to make a
18 determination at this point. I mean we've discussed
19 all of them, even the inspectors in the plant
20 apparently is a variable that plays into this.

21 So from my standpoint, I want some new
22 tools that will allow me to do my job better and to

1 allocate my resources and my people's time to do that
2 job. And I think this is a good idea but until I see
3 that and can work with it and see if it's really on
4 target or not, and can manipulate it to do what we
5 need it to do, I don't think we can make a decision
6 on a window. I don't think we can make any decisions
7 on this until we've let it run and see how it works.

8 DR. DICKSON: Okay. Jim Dickson here.
9 Just -- go ahead.

10 MR. RICE: I --

11 DR. DICKSON: If you would identify
12 yourself.

13 MR. RICE: John Rice, Sanders Farms. I
14 think in order to look at differences seasonally and
15 also to get a picture of what's going on, along the
16 time period such as a year, would be more -- and
17 you've also got to look within that year to see what
18 the trends are, whether NRs have been increasing or
19 decreasing. And we also have a tool which should be
20 used by all plants now where you can go and look at
21 the record and see what percent of tasks or different
22 categories were failed by what. So this is already

1 out there and this should be part of what's looked
2 at.

3 DR. DICKSON: And Jim Dickson here. The
4 one thing I did want to go back to is in the original
5 conceptual approach, this component, the NRs and the
6 verification testing, as I understand it, is intended
7 to reflect the day-to-day operation of the plant. Is
8 that essentially correct? We have the volume,
9 production volume, public health attribution, then we
10 have the events if you will, the episodic measures.
11 This component is to really measure the day-to-day
12 operation of the establishment.

13 So just a general question here as we're
14 kind of transitioning from question 2 to question 3,
15 is there anything else that would capture day-to-day,
16 week-to-week, month-to-month operations within the
17 establishment outside of verification testing,
18 outside of NRs? Is there anything else that should
19 be incorporated into this that is currently not being
20 incorporated into this? Is there some piece we're
21 missing? Yes, ma'am.

22 MS. BUCK: This is Pat Buck from CFI. And

1 I may not be answering your question appropriately
2 and if I am not, I apologize, but I have thought long
3 and hard about that, just what you're talking about,
4 because what it basically is, is accountability.
5 What are we going to have when the inspectors are not
6 there? As soon as they leave, who knows what's going
7 to happen, and in many cases, you can have a very
8 good plant that over time has done an excellent job
9 and then all of a sudden, there is a catastrophe that
10 strikes, even when you are dedicated to -- practices.

11 So one of the things that I would like to
12 see, and I don't know again if this is appropriate,
13 but I think FSIS as well as FDA should work towards
14 having some kind of trace back accountability system
15 so that that would be an underlying issue that could
16 be worked in with this new protocol. But you have to
17 ask for it.

18 DR. DICKSON: Okay. Other comments here?
19 Is there anything that we are missing? Is there
20 anything and this could be from FSIS, it could be
21 from industry, it could be from the general public,
22 is there any component, and again trying to focus

1 very specifically on day-to-day establishment
2 operations, is there any component that needs to be
3 included that is not being discussed right now? Is
4 there something we're missing? Sir.

5 DR. SHAW: Dr. William Shaw from Food
6 Safety and Inspection Service. Actually one of the
7 things that you should in -- within our new system,
8 things such as regulations that are verified while a
9 procedure is being done, not just those that are not
10 compliant, but those that was verified during the
11 procedure. This is the more -- and you would also
12 want to consider affirmative findings during the
13 procedure, not just the not compliant findings.

14 DR. DICKSON: Michael.

15 MR. KOWALCYK: This is Michael Kowalcyk.
16 Is that information currently captured in existing
17 systems --

18 DR. SHAW: No.

19 MR. KOWALCYK: -- where the Agency can go
20 back and review?

21 DR. SHAW: No, it's one of the things that
22 we are looking in, in the design of our new system is

1 that right now in our present system, you know a
2 procedure was done, you know it wasn't done, and you
3 know if a NR was written, you know that it was not
4 complaint or something. You don't know what
5 regulation -- the system does not let you know what
6 regulations were verified during that procedure and
7 you don't know what, of those regulations that were
8 verified, which ones were actually compliant. You
9 just know the ones that weren't, that were not
10 compliant.

11 MR. KOWALCYK: How reliable is that system
12 currently? Is the data in there trusted by the
13 Agency or is it -- I mean has it been vetted from a
14 QA perspective?

15 DR. SHAW: Well, I mean since you only have
16 three pieces of information, I mean it's not, it's
17 not very complicated.

18 MR. KOWALCYK: Well, I've seen very
19 simple --

20 MR. PAINTER: He keeps looking at you --

21 DR. SHAW: What was the comment?

22 MR. PAINTER: Stan Painter with the

1 National Joint Council. I turned around to look at
2 Bill and I was waiting for his comment because it
3 seemed like you were waiting for an answer from him.
4 You kept looking to Bill, so I turned to Bill to get
5 a response.

6 DR. SHAW: I mean I think we are -- to tell
7 you that procedures are being done. I mean we have a
8 whole assurance in that system that's managing
9 whether the procedures are being done and knowing
10 ones that aren't being done and we are constantly
11 reviewing our noncompliance reports and there is an
12 appeal process for a noncompliance report. So if
13 they are inaccurate, the plants have the ability to
14 appeal them. So I mean I think we are confident in
15 those three pieces of information. We would like to
16 have more information.

17 DR. DICKSON: Yes.

18 MR. SMITH: Bill Smith. In today's system,
19 I mean I don't think there's any doubt about
20 regulatory references, may or may not be right, and
21 yet we don't have, we understand not all regs may be
22 written up in the NR as today. In the new system,

1 that will be captured and we do have confidence that
2 it will be triggered, so when a procedure is done,
3 those references will pop up, it will be triggered
4 and it will be clarified. So, yes, you're right.
5 What Bill said was right about the information going
6 in, except on the text on the NRS itself. The
7 regulatory cites, you know, we know we need
8 improvement and we said that ourselves. We found
9 that in the SMR audit. We found it in several. And
10 that is something that is being built into the system
11 now. You might want to explain how it works a little
12 bit.

13 MS. JEFFERSON: I --

14 DR. DICKSON: You have to identify
15 yourself.

16 MS. JEFFERSON: Val Jefferson. I'm sorry.

17 MR. SMITH: How the cites will be available
18 to the inspector when --

19 MS. JEFFERSON: When they're documented,
20 the actual activity that they perform, they'll
21 identify the actual -- say, for example, it's a HACCP
22 procedure, they'll identify that critical control

1 point, where it corrects the program, that they
2 perform an inspection on, and it will actually
3 document the regs, the regulatory citations like the
4 417s, what they actually verify and of those regs
5 they verify, they'll identify the ones that are not
6 compliant. Now if there was an all compliant
7 situation, then they'll also document, they affirm
8 the --

9 DR. DICKSON: Dr. Bratcher.

10 DR. BRATCHER: Chris Bratcher, NAFV. The
11 thing that I would like to see that you would add to
12 the system is that the example Stanley gave earlier,
13 where he went through the front door and went out the
14 back door, what I find some of my inspectors will do
15 is that they'll say, okay, I don't have enough time
16 to do anything but perhaps a record review, and so
17 they review what documentation was present that day,
18 and when I go in and check to follow up on that, I
19 find the last 10 times they've had that task, all
20 they've done is records.

21 MS. JEFFERSON: The system will also
22 capture the component --

1 DR. BRATCHER: Okay. That's what I want to
2 see.

3 MS. JEFFERSON: Yes.

4 DR. BRATCHER: If they do an observation,
5 did they do the other components of that task and did
6 they do it randomly.

7 MS. JEFFERSON: Yes, the system will have
8 the ability to say, hey, you've done record review
9 five times.

10 DR. BRATCHER: Right, and if they did,
11 let's say, for example, if they had an O2 task, and
12 they didn't have time to do it today, let them do it
13 tomorrow when they've got time and do an adequate O2
14 review rather than just, you know, doing it
15 haphazardly.

16 MS. JEFFERSON: Right. Also there's the
17 ability and flexibility for them to actually schedule
18 those procedures themselves. If it's currently an
19 existing system, it's scheduled for one day. If they
20 performed it, if not, they have to say not performed,
21 but again we would like to -- we're going to build in
22 that flexibility where if they don't have the time to

1 perform it or if they don't have the time to complete
2 it, they'll document all those activities that have
3 taken place up until that point and then they deal
4 with it the next day or the day after, and then pick
5 up that documentation process. So we'll get the
6 documentation throughout when they start up until
7 completion, and also the component, record review
8 or --

9 DR. SHAW: And then what goes to your point
10 is that I'm sure you are familiar with the current
11 FRSE system --

12 DR. BRATCHER: Right.

13 DR. SHAW: -- the way that our inspectors
14 are taught, the thought process and in this decision
15 I choose this, this component, I choose this CCP.
16 You go through this thought process. Our system now
17 does not collect that, the thought process, how they
18 went about doing that procedure. We will now be
19 collecting what were the decisions made along that
20 way in that procedure, not just the end point. What
21 were you making your decisions upon all through that
22 procedure and you know as well -- you know about the

1 FRSE recess, that they have to make sure -- because
2 they can't do everything to keep -- and we want to
3 know what choices were made when you make this
4 decision.

5 DR. BRATCHER: Chris Bratcher again. And
6 the only way to capture that now is in the interviews
7 and that's something that's almost impossible to go
8 back and pull out.

9 DR. SHAW: But that's periodic. It's not
10 the same process.

11 DR. BRATCHER: Right.

12 DR. SHAW: It's not the standard.

13 DR. BRATCHER: Exactly. So that would be a
14 lot better tool than what we've got now.

15 DR. SHAW: We hope so.

16 DR. DICKSON: I'm sorry. Ms. Nestor.

17 MS. NESTOR: Felicia Nestor, Food and Water
18 Watch. I'm really happy that the Agency is going to
19 go into more detail because it was just so much that
20 was under the radar, you just couldn't determine
21 anything at all. One thing that I would like, you
22 know, you keep asking, what have we forgotten? What

1 have we left out? Again, in talking to inspectors, I
2 would like to see some how recorded when they didn't
3 write an NR because their supervisor told them not
4 to. When they recorded the procedure that was as
5 performed when it was not performed. I mean many
6 inspectors tell me when I tell my supervisor I didn't
7 do this procedure because I didn't have the time,
8 they tell me that is not an adequate answer. That's
9 not sufficient.

10 The other thing is it sounds like what
11 you're saying is going to happen, the O2 procedures
12 is going to have to do the review from the beginning
13 of the HACCP process to the end. Is that correct?
14 They have to check every CCP along the line.

15 MS. JEFFERSON: All --

16 MS. NESTOR: Right. And as far as I know
17 right now, inspectors in practice are recording the
18 task as performed if they do even one of those
19 things. So I'm hoping that your new system will
20 capture all those. They will have to document that
21 they did every single one of those things along the
22 way.

1 DR. SHAW: We recognize that there are
2 positive --

3 DR. DICKSON: Please identify.

4 DR. SHAW: Bill Shaw. Sorry. We recognize
5 that, that there are processes, that there are
6 products being produced that may take two to three
7 months from the beginning to end, and we recognize
8 that these are --

9 DR. DICKSON: Yes, ma'am.

10 MS. BUCK: This is Pat Buck, CFI again. I
11 really like, Felicia, I like what you're talking
12 about with AssuranceNet and I have read it. One
13 thing, of course, we talk about is we don't have
14 enough data yet to make it as robust as you want, but
15 the other thing that's missing, we don't have enough
16 inspectors, and when FSIS, when they're thinking
17 about putting this new system in place, it's going to
18 rely on this kind of a detail, that's going to give
19 us the type of information that we need to assure
20 products are really, you know, inspected at a level
21 with the confidence that the American people want,
22 you're going to have to address the fact that you

1 don't have enough inspectors, you don't have enough
2 veterinarians.

3 DR. BRATCHER: One thing I'd like to be
4 able to add to the system --

5 DR. DICKSON: Chris Bratcher.

6 DR. BRATCHER: Chris Bratcher -- to the
7 system we have in place now, and in some cases we've
8 been allowed to do that but if a facility, an
9 establishment decides that they're going to change
10 their process or they're going to do something
11 different in that facility, they may have a new HACCP
12 plan, a new process, new supporting documentation, a
13 lot of different things, and I would like to be able
14 to utilize a Ph.D. that was EIAO trained to go in and
15 just look at the hazard analysis and supporting
16 documentation in a risk assessment, not do a complete
17 FSA but just to go in and use those people to make
18 sure that the inspector that's in that facility
19 doesn't get caught off guard somewhere down the road
20 when they're operating with an inadequate HACCP plan.
21 And, you know, I can't be there 100 percent of the
22 time, and if I could utilize people that have that

1 knowledge and resource, it would greatly help me and
2 I think it would help the inspection team in that
3 facility.

4 DR. DICKSON: Jim Dickson. I think
5 probably everybody in this room and probably the FSIS
6 personnel most of all would agree it would be nice to
7 have more people. I don't think we would generate
8 much of an argument on that subject right now.
9 Unfortunately that's not one of our questions. So --

10 MS. BUCK: I differ from -- Pat Buck.

11 DR. DICKSON: Thank you.

12 MS. BUCK: It's not that it wouldn't be
13 nice to have more people or more inspectors, but
14 that's not the point. It is necessary if we are
15 going to provide the level of inspection that the
16 American people are counting on their Government to
17 deliver. It's not nice. It's necessary.

18 DR. DICKSON: Okay. Any --

19 MR. SMITH: I just want to add one thing
20 here. Bill Smith.

21 DR. DICKSON: Thank you.

22 MR. SMITH: We do need to, you know, take

1 all that into serious consideration about resources.
2 One of the things that this system though, you did
3 see and you're seeing in 0157:H7, while it may not be
4 perfect or less than perfect, it was a major move
5 from just the static that we had to date on the
6 0157:H7, the checklist. And so every plant will have
7 a profile. Every plant's interventions will be in
8 there. So any change to that will trigger the
9 system. You may not need a person, if the system, if
10 the inspector didn't document that something is
11 changed, the system will flag it and knows. So I
12 understand what you're saying but we're trying to get
13 a little bit better at it, the system doing the data
14 analysis, we don't always need the capability, the
15 system can do it, and then target your resources what
16 you do have to make a public health effect. And so
17 that's something this system is bringing to the
18 table.

19 MS. BUCK: Pat Buck again. What I think is
20 very, very important, you need people to put that
21 data into the system so the system can analyze for
22 you what the flags are, and you do not have enough

1 people. You need more people, and you need a
2 mandatory trace back system, so that when you're not
3 there, there will be some accountability worked into
4 the system.

5 DR. DICKSON: Thank you.

6 DR. BRATCHER: Chris Bratcher again. Bill,
7 would that allow them to -- if there were things that
8 they felt that generated a no answer, would that
9 generate that in a FSA or could we just have someone
10 go in and take a look at their system?

11 MR. SMITH: Well, let the expert, Dr. Shaw
12 answer that.

13 DR. SHAW: Okay. William Shaw. So the
14 plant, okay, the plan in the new system is that, you
15 know, the profile will be gathering a lot of the
16 information regarding the plant's practices, like,
17 you know, the aspects of their HACCP plan and their
18 individual procedures. Then there will be certain
19 things that when they change, and the inspector
20 updates that profile, there will be certain pieces
21 that we deem critical that will then, okay, the
22 front-line supervisor, once that change happens, the

1 front-line supervisor will be alerted to that, and
2 then you would hope that the front-line supervisor
3 and the IIC would have a discussion as to, okay, so
4 ownership has changed. They have created a whole new
5 HACCP plan. They have dropped the CCP now that they
6 once had before. Then that conversation should
7 happen and say, do we need a FSA, do we need an EIAO
8 to come in? Is this -- and so that conversation
9 happened and they do deem that you do need an EIAO to
10 come in, that it moves up to the district level and
11 needs the case specialist to say, you know, send out
12 an EIAO to review that process. Do you need a whole
13 FSA? You do not. And right now we don't have a
14 system in place that allows for that conversation and
15 that information to transfer from one person to
16 another. We don't have a system that does that. We
17 have phones.

18 DR. DICKSON: Dr. Grondahl, do you have a
19 comment?

20 DR. GRONDAHL: It's going onto something
21 different than this conversation.

22 DR. DICKSON: Michael, did you have one?

1 MR. KOWALCYK: Yeah, just a follow up to
2 that. Michael Kowalcyk.

3 Is the system that -- is your concept that
4 it be a system where good examples, an ownership
5 changed, that will be a change to the profile of the
6 plant. Is your vision for this system to have a set
7 of triggers to automatically direct a certain task or
8 is it, having that information to allow people at the
9 field offices, let's say, okay, Joe's Packing Plant
10 has a change in ownership now, and that can be
11 communicated through that --

12 DR. SHAW: Bill Shaw. It's both of them
13 because one thing I will tell you, ownership is not
14 the only deciding factor. Ownership can change but
15 the HACCP plan that's used to produce that product
16 may not change. It's the HACCP plan change, the
17 change in their process, that dictate what we do.
18 That's the importance. That's the food safety.
19 That's the public health part. Just because it
20 changed ownership doesn't necessarily mean that they
21 changed their process. So when we're collecting
22 profile data and we have data on a HACCP plan that

1 makes their product, it's whether the HACCP plan
2 changes is the important part, to use along with the
3 ownership change. It's not only the ownership that
4 makes -- that solely impacts public health. It's
5 both.

6 DR. BRATCHER: Correct. I was actually
7 using that as an example, some change to the profile.

8 DR. SHAW: Well, we would use both of them.
9 One of the things is you can only put in so many
10 mandatory actions. Yes, there are higher levels
11 where there are mandatory actions, or we will have
12 certain things that will happen, but then there's a
13 secondary level where we are an agency of people and
14 people need to make decisions. We can capture their
15 decisions and why they make them but really people
16 still need to make decisions and we need supervisors
17 to help their subordinates and the subordinates to be
18 communicating with their supervisors and so you get
19 decisions made that use our resources to their best
20 effect. You know, -- a full number of, we're going
21 to do this, this, this, this and this, without having
22 people actually talk to each other. That's not a

1 full system either.

2 DR. DICKSON: Any other comments on this?
3 Dr. Grondahl?

4 DR. GRONDAHL: Andrea Grondahl. I have a
5 question for Chris or Stan. Under the current
6 system, is the plant's response to a NR currently
7 electronically captured?

8 MR. PAINTER: Stan. No.

9 DR. GRONDAHL: I didn't think so and that's
10 one thing I would like to see added to this system
11 and maybe as a consideration to answering number 3,
12 going back to the variability of inspectors, if you
13 have a ambitious inspector at a good plant and a less
14 ambitious inspector at a bad plant, sometimes the
15 only way to sort that out is to look at the plant's
16 response, and how diligent they are in trying to
17 correct any noncompliances.

18 DR. DICKSON: Joe.

19 DR. HARRIS: Joe Harris. Just to clarify,
20 the inspectors already verify whether or not the
21 plant did follow through with the appropriate
22 corrective action relative to restoring a condition

1 of compliance, whether it is sanitation or whatever.
2 Currently plants aren't even required to respond in
3 writing, either electronically or any other way.
4 They are required to correct the noncompliance.
5 They're not required to actually write a response.

6 DR. HENRY: And Craig Henry. That said, in
7 virtually every plant, virtually every inspector,
8 every inspector looks for response within 24 hours
9 period, end of story, or written response. Even
10 that's the unwritten rule, too. So, you know, it's a
11 little bit of both.

12 DR. GRONDAHL: Just a final comment on
13 that, Andrea Grondahl again. You know, that's one
14 component that I think may be something added into
15 the electronic system if a plant responded, if they
16 did not, and if so, what was the response, either
17 written or just an action.

18 MS. JEFFERSON: Val Jefferson with FSIS.
19 With the new system not incorporating that option to
20 be able to enter that information, the plant response
21 to a NR, we won't be able to capture that information
22 on a --

1 DR. DICKSON: Thank you. Stan.

2 MR. PAINTER: Stan Painter with the
3 National Joint Council. Currently as was said
4 earlier, the plant doesn't have to give a response in
5 writing, but if they give us a verbal response, then
6 we're required to document on the NR the plant's
7 response, and we do so, and certainly to enter that
8 into some kind of data system would certainly help
9 and as I mentioned earlier, when you got the pretty
10 much boiler plate answer, when there was personnel
11 involved, retrain the team member, it would certainly
12 show that but, you know, we need to keep in mind of
13 something that I brought up earlier, and that is, you
14 know, we're spending a ton of time behind the
15 computer. We're downloading things that sometimes
16 take 8 and 10 hours to download when we're not in the
17 plant, you know. You're on an e-mail system that's,
18 you know, the plants have e-mail systems of their
19 own, and they're on just like that and we're trying
20 to dial up and whatever, and if you're in a
21 processing facility, and let's say that you have four
22 places to cover, then you have to go to that location

1 and set your computer up at every location and log on
2 at every location, and it's cumbersome. It takes a
3 lot of time in order to do so, and having that
4 information is good but it certainly takes away a lot
5 of inspection time.

6 DR. DICKSON: Okay. Yes, Brian.

7 MR. COVINGTON: Brian Covington. Just a
8 point to add to that. If those components are going
9 to be part of the new system and capture all of that,
10 I would request that the system has the flexibility
11 to capture all components of a NR because a lot of
12 times if there's disagreement on the actual
13 regulatory citing or some of the verbiage that's
14 captured verbally between the inspector and the
15 plant, and portions of that may be removed and the NR
16 reissued, but I think all that needs to be
17 encompassed as part of the overall concept behind the
18 NR if it's going to be included in the system.

19 MS. JEFFERSON: Val Jefferson, FSIS. Are
20 you referring to like an appeals process of the
21 information captured?

22 MR. COVINGTON: In a written, a formal

1 appeal, yes, but a lot of times there are informal,
2 verbal conversations that ask for clarification of
3 language in the NR if it's written or if the
4 regulatory citing is going to be put on the NR, and a
5 lot of that happens just one-on-one in communication
6 and so that never gets captured on the actual written
7 documentation. The reasoning and the process behind
8 why things may have ended up on the NR may not be
9 what's actually documented or, you know, transcribed
10 in the original citing.

11 DR. BRATCHER: Chris Bratcher, NAFV. In
12 that same regard, even on the appeals process, we
13 need more room and more characters to be able to put
14 that information into the system because sometimes
15 it's so complex that you really can't explain or
16 describe what the issues are and what was removed and
17 what was retained in the NR.

18 DR. DICKSON: Okay. We're going to move to
19 the final question here and I'm not trying to
20 terminate any conversation but --

21 MR. TYNAN: I want to give you one hour of
22 warning.

1 DR. DICKSON: One hour of warning. We'll
2 be done.

3 MR. TYNAN: Okay. Great.

4 DR. DICKSON: And we're going to need a
5 break before we go back.

6 MR. TYNAN: There's cokes and some things
7 outside. So if anybody wants to kind of grab --

8 DR. DICKSON: We have a long break before
9 we go back.

10 MR. TYNAN: Quarter to 4:00.

11 DR. DICKSON: Yes, sir.

12 MR. TYNAN: Excellent.

13 DR. DICKSON: Our last question, what other
14 recommendations does the Committee have regarding the
15 use of process control indicators included in the
16 algorithm for establishing levels of inspection?
17 Process control indicators. And perhaps I can call
18 on one of you two ladies over here to expand on
19 process control indicators.

20 DR. CATLIN: Michelle Catlin, FSIS. And if
21 you remember back from Curtis Travis' -- Dr. Travis'
22 presentation, to very popular slide number 5, where

1 he talked about the portion of risk that the hazards,
2 which are indicated in process control, and that's
3 where we're locating NRs as an indication of process
4 control in a facility. So how the indicators, how a
5 given facility has put controls in place to help the
6 food safety system be, you know, be operating at.

7 DR. MACZKA: And I can add to that.

8 DR. DICKSON: Dr. Maczka.

9 DR. MACZKA: Carol Maczka. -- level 1, 2
10 and 3, those were indicators of process control. So
11 you can look at those and see if there is anything
12 else you can add.

13 DR. HARRIS: So the issue really is levels
14 of process --

15 UNIDENTIFIED SPEAKER: Is the list of
16 those --

17 DR. MACZKA: Yes --

18 UNIDENTIFIED SPEAKER: -- that were
19 considered, is that a convenient place we can have
20 them all --

21 DR. MACZKA: Actually, they're over a
22 number of slides.

1 UNIDENTIFIED SPEAKER: Slide 10 I believe?

2 DR. MACZKA: Slide 10 and 11 are the ones
3 that get you into Level 3. I can give you sort of a
4 quick list that might help because what happens is
5 you're looking at Level 2 and 3 on 1 and the same
6 overlap. So your test results that would be for
7 0157:H7 in ground products and your *Lm, Salmonella*
8 and 0157 ready-to-eat products. So your FSIS
9 verification testing. *Salmonella* category, whether
10 or not you can link to a disease outbreak, whether or
11 not the establishment has sustained structural damage
12 due to a natural disaster. Yes.

13 MR. COVINGTON: Brian Covington. Just a
14 point of clarification. So an establishment,
15 *Salmonella* Category 3, are we just talking about
16 broiler establishments at this point?

17 DR. MACZKA: That would be -- I think
18 actually all of them -- it would be all of them
19 overall.

20 DR. HARRIS: Subject to *Salmonella*
21 performance standard.

22 DR. MACZKA: Yeah. The STEPS database.

1 STEPS database, that's the database that is those who
2 have been linked to a recall. And then enforcement
3 action which should be a misbranded product, NR
4 rates, and then there's *Salmonella* serotyping and --
5 presented. And also for the lower categories we look
6 at percent of the *Salmonella*. It's slightly
7 different than the *Salmonella* outbreak. They're on
8 slides 10 and 11 as I said before, Level 1 and slides
9 -- for Level 3, and slides 13, 14 and 15 for Level 1
10 to 2, and then they're ending Level 2 --

11 DR. DICKSON: Jim Dickson here. I want to
12 ask a question to those of you from FSIS in general.
13 I didn't see anything referencing the generic biotype
14 1, biotype 2 *E. coli* testing in any of this. Is that
15 part of this? Is that separate from this? Are we
16 not looking at the generic biotype 1 *E. coli*?

17 DR. CATLIN: Michelle Catlin, FSIS.
18 Currently generic *E. coli* is not listed as one of the
19 criteria between --

20 DR. MACZKA: But it is used as a prompt to
21 -- to make -- it is an indicator and prompt as a
22 control.

1 DR. DICKSON: So, again, thank you,
2 Dr. Maczka. Jim Dickson here. If an unusually high
3 level of biotype 1 *E. coli* was determined in routine
4 testing, then the response from the inspector would
5 be?

6 DR. MACZKA: To probably prompt the
7 inspector to move upstream to look at certain
8 vulnerable points and to answer those yes/no
9 questions. So that's what it would do.

10 DR. DICKSON: So would -- again Jim
11 Dickson. For clarification purposes, this would fall
12 into one of those directed activities. Is that
13 correct?

14 DR. MACZKA: Yes.

15 DR. DICKSON: Okay.

16 DR. CATLIN: This is Michelle Catlin.
17 You'll be hearing more about generic *E. coli*, and
18 what's under consideration for performance standards
19 tomorrow.

20 DR. DICKSON: Okay. Other process control
21 indicators or comments on the ones that are already
22 incorporated? Michael.

1 MR. KOWALCYK: Michael Kowalcyk. I have a
2 couple of questions about these slides. It's
3 discussed about upper percentiles and lower
4 percentiles and NR rates or scores on in plant
5 verification questions. With respect to these
6 percentiles, is the Agency still in the process of
7 determining what the appropriate percentile cutoff
8 would be?

9 DR. MACZKA: Yes.

10 DR. CATLIN: Yes.

11 MR. KOWALCYK: When is that analysis
12 scheduled to be completed?

13 DR. CATLIN: This is Michelle Catlin. As I
14 said before, we are currently looking at the
15 distribution of plants, you know, looking at
16 different cutoff points and looking at different time
17 windows and the percent of plants, you know, with the
18 percentile cutoffs, I think and other people can
19 contradict me or say something different, but part of
20 it has to be done based on public health and then
21 part of it also that our resources would have to be
22 allocated so it would based in part on --

1 MR. KOWALCYK: So there is -- you're
2 thinking about some type of resource constraint that
3 you would have to apply.

4 DR. CATLIN: And I think that was a
5 factor --

6 MR. KOWALCYK: Is that going to be put to
7 this Committee at sometime in the future because I
8 think as stakeholders, I think people would be very
9 interested in understanding how a level of inspection
10 would be changed throughout a certain segment of
11 producers potentially.

12 DR. CATLIN: Yeah, that -- this is Michelle
13 Catlin. As Carol Maczka said before, we are
14 currently doing a lot of the calculations to look at
15 the numbers of the plants that would fall in
16 different levels based on variations of the
17 algorithm, and that will be going --

18 DR. MACZKA: Carol Maczka. Tomorrow you'll
19 hear about poultry slaughter, you know, the analysis
20 we did there. We're still working on the processing
21 analysis.

22 MR. KOWALCYK: Okay. And then my other

1 question is, in looking at this slide 5, the
2 magnitude and hazard indicators, is it correct to
3 take away from the presentation this morning that
4 these factors will be weighted equally?

5 DR. MACZKA: Correct.

6 DR. CATLIN: They're not weighted.

7 DR. MACZKA: So they're treated like
8 independent --

9 MR. KOWALCYK: Okay. Does that
10 hypothetical -- well, we see in the Carnegie Mellon
11 analysis about NRs and what those statistics are
12 showing us, and then let's, for argument's sake,
13 let's use FSAs, an analysis is done, more analysis is
14 done with those FSAs and they're borderline
15 significant. Wouldn't it make sense if you're
16 looking at focusing your resources in improving
17 public health, and let's say you're adverse outcome
18 is a positive sample or recall, something that is
19 maybe twice as predictive of that adverse event, NRs
20 for example, wouldn't you take that approach applying
21 more weight to that factor than something like FSAs
22 which through analysis you find that there's some

1 association but very weak?

2 DR. CATLIN: That's definitely something to
3 consider, Michelle Catlin, something to consider.
4 Another way of looking at it, sort of modifying the
5 percentile that you take based on whatever it is. If
6 it's less, you might want to take a lower percentile.
7 Does that make sense?

8 MR. KOWALCYK: Yeah. I would be interested
9 to see how you would validate that and how it would
10 be stable whereas taking more of a regression type
11 approach where certain coefficients in that
12 regression equation will have different weight and
13 all that, seems to be a more robust and stable
14 methodology, especially if you have some things in
15 here like volume and attribution which there's a lot
16 of discussion about the source of attribution data
17 and where something like NRs can actually be made
18 very, you know, it's collected systematically and
19 there's already evidence that there is a strong
20 association. So it seems like there's maybe not so
21 much adding factors but looking at how these factors
22 are -- can go into incorporating an overall score

1 whereas -- rather than just looking at each element
2 and a ranking based on each one independently.

3 DR. DISNEY: This is Terry Disney from
4 FSIS, Risk Assessment Division. I think tomorrow my
5 boss, Janell Kause, will present a short presentation
6 on -- looking at microbial prevalence as a -- factors
7 in the plant such as volume, all the NRs that are
8 done, all the different procedures that are either
9 completed or not completed, as -- associated with
10 coefficient based on --

11 MS. BUCK: This is Pat Buck from CFI. A
12 lot of that was over my head. Does this mean you're
13 going to be collecting different data? And what has
14 been collected, has there been an investigation to
15 make sure we're collecting the right data? I'm just,
16 you know, --

17 DR. DISNEY: I think that's a big part of
18 where we are in the effort right now, is in the past
19 there's been a lot of -- in the data that we've
20 collected, and a big part of why we're sitting here
21 now is we're looking forward to the data that we
22 should be collecting and I think right now we're

1 having --

2 MS. BUCK: Okay. Given that, that this is
3 an ongoing process that FSIS is doing, is there some
4 reason we're putting this in place right now then? I
5 mean it seems to me that if you haven't made some
6 basic determinations about the type of data, then
7 maybe you need to take a pause and get our business
8 together. I mean we have a major war we're fighting
9 on foodborne illness not for, you know, the immediate
10 causes right now but we have 400 million people that
11 are going to be here in 2040. We've got to provide
12 safe wholesome food for all of them. So we need to
13 get this system ranked.

14 DR. DICKSON: Okay. Dr. Maczka.

15 DR. MACZKA: This is Carol Maczka. I'm
16 mean I'm sorry you missed the presentation early this
17 morning but if we can tell that the approach we're
18 moving towards is very transparent. Some of the
19 things that move you into Category 3, you would not
20 want us to not consider, like if you would have a
21 positive *E. coli* result. If you have a positive
22 *Listeria*, *Salmonella* or *E. coli* -- product, are you

1 in *Salmonella* Category 3, have you been associated
2 with an outbreak? These are things that, excuse the
3 expression, like sort of a no-brainer as to why you
4 would be moving into a Category 3, Category Level of
5 Inspection 3, you would want us to actually get
6 samples of those establishments in more detail. So I
7 think a lot of the data we are already collecting.
8 There is some new data that we will be collecting
9 such as these answers to these questions at
10 vulnerable points, the FSAs when we get data, but to
11 a large extent, much of the data we've already
12 collected, and it's stuff that we should be using.

13 MS. BUCK: This is Pat Buck. You know,
14 you're right and there's lots of things that I see
15 about the system that I'm really quite happy with as
16 being opposed. The thing I'm a little nervous about
17 is this is definitely in transition. I mean this
18 whole system is based on the fact that as we move
19 from this point forward, we're going to continue to
20 be upgrading with new data and everything else,
21 right? Isn't that sort of the whole plan here?

22 Well, you know, when they put the HACCP

1 rule in place, it was agreed by everybody, that they
2 were going to redo those baseline studies. It was
3 agreed that that was going to happen, and I know for
4 a fact that we, some of us in this room went and
5 talked to Congress and we got money to do baseline
6 studies but it's been on new products and you have
7 not redone the original baseline studies. So I get a
8 little nervous when FSIS tells me we're going -- this
9 is going to be transitional, and we're going to, you
10 know, keep adding to it. I want evidence that you're
11 going to keep adding to it. I want you guys to
12 become very proactive and go out after the
13 enforceable performance standard and I want you to go
14 after a mandatory trace back system. I want you all
15 proactive.

16 DR. DICKSON: Brian, yes.

17 MR. COVINGTON: Brian Covington. A
18 question, if using one of the examples here of, of a
19 routine test for *E. coli* 0157:H7 by the Agency and it
20 came back positive, that would trigger you into Level
21 3. Has the Agency determined what an acceptable FSA
22 result will be in order to get you back to Level 2 or

1 is that part of the quantitative score that's yet to
2 be determined in that as well?

3 DR. CATLIN: This is Michelle Catlin. As
4 for the quantitative score, no, that is yet to be
5 determined. Right now, others can correct me or add
6 in, FSAs are now currently done if you have *E. coli*
7 positive. This actually isn't anything new or
8 revolutionary. We're doing this. And when they go
9 in, they look and see if anything needs to be done,
10 what corrective actions may need to be taken in the
11 plant, if enforcement actions need to be taken, and
12 whether or not the plant is actually in compliance.
13 And that's the same as we'll be doing, you know, as
14 we move on, and it will -- except there will be a
15 scoring component. We are currently trying to get
16 FSAs in having piloted with the new format with a
17 score and we'll be analyzing those data as we go
18 along and get those in to try to come up with --
19 score, what the distribution scores are and what it
20 should be. Does that answer your question? Bill.

21 DR. SHAW: Let me add onto that. It's not
22 like we started thinking about this yesterday. I

1 mean we have been thinking about this for a while,
2 and there are pieces of this that are starting to
3 come out and one of them is the FSAs. I believe that
4 FSIS Notice 64-07, that outlines the mandatory --
5 basically the criteria where we would schedule FSAs
6 after positive results, and we are moving towards
7 that, towards that, in that direction and we are
8 starting to implement things that we can under our
9 current system to better protect public health. We
10 are doing that. So that's current policy right now.

11 DR. DICKSON: Other --

12 MR. SMITH: This is Bill Smith. I think
13 what we're getting -- like we said, it's exactly what
14 we're doing. I think with the checklist, it's sort
15 of standardized. It's just like we said, the
16 inspectors, there's 175 EIAOs out there and another
17 400 plus trained Ph.D.'s that are applying this
18 method. And so you want some uniformity and I think
19 that's what you're looking for and what is a
20 significant intervention as a process control, and
21 this checklist do that but at the end of the day,
22 they're still going to have to make a determination

1 like we're doing today, compliance -- meet the
2 requirements and no action or when you finish your
3 IME or -- whatever, you go to the suspension, that's
4 where the end would be but the checklist will help
5 frame the thinking in O157, so that for RTE where one
6 person may focus on filters in the ready-to-eat room
7 and somebody may not have looked at that, now we're
8 trying to standardize the methods we apply and then
9 support that.

10 DR. DICKSON: Okay. Stan -- Chris.

11 DR. BRATCHER: Chris Bratcher. Question
12 number 4, I think we danced all around it but one of
13 the things that I would like to see captured, a lot
14 of the processors now have GMPs or programs that are
15 in place by other entities, you know, that they're
16 using for -- well, for audits and for other things,
17 people that they're selling product to. Could we
18 capture those as a form of process control? Maybe,
19 maybe the prompts would come up. Is there other
20 documentation within the plant that would prove that
21 the process was under control, and it might be that,
22 you know, they've got statistical process control

1 charts on a particular product that they're producing
2 for Burger King or somebody like that, that shows
3 that that process was under control during that
4 period.

5 MR. SMITH: This is Bill Smith. I can't
6 say 100 percent of what you just said but I think
7 some folks will tell you a good proportion, at least
8 80 percent of the things you just mentioned will be
9 in the plant profile.

10 DR. BRATCHER: Good.

11 DR. SHAW: Bill Shaw. Especially when that
12 GMP or other program supports the decision made in
13 the hazard analysis.

14 DR. DICKSON: Okay. Michael.

15 MR. KOWALCYK: Michael Kowalcyk. One
16 question I have, actually it's a concern. The
17 classification of plants that would be high risk is
18 rather reliant on microbial testing. Does the Agency
19 have the proper amount of resources to consistently
20 do that so that this data is updated timely and that
21 it's reflective of what's happening almost real time
22 because it seems like you're trying to react to

1 something proactively which is good. I think
2 everybody's, you know, it makes sense to do that. If
3 you can see the bus coming and get out of the street
4 before it actually is there, that's good.

5 My concern is making sure that that testing
6 is done in a manner that's robust and consistent so
7 that the data is there and there's not a whole lot
8 of, you know, six months into a prototype of this or
9 even after rollout of something like this, there's a
10 whole bunch of missing data in the system because of
11 resource constraints. Is the Agency planning on
12 addressing that if that is an issue?

13 DR. MACZKA: I think, Carol Maczka, that
14 was, as we laid out these criteria, we considered the
15 availability of that, and so that's why the
16 timeframes are important, but in terms of testing,
17 yes, we did consider that, but I would disagree that
18 that is the only factor because there are other
19 factors other than testing in these lists, such as
20 getting answers to these questions about whether you
21 have a control in place and has it been implemented,
22 things like NRs, whether you're in a Category 3 of

1 *Salmonella*, recalls. So there are enforcement
2 actions. There are other things other than testing
3 but each of the factors that we're considering, we're
4 -- that there is sufficient data so that we can use
5 that. So, for instance, you'll see that we didn't
6 use this in the plants. One of the reasons we didn't
7 use that is because we don't feel that --

8 DR. DICKSON: Go ahead.

9 DR. HARRIS: Joe Harris. In response to
10 question 4, I'm not aware of any other process
11 control indicators that would need to be considered.
12 I think that's a pretty comprehensive list that's
13 already being considered.

14 DR. DICKSON: All right. Stan.

15 MR. PAINTER: Stan Painter, National Joint
16 Council. I just want to make this comment based on
17 something that was said regarding USDA policy being
18 FSIS Notice 64-07. These notices are just good for a
19 year, and they either expire or they're renewed, and
20 I just got one recently that was issued back in
21 December that's already changed now. So, you know,
22 you have to have your regulations and then you have

1 your directives and then you have your notices. So,
2 you know, the notice may be in place a year from now
3 and then again it may not.

4 DR. DICKSON: Well, I need to sum this up
5 because sometime in the next 40 minutes, I have a
6 presentation to give at 4:00. Are there any final
7 comments first from the Subcommittee here to
8 incorporate -- matter of recordkeeping? The report
9 presented at 4:00 will be in draft form. Everybody
10 will have a chance, the Subcommittee will have a
11 chance to review it to make any corrections either in
12 the accuracy of the statements or the impressions or
13 anything. So it won't be the official final report,
14 but it will be a draft version. So everybody here
15 will have a chance to look at it before it goes
16 officially into the records.

17 Final comments from the Subcommittee?

18 (No response.)

19 DR. DICKSON: Okay. Any other general
20 comments from the group here? Yes, ma'am.

21 DR. ARNOLD: Ilene Arnold, FSIS. I've been
22 with the Agency a while and I've implemented a lot of

1 different programs and evaluated quite a lot of data
2 over the years and looked at differences, and I've
3 learned from the lessons that are gone over and over,
4 and so I would like to propose some assistance with
5 the first question related to the timeframe. Back in
6 2002, when Bill Smith was a member, we implemented
7 the district early warning system. There we
8 identified certain parameters that we hoped were
9 these little warning lights to the district, that
10 hey, you've got an establishment out here that you
11 might want to take a look at, might send your, at
12 that time, it was still a CSO, out to the
13 establishment to take a look because our system is
14 showing -- a number of different resources that this
15 plant has a problem, and in that system, you used a
16 90 day timeframe.

17 And my personal opinion, I was the
18 administrator of the system, I thought that worked
19 very well.

20 DR. DICKSON: Thank you.

21 DR. ARNOLD: That's what I wanted to add.

22 DR. DICKSON: Any other comments from --

1 yes, Ms. Nestor.

2 MS. NESTOR: Felicia Nestor from Food and
3 Water Watch. This is in response to what you were
4 saying before, with all due respect, as a consumer
5 and a taxpayer, you know, it really rankles me when I
6 hear you say that this system is going to be
7 transparent. When taxpayers cannot even find out
8 whether plants are being inspected or not, because
9 the Agency refused to report that information, that
10 to me is not transparent, and when I brought this up
11 in the past, Ken Peterson says, well, you know, if I
12 wanted to know if that's happening, then I can call
13 the District Office. You can then get in touch with
14 the circuit supervisor who can then get in touch with
15 the inspectors and find out why six months ago they
16 didn't go into a plant or why this inspection task
17 was not done. So the fact that the Agency is
18 maintaining a system which makes this impossible to
19 record, that is not a transparent system. That is a
20 very -- system.

21 DR. DICKSON: Final comments?

22 (No response.)

1 DR. DICKSON: If not, I'd like to thank the
2 Subcommittee. I'd like to thank all of you who took
3 the time this afternoon to stay with us. Again, I'm
4 going to be reviewing what I hope is a pretty
5 accurate draft report so that Mr. Tynan will not be
6 mad at me at 4:00, and we're on break until 4:00.
7 Thank you.

8 (Whereupon, at 3:30 p.m., the meeting was
9 concluded.)

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C E R T I F I C A T E

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

NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

SUBCOMMITTEE 2

ISSUE II: ACROSS ESTABLISHMENT PUBLIC HEALTH

RISK-BASED INSPECTION ALGORITHM

Arlington, Virginia

February 5, 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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