

## 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: SUPPORTING DATA ANALYSIS AND PERFORMANCE  
STANDARDS

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February 6, 2008

1:15 p.m.

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Arlington, VirginiaCHAIR: DR. JAMES DICKSON  
Iowa State University

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Given your knowledge of contamination events, are there additional activities such as inspection activities, performance standards, et cetera, FSIS should consider to improve the proposed public health risk-based inspection system? If so, please describe these and provide your reasons.	6
Are there additional sources or variables that FSIS should consider for data analyses supporting the public health risk-based inspection system? Are there additional analyses that the Agency should consider performing to enhance the development of the proposed system?	47

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

2 (1:15 p.m.)

3 DR. DICKSON: Good afternoon. I think  
4 we'll go ahead and get started. Craig is coming.  
5 He's out in the hallway right now with Dan. So --

6 Real quickly, ground rules again -- see  
7 you. So it's important that you introduce yourself  
8 every time you speak and for our guests as well.

9 The Committee -- Subcommittee should have a  
10 draft report from yesterday. Any and all comments  
11 are welcome. Dr. Tynan would like me to finalize  
12 this before I leave this afternoon. So I'd like your  
13 guidance. I'd like your comments yet this afternoon.  
14 The main thing I want to be sure of is that we have  
15 not inadvertently missed anything as far as either  
16 interpretation or substance or anything like that.  
17 If you do have any comments, deletions, whatever, if  
18 you would be good enough to get those to me yet  
19 today, so I can go home.

20 MR. PAINTER: Stan Painter with the  
21 National Joint Council. I didn't get a copy of that.  
22 Where can I obtain a copy of that? Is it on the

1 table outside?

2 DR. DICKSON: You can -- no, they're not  
3 out there. It's a draft copy. You can take a look  
4 at mine --

5 MR. PAINTER: Okay.

6 DR. DICKSON: -- and you're welcome to mark  
7 it up if you want to.

8 DR. MURINDA: I didn't get a copy.

9 DR. DICKSON: It should have been on your  
10 notebook, I put it on at the break. So you should  
11 have it. If you don't, I'll get you one.

12 Does anyone need a copy of the questions  
13 that we are addressing this afternoon?

14 (No response.)

15 DR. DICKSON: Well, in that case, to get  
16 started again, I'm Jim Dickson. I'm going to read  
17 our charge for this afternoon, and then we'll take  
18 this one step at a time. I think I'll read the  
19 problem definition because the problem is a little  
20 different from some of the questions.

21 FSIS has carried out several data analyses  
22 and developed public health based performance

1 standards to support its proposed public health risk-  
2 based inspection system. Those data analyses include  
3 studies examining the relationship between  
4 noncompliance rates, we talked about NRs yesterday,  
5 and laboratory verification test results and a risk  
6 assessment on poultry slaughter. The proposed public  
7 health based performance standards apply to poultry  
8 slaughter and include *Salmonella*, *Campylobacter* and  
9 generic *Escherichia coli*.

10 FSIS would like the Committee to comment on  
11 the data analyses carried out to support the proposed  
12 public health risk-based inspection system and would  
13 like suggestions for further data analyses to be  
14 carried out and Agency activities that should be  
15 included in the public health risk-based inspection  
16 system.

17 Specifically, the Company should consider  
18 the following questions in its discussion.

19 And so we'll start with question 1: Given  
20 your knowledge of contamination events, and again  
21 we're referring specifically here to poultry  
22 slaughter, are there additional activities such as

1 inspection activities, performance standards, et  
2 cetera, FSIS should consider to improve the proposed  
3 public health risk-based inspection system? If so,  
4 please describe these and provide your reasons.

5 Okay. So we'll open it up for comments.  
6 In addition to what FSIS has done, what should they  
7 be doing? Suggestions or comments, and this could be  
8 inspection, performance standards, anything.

9 DR. MURINDA: Shelton Murinda. I  
10 previously asked that question with relevance to  
11 *Campylobacter* species. Just like *Salmonella*, with  
12 *Salmonella* we have I think over 2,300 different  
13 serotypes. Some of them are not of relevance to  
14 human pathogenesis. *Campylobacter* species, there's  
15 only about five or six of them, and only two of them  
16 of relevance to public health. So the answer that I  
17 go to as we are going to be analyzing all  
18 *Campylobacter*, that doesn't seem to be cost  
19 effective. I think they need to target *Campylobacter*  
20 species with significance to human health,  
21 specifically *Campylobacter jejuni* and *Campylobacter*  
22 *coli*. So they need to target species here.

1           With regards to what serotypes of  
2 *Campylobacter*, I'm not too sure which ones are  
3 involved in human diseases. But we need those two  
4 species to be defined instead of just blood kit  
5 analyzing all *Campylobacter*. I don't know whether it  
6 makes sense to others.

7           DR. DICKSON: Joe.

8           DR. HARRIS: Joe Harris. The first thing,  
9 I'm working from the assumption that in the context  
10 being used here, a contamination event, we're  
11 referring to incidents of pathogen contamination, not  
12 any other type of contamination. Can we clarify  
13 that?

14           And relative to the first question, in the  
15 data analyses, I would be interested to see the  
16 Agency's data confirming the public health  
17 implications of some of the things that are included  
18 in these performance standards. For example, I have  
19 not seen any data offered that would indicate fecal  
20 contamination has a direct public health consequence,  
21 not that I would attempt to insinuate that fecal  
22 material is okay in any form or fashion on carcasses

1 or on meat products. We have a zero tolerance  
2 standard in place right now.

3 The presentation I saw today at least did  
4 not offer any data to support the claim that fecal  
5 contamination is a well-known or common vehicle for  
6 transferring pathogens. I think there is some, you  
7 know, there's some logic there, one would intuitively  
8 think so but I know at least in the red meat sector,  
9 there's been some studies done on that that show a  
10 very poor correlation between incidence of fecal  
11 contamination and pathogens, or where we actually  
12 looked at fecal contamination and tried to identify  
13 pathogens in it and couldn't.

14 So, that is a data gap in my opinion, and  
15 they'd at least not present it if it exists.

16 DR. DICKSON: Jim Dickson. Just to  
17 clarify. You're identifying a data gap relating some  
18 of these performance standards or specifically fecal  
19 contamination to public health.

20 DR. HARRIS: Correct.

21 DR. DICKSON: Okay.

22 DR. HARRIS: I guess that would be an

1 activity I would suggest they consider to improve  
2 their system.

3 DR. MURINDA: Shelton Murinda again. With  
4 relevance to analysis of some products, for example,  
5 water, they use the presence of generic *E. coli* as a  
6 possible indicator of presence of pathogens that are  
7 associated with -- but as you say, the correlations  
8 are sometimes not there merely because the generic *E.*  
9 *coli* or conventional *E. coli* from the  
10 gastrointestinal track does not mean that there are  
11 pathogens that are in that sample. It's just I guess  
12 a red light.

13 DR. DICKSON: Jim Dickson again. We have  
14 two issues that have come out and they are somewhat  
15 related. The first one was specifically on  
16 *Campylobacter*. Does anyone have any further comments  
17 on *Campylobacter*? The issue was not all  
18 *Campylobacter* species are pathogenic. Should the  
19 performance standards target the pathogenic species?  
20 As I understand it from the presentation this  
21 morning, the *Campylobacter* performance standard will  
22 be a quantitative standard for all *Campylobacter* and

1 not just pathogenic strains. Any further discussion  
2 on that issue?

3 DR. HENRY: This is Craig Henry with GMA.  
4 I think that we need to come around a little bit  
5 relative to the contamination issue and which Shelton  
6 has spoken to, and that is first, what is going to be  
7 considered an acceptable raw product coming out of  
8 any given plant? Is that acceptable product going to  
9 be based on, for today, the current *Salmonella* and  
10 for tomorrow, tomorrow's *Campylobacter* incidence  
11 levels or is it going to be based upon the serotype  
12 of the day?

13 We've got multiple indicators here of  
14 process control being put forth. They all may have  
15 very good merit but this is a little bit like being  
16 half pregnant, you know. If you have a product  
17 coming out of a plant that is compliant with whatever  
18 the incidence level is on the data set but yet you  
19 have *Campylobacter jejuni* and/or *Salmonella*  
20 Heidelberg or *typhimurium*, you name it, it's there,  
21 is it in or out of standard?

22 So I think that we have a bit of an issue

1 here again to wait and see what the baseline data  
2 tells us but with that said, what are the  
3 interventions today being used on raw product to  
4 control specific serotypes?

5 DR. DICKSON: And?

6 DR. HENRY: Please James. Dr. Engeljohn,  
7 you were kind enough to join us today. You may  
8 regret that. Would you like to comment on that  
9 last -- on the issue, what if you're in compliance  
10 with the standards but are -- contain a or testing  
11 positive repeatedly for a serotype of interest?

12 DR. ENGELJOHN: Sure. I'll give you my  
13 perspective on the issue.

14 Presently the Agency is intending to move  
15 forward in the same way that we managed the  
16 *Salmonella* program which is we establish a standard  
17 and then look to see whether or not operations over  
18 time are within that standard. So that's one issue,  
19 the bottom line being that on a sample by sample  
20 basis today, *Salmonella* is not an adulterant in raw  
21 product, nor is *Campylobacter* determined to be so.

22 Now that may change in the future as we go

1 forward, but I don't think that that's -- I mean I  
2 think your Committee should ask the question if  
3 that's what you need to have answered in terms of  
4 clarity, but I think you should be viewing the  
5 Agency's intention in the short term as to proceed  
6 along the lines of what we're doing today with  
7 *Salmonella*. We are reacting to all serotypes within  
8 a type of organism. All serotypes for *Salmonella* are  
9 treated the same with regards to the current  
10 standard, and I would view that to be the case in the  
11 future as well for *Campylobacter* until we have more  
12 discernment about needing to treat an individual  
13 subspecies or serotype differently, and that raises a  
14 whole host of other issues.

15           But the Agency's intention as we tried to  
16 present was that a standard would be put in place.  
17 We would establish a mechanism to drive optimal  
18 performance meaning trying to categorize it in three  
19 different categories. This is what we have now, and  
20 informing the facilities of the serotypes and phage  
21 types and other genetic related information to those  
22 pathogens so that the establishment is informed about

1 it so that they can go back to the farm. Our goal  
2 would be to be able to identify what serotypes you  
3 have that are common causes of human illness, make  
4 sure that you're aware of that if it's a common  
5 supplier in your review, that is perhaps the only  
6 ones that's affected by sending birds to the  
7 slaughter facility for that particular organism.  
8 Perhaps that thing could focus where there needs to  
9 be discussions and potential mitigation put in place.  
10 But the intention is not to regulate on an individual  
11 basis as we do now because you won't have those  
12 results back within a two-week time period.

13 As you well know that the science isn't  
14 available yet today for us to have a mechanism to do  
15 that, but it is intended to provide information back  
16 to the chain of distribution here, in this case to  
17 the extent possible back to the farm where there may  
18 be mitigations that can be put in place, and we  
19 discover through research that there are mitigations  
20 that can be put in place, then make that information  
21 known.

22 But our belief is that it's best to look

1 for the types of *Salmonella* and *Campylobacter* in this  
2 case that are there, inform the operation and let  
3 them know whether they're in a high, medium or low  
4 incidence rate with regards to their peers so that we  
5 have some means to judge, is there some increase,  
6 some decrease? Is there baseline changing over time?  
7 And that's information that the Agency at this time  
8 finds valuable and as we are able to construct  
9 mitigation strategies, we will incorporate them. So  
10 I hope that gets -- right.

11 I don't think you should do the Agency  
12 identifying a particular serotype in a raw product  
13 today as being an adulterant. Although there is  
14 pressure to do so, I don't think that we are in a  
15 position to believe that that is necessary at this  
16 time. And so process control over time is what we're  
17 looking at. Okay.

18 DR. HENRY: Thank you.

19 DR. BRATCHER: Chris Bratcher, NAFV. Back  
20 to that same thing, and I'm a regulator. So this may  
21 sound funny from me, but I hear this argument from  
22 industry repeatedly because if you send in a

1 *Salmonella* set, all you have is -- you could have one  
2 colony forming unit in that test on that bird as  
3 positive. And I guess the question that they have is  
4 that they have -- if they put in interventions and  
5 they have significantly dropped quantitatively the  
6 level of *Salmonella* in their sampling and in their  
7 birds, but they still have some positives, how do you  
8 deal with that? I don't know how to answer it  
9 because I know that I have to go by what we have in  
10 place today but, you know, I hate to beat them over  
11 the head because they still have some positive  
12 *Salmonella* samples.

13 DR. ENGELJOHN: This is Engeljohn. I think  
14 the Agency's belief is and science would support,  
15 that there likely is a level of presence that we'll  
16 never be able to get below, and we don't know what  
17 that is. But we do know industry is capable of  
18 controlling pathogens on their products. We have  
19 varying levels across the country and when  
20 mitigations are put in place or when attention is put  
21 towards the food safety system, particularly after a  
22 food safety assessment, there generally is dramatic

1 improvement in terms of performance. So even though  
2 that there is still this, this positioning where the  
3 control -- contamination will be there.

4 But I would also point out, you know, the  
5 Agency's procedures right now as I think you  
6 identified, where we only collect one colony on a  
7 petri dish. There are many colonies there, and  
8 there's research to suggest that there may be  
9 multiple types of *Salmonella* in a flock coming to  
10 slaughter but we just collect the most distinguished  
11 colony on that plant.

12 Well, I think you should expect in the  
13 future the Agency will continue to look to see should  
14 we analyze all, everything that's there, you know.  
15 That's a cost issue but it's also one that we need to  
16 have more information on.

17 But we also have to be aware that there's  
18 concern that one intervention may favor the  
19 destruction of one organism and perhaps also favor  
20 the growth of another. So we don't know that and I  
21 think that's part of the issue of why we treat all of  
22 them the same with the expectation that the

1 intervention is taking care of them all equally. We  
2 know with heat lethality that isn't true. But we  
3 don't have enough information about the  
4 interventions. So at this time, the issue becomes  
5 one of controlling the operation and it may just be  
6 there isn't a means to control the presence lower  
7 than a certain level. But we don't think we're there  
8 yet, and we certainly know that industry as a whole  
9 has variable --

10 MR. COVINGTON: Brian Covington. A  
11 question for Dr. Engeljohn or probably for the --

12 (Laughter).

13 MR. COVINGTON: Of the data that the Agency  
14 has relative to *Salmonella* serotypes, what percentage  
15 would you guesstimate is outside of the CDC top 30  
16 or --

17 DR. ENGELJOHN: We have that, but I know  
18 that -- we do know that -- I think it's perhaps just  
19 under 50 percent. So I think -- and I'm just trying  
20 to go by memory of the latest serotype table that we  
21 had was Kentucky, and those types that are not in the  
22 top 30 list and then the rest of them would fall into

1 the top 30. So I think it's just under 30 percent of  
2 all the positives we get are in that top 30 list, if  
3 we look at the overall percent positives.

4 DR. DICKSON: Okay. Kind of directing back  
5 to the question as we announced, given your knowledge  
6 of contamination events, are there additional  
7 activities FSIS should consider, whether these are  
8 inspection activities, performance standards or  
9 anything? Your thoughts in general on the subject.  
10 Is there anything that FSIS could be doing that they  
11 are not currently doing? Yes, Michael.

12 MR. KOWALCYK: This is Michael Kowalcyk.  
13 You know, I go back to the issue of line speed and it  
14 was mentioned earlier in the full Committee meeting  
15 that FSIS was going to be considering that, and that  
16 seems to me a factor in the production of anything.  
17 It doesn't matter what you're producing, that speed  
18 does play a role in the quality of a product. We  
19 talked about interventions such as scalding,  
20 defeathering, rinsing, all that. The speed by which  
21 carcasses are processed through those various  
22 interventions I would have to think has an effect on

1 the quality of the product and the quality of the  
2 intervention on that product.

3           And, you know, I would recommend that this  
4 Subcommittee states in our report back that we direct  
5 the Agency to an explicit consideration of line  
6 speeds and where there exists variability to do more  
7 in depth analysis. In their literature search, they  
8 quoted one study which was, they referred to as a new  
9 test study. That raises some questions about what  
10 are the other variables going on in that study --  
11 particular technology plays more of a factor than  
12 line speed. How many people are working on that  
13 line? There's a lot of questions there, and it's  
14 only one study. So I think it's incumbent upon this  
15 Committee to let FSIS know that that's a critical  
16 factor, which I believe so.

17           DR. DICKSON: Further discussion on line  
18 speed within the Subcommittee here?

19           DR. HENRY: This is Craig Henry. I think,  
20 you know, that line speed continues to come up. If  
21 the Agency at this point in time does not have  
22 sufficient data about line speed in every plant that

1 they manage, along with the appropriate *Salmonella*  
2 data, to correlate to that line speed, be it up or  
3 down on the *Salmonella*, we've got a bigger problem  
4 than we started with, but I'm totally advocated that  
5 analysis hasn't been done and it's long overdue.

6           And certainly industry has an equal  
7 responsibility to meet the performance standards  
8 regardless of line speed, be they manually being done  
9 or by automated evisceration, et cetera. So I think  
10 if that clarification needs to be brought to bear, it  
11 should have already been done, and I'm sure it has  
12 been much prior to this meeting, but I would concur  
13 with Michael. Let's get that out on the table and  
14 put it to bed.

15           DR. DICKSON: Any of the FSIS staff have  
16 any comments on any work that's being done? There  
17 was some work, correct me if I'm wrong, Jim Dickson  
18 here, I'm violating my own rule, I'm sorry.

19           There was work done on beef processing, and  
20 this probably goes back seven or eight years ago  
21 maybe, that looked at line speed and contamination  
22 and I don't remember what organism they looked at but

1 as I recall, at the time, there wasn't a direct  
2 correlation between line speed in beef processing.  
3 Am I remembering something that never happened?

4 DR. ENGELJOHN: We can certainly dig that  
5 up and find out, but I can say more specifically on  
6 the issue of line speeds and poultry and broilers in  
7 particular, there is a more recent study that the  
8 Agency has completed for which line speed was a --  
9 one of several questions asked about the  
10 interventions in place, when the sample was  
11 collected, the types of things that Michael stated,  
12 whether the variables associated with that sample  
13 result, so they could then see what the relation --  
14 and I don't remember if that was an attachment, I'm  
15 sorry, the -- FSIS study. It is in the form of some  
16 published work that is to be done, but in any case,  
17 that is information that we can make available to you  
18 as well.

19 DR. DICKSON: I think that everybody --

20 DR. ENGELJOHN: And just for the record, if  
21 you're keeping a record, the Agency would agree line  
22 speed is a critical issue that we need to lay to rest

1 and we will construct any and all the type  
2 *Salmonellas* that need to go along with that, that  
3 address that issue.

4 DR. DICKSON: Ms. Nestor, you had a  
5 comment.

6 MS. NESTOR: Not on line speeds. On  
7 contamination.

8 DR. DICKSON: Yes.

9 MS. NESTOR: FSIS has specific definitions  
10 on what fecal is. It has to be a certain color, has  
11 to be a texture, a different substance, and I talked  
12 to poultry inspectors and hog inspectors who have  
13 said, you know, what they want at the end of the line  
14 to prove it, cut open the, you know, a gut, show  
15 them, this is what the fecal looks like from these  
16 animals and they still can't get it as fecal. So I  
17 mean that's definitely something that has to be  
18 concentrated on, you know. If it's coming out of the  
19 intestine, it sounds like fecal to me and --

20 DR. DICKSON: Coming from anybody on the  
21 inspection side, is that -- go ahead.

22 MR. PAINTER: Stan Painter with the

1 National Joint Council. I'd like to address two  
2 issues, one with the line speed and one with the  
3 fecal. And we get into that a lot, you know. It's,  
4 you know, you -- the color, is it pasty, you know,  
5 what's the texture and things of that nature, and  
6 it's swabbed and smeared and what have you and, you  
7 know, in my career, in my dealings in poultry plants  
8 which has been some 25 years now, I have saw a direct  
9 correlation in line speeds and contamination, whether  
10 it be contamination from beyond -- past the gizzard  
11 or prior to the gizzard, you know, and you do have to  
12 separate that out. Now if it's prior to the gizzard,  
13 it's considered ingested -- after the gizzard it's  
14 considered fecal contamination, you know, and you get  
15 into so many arguments with that, you know.

16           And I'm currently stationed at a HIMP plant  
17 now, and the line is going like almost 200 a minute,  
18 you know. The plant can't do what they need to do.  
19 We can't do what we need to do. The window is so  
20 small in even trying to get product off a line when  
21 you're doing your testing, you're supposed to get  
22 every fifth bird of the line doing testing, and

1 there's no way going 200 a minute. That is not  
2 possible and, you know, there's safety issues  
3 regarding food safety in my opinion.

4           And then there's safety within the plants.  
5 I have saw people have their arms pulled off, have  
6 fingers pulled off, and was working in a plant  
7 recently where a young lady lost her thumb, you know,  
8 she got it hung in a shackle, and she went as far as  
9 she could, and she pulled her thumb off to keep from  
10 going through the equipment, and that was going 91 a  
11 minute. Try that at 200 a minute and see and find  
12 out what you may get with that.

13           So we have several issues going on here  
14 with line speed, you know, with product going out the  
15 door and the safety of the workers there at the  
16 plants and the inspectors in the plants as well.

17           DR. DICKSON: Yes, sir.

18           DR. BRATCHER: Chris Bratcher. There are  
19 so many variables that come into play with feces.  
20 Line speed is definitely one of those but feed  
21 withdraw, water withdraw, the amount of light that  
22 they're getting in the houses, where they ran out of

1 food, the catching crews, when they're catching them  
2 when they should. There are so many variables that  
3 affect feces that it's almost impossible to say that  
4 the only thing is line speed.

5 In fact, we've looked at that a lot of  
6 times and we finally made a bumper sticker that says  
7 feces happens but, you know, you just can't say that  
8 that's one thing.

9 There is a safety issue though with these  
10 extremely high line speeds, and the plant has to  
11 address that through their OSHA requirements. We  
12 have to address that through our OSHA requirements  
13 that we have to meet as well because we're in those  
14 facilities, and I don't know that -- I don't think  
15 that's our area of concern. I think we have to  
16 address it for our employees and then let it go at  
17 that, and a lot of times we tell our employees not to  
18 be doing things that are going to be a hazard, and if  
19 they're not able to accomplish their task or their  
20 mission, then we're going to have to do something  
21 else to be able to do that.

22 DR. ENGELJOHN: I just perhaps to get on

1 the issue that Felicia raised --

2 DR. DICKSON: Dan Engeljohn.

3 DR. ENGELJOHN: Dan Engeljohn, and perhaps  
4 to give you something to think about, not that I'm  
5 trying to plant seeds in their head but the issue of  
6 what is feces, what is ingested and how we deal with  
7 it is a longstanding issue. ARS did do a study and  
8 they actually have developed technology that can be  
9 used to discern chlorophyll containing material from  
10 that that's not and whether or not the use of that  
11 kind of equipment, particularly for FSIS' on  
12 reconditioned birds, the birds normally that were  
13 contaminated but then reconditioned, if there would  
14 be value to have an additional tool beyond just the  
15 visual eye inspection if that's something that the  
16 Agency should be pursuing. I think it would be  
17 helpful to get some feedback on other than just  
18 relying on visual determination of what is or isn't  
19 and other types of features to get at the issue of is  
20 sanitary dressing -- insanitary dressing contributing  
21 to birds becoming contaminated but then cleaned by  
22 the antimicrobials, is a concern to the Agency.

1           And so I think that that is part of the  
2 issue here, are there other tools available that  
3 might be able to help better define contamination.

4           DR. DICKSON:     And again I'll ask, Jim  
5 Dickson here, ask the FSIS personnel, in the ARS  
6 study, wasn't there an evaluation of fecal  
7 contamination and factors involved in fecal  
8 contamination? Or again, am I remembering something  
9 that didn't happen?

10           DR. ENGELJOHN:   I don't remember.

11           DR. CATLIN:     The one I'm looking at, I  
12 don't remember doing that but in the meantime I'll  
13 take a quick look at our --

14           DR. DICKSON:     Again, Jim Dickson.   On the  
15 performance standards, are there any comments on the  
16 presentation this morning relating to *Salmonella*,  
17 *Campylobacter* or generic *E. coli*, specifically in  
18 reference to the performance standards? Brian.

19           MR.     COVINGTON:           Brian     Covington.  
20 Understanding that I'm not a statistician, and I  
21 will, unless excepted, what I understood you to say  
22 this morning concerning the generic *E. coli* is that

1 there's a correlation that as the process proceeds,  
2 the decrease in generic *E. coli* lends itself to a  
3 decrease in *Salmonella* incidence post-chill, correct?

4 UNIDENTIFIED SPEAKER: Yes, and if I  
5 remember correctly, the presence -- but also the  
6 enumeration.

7 DR. BRATCHER: Okay. Given that, what --  
8 has the Agency given thought to I understand the  
9 performance standards aren't completed yet, but has  
10 the Agency given thought to when an establishment may  
11 be outside of those advisory performance standards I  
12 believe is the language that was in the Federal  
13 Register notice but is negative for *Salmonella*. And  
14 how that fits into the Public Health Information  
15 System and the levels of inspection?

16 DR. CATLIN: That was one question that  
17 actually came up in our -- Michelle Catlin, FSIS.  
18 That was a question that actually came up in the  
19 Subcommittee discussion about this as well, and  
20 that -- how did the performance standards interplay  
21 in the end, and it was something that he actually  
22 said he was going to think about, and that was

1 Engeljohn. It was something that was, okay, it's  
2 still under consideration.

3 DR. ENGELJOHN: This is Engeljohn. And I  
4 would say that in part -- again, the purpose of the  
5 generic *E. coli* would be to replace what is there  
6 now, which we think are not affected, the performance  
7 criteria that the plant is required to make. So it  
8 would be to make a better use of the generic *E. coli*  
9 that the plants are doing today and to use it more in  
10 line with what would be effective process control.

11 And it is established at the moment,  
12 starting at rehang, which is before the birds are  
13 eviscerated. So before -- this would be a truer  
14 reflection of the level of contamination on birds  
15 coming into the slaughter operation. So it's before  
16 they're eviscerated, before all the other problems  
17 that are associated with it, and there may be  
18 interventions that apply that would be perfectly  
19 acceptable and a multiple hurdle approach is not a  
20 bad feature for any operation.

21 But the Agency could and certainly could  
22 take recommendations on constructing, when it would

1 be appropriate, to also use the generic *E. coli* in  
2 combination with pathogens. Like you say, the  
3 pathogens are controlled and as well as it's --  
4 they're not control just simply by cleaning them up  
5 later in the slaughter dressing practice because we  
6 don't want there to be poor sanitary dressing that's  
7 just cleaned up later.

8           But if the process is such that the birds  
9 are coming in clean, relatively clean, they're coming  
10 in relatively free or with low incidence of the  
11 pathogens, that may not be the appropriate time when  
12 to institute that additional measure.

13           So it isn't an all or nothing that we're  
14 looking at. We're looking at when best would this be  
15 a supplement. So your comment being perhaps when the  
16 pathogens are controlled, generic *E. coli* in  
17 addition, may not be a necessary -- and I would say  
18 we would not necessarily disagree with that and would  
19 be looking to see how we could construct a process  
20 that would require additional evidence that the  
21 process is controlled, and that may be one way to do  
22 it, when there's evidence of dirty birds coming in

1 and poor control. So that's a consideration.

2 DR. DICKSON: Jim Dickson. Any other  
3 thoughts on inspection activities, performance  
4 standards that FSIS should consider in addition to  
5 what is being proposed? Michael.

6 MR. KOWALCYK: This is Michael Kowalcyk.  
7 In regards to performance standards, given -- in the  
8 presentation we had this morning, there was a  
9 recommendation to possibly insert preliminary data or  
10 state that actual values will be determined. I would  
11 be very, you know, I would be very cautious in taking  
12 that route. Actually, I would not take that route.  
13 I would wait until a baseline was complete and vetted  
14 not only through this Committee but also vetted  
15 through our sister Committee, NACMCF. I mean their  
16 charter is more in line with microbiological  
17 criteria, and this is exactly that, is the way I'm  
18 interpreting that.

19 Again the baseline standards were based on  
20 industry averages when they were taken some years ago  
21 and again the same methodology is being employed  
22 which ideally you would want to pull down the

1 industry average, everybody get better and those that  
2 can't keep up, they change the way of doing business  
3 or they would leave the market.

4           Is that truly a public health goal? Can  
5 the Agency demonstrate that by that industry average  
6 moving, is that even its public health objectives or  
7 should the baseline be more in line with a certain  
8 level to expire to meet a public health objective,  
9 and I think bringing those two together, I think  
10 there seems to be some work that needs to be done.

11           I don't know if anybody from the Agency can  
12 address that at this point.

13           DR. ENGELJOHN: Engeljohn. I would say  
14 that the Agency is, in fact, looking at the current  
15 *Salmonella* standards and seeing how they relate to  
16 meeting the public health goals which we do recognize  
17 that we are not meeting our public health goals for  
18 *Salmonella* and for *Campylobacter*, and that we need to  
19 continuously drive down the percent positive rate as  
20 instructed now, and that is the reason why the  
21 Category 1, 2 and 3 came about which was a means to  
22 have a standard and then to drive down performance in

1 that to the lowest -- the lower level, so that all  
2 the plants, or the majority of the plants are  
3 producing at the 25th percentile, in essence down --  
4 standard.

5           So from our perspective, it's -- we  
6 constructed the baselines of the standards at the  
7 industry average at the time and put in mechanisms to  
8 drive improvement in that, and then continuously do  
9 baselines in the future to reset those standards and  
10 thus that would all be tied to what we believe would  
11 be the public health benefit from doing so.

12           So anything we put forward would have a  
13 defined measurable goal with regards to public  
14 health. So what we put forward will say what --  
15 system would accomplish.

16           DR. DICKSON: Jim Dickson. In my knowledge  
17 of this, and I'm more than willing to be corrected on  
18 this, I'm not personally aware of any convincing data  
19 that shows that a reduction of a pathogen in a  
20 specific or broad class of foods can be directly  
21 related to a public health benefit.

22           The assumption is that if you reduce it in

1 what people are eating, then you will get a reduction  
2 in foodborne illnesses, but I'm not personally aware  
3 of any data that shows that very clear cause and  
4 effect relationship between any broad class of foods,  
5 and like I said, if someone else is, I'm more than  
6 happy to be corrected on that, but that's -- I think  
7 that's one of the challenges that we have all  
8 wrestled with.

9           Several years ago, not to regress, but  
10 several years ago, there was a discussion on hand  
11 washing, and remarkably there are very few studies  
12 that demonstrate a benefit of hand washing. That  
13 doesn't mean that I don't want the surgeon operating  
14 on me not to wash their hands but there are --  
15 sometimes you have to make assumptions, but I think  
16 that's what we're doing.

17           I'm sorry. Ms. Nestor, you had a comment.

18           MS. NESTOR: Yes. Felicia Nestor, Food and  
19 Water Watch. Again, if I'm understanding the  
20 question correctly, I mean it's a pretty broad  
21 question. They're asking if there are any additional  
22 activities that inspectors should perform --

1 DR. DICKSON: Right.

2 MS. NESTOR: -- to improve the proposed  
3 system. I don't exactly know what the proposed  
4 system is. I mean you kind of went over it pretty  
5 quickly this morning, you know, reading between the  
6 lines. I'm assuming it's something like HIMP  
7 currently because they're talking about taking  
8 inspectors off the line, and I've been doing some  
9 affidavits with HIMP inspections and what I find --  
10 what I've heard is that the carcass inspector  
11 basically has lost just about all the authority that  
12 the traditional inspector has. Basically what the  
13 carcass inspector does is look to see if there's  
14 feces on the back of the bird. They're not allowed  
15 to look inside the bird. They're not allowed to  
16 touch the bird. -- capable of turning the bird to  
17 look at the front of the bird to see if it's got, you  
18 know, tumors, abscesses, whatever, because the line  
19 is configured that way. They can't turn the shackle.

20 So I mean I think that -- federal  
21 inspectors performing those activities needs the  
22 authority and has to have a discretion to actually

1 look at these birds, and I'm still kind of on the  
2 fence about the viscera. I mean FSIS recently  
3 released I think it's 6100.3 which is about post-  
4 mortem inspection and the necessity of a viscera for  
5 making a judgment call about whether or not a  
6 potentially localized condition is actually systemic  
7 and you need a viscera to do that, and from what I'm  
8 hearing in any of these plants, there are no viscera.  
9 And the inspectors can't -- so they can't look at  
10 that, and since they can't look inside the bird, they  
11 can't even look at what signs you might have of the  
12 inside of the cavity to see you've got a disease  
13 that's systemic.

14 Now I've heard that some of these diseases,  
15 all you have to do is smell the bird and you know,  
16 but, you know, I'm wondering about those borderline  
17 cases.

18 MS. KRUSHINSKIE: Can I make a comment?  
19 This is Beth Krushinskie. I'm with Mountaire Farms.  
20 I think there's a little disconnect at least my  
21 perception of HIMP. There are 10 bird checks or  
22 multiple 10-bird checks done for processing defects

1 and for other OCD and diseases, and that is not the  
2 function of the carcass inspector sitting in that  
3 line. Those characteristics or those factors and  
4 variables are looked for and identified in using a  
5 different system. So I just want to clarify that.  
6 You're kind of giving me the impression that the  
7 carcass inspector is supposed to be like traditional  
8 inspection identifying all the animal diseases and  
9 processing defects -- and that's not the intention.

10 MS. NESTOR: I know that. I know that's  
11 the way HIMP works. What I'm saying is if all the  
12 plants in the country are going to this other system,  
13 I'm saying that I think it should be more like a  
14 traditional rather than the HIMP where all the  
15 authority is taken away from the carcass inspector  
16 because, you know, if you've got a quarter million  
17 birds coming out of the plant, looking at -- per day,  
18 doesn't give you that much of --

19 MS. KRUSHINSKIE: There's some control  
20 built into the HIMP system. I'm actually a strong  
21 supporter of HIMP. I'm hoping that we can move to  
22 that and allow federally paid inspectors to do higher

1 level functions and activities than inspect  
2 carcasses.

3 MS. NESTOR: Well, I need somebody to take  
4 the -- carcass off the line.

5 DR. DICKSON: Michelle.

6 DR. CATLIN: Michelle Catlin. I just want  
7 to clarify one thing with these questions. When  
8 we're talking about the public health risk-based  
9 inspection system, we're not talking about a HIMP  
10 system necessarily. We're talking about what was  
11 discussed this morning which is the within and across  
12 performance standards that were discussed. We're not  
13 talking about online versus offline inspection people  
14 and we're not talking about line speed, specifically  
15 what the inspector does.

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

17 MR. PAINTER: Yeah. This is Stan Painter  
18 with the National Joint Council and if I understand  
19 what Dr. Catlin just said, the new proposal, whatever  
20 that may be, is not going to be like HIMP?

21 DR. CATLIN: Michelle Catlin. If you  
22 remember when Mr. Almanza started out this morning,

1 he referred to the fact that we're not specifically  
2 talking about the rule today, we're not specifically,  
3 you know, that wasn't the focus of today. It was the  
4 application of -- system that we discussed yesterday  
5 specifically to poultry slaughter. So there is sort  
6 of a distinction between --

7 MR. PAINTER: Stan again. Is that a yes or  
8 a no?

9 DR. CATLIN: -- is the revision of the  
10 system and then if the Agency is moving forward with  
11 the poultry slaughter rule, they're sort of separate  
12 issues. So there is no yes or no. It's -- I'm not  
13 speaking to what would be or wouldn't be in the rule.  
14 I'm speaking to --

15 MR. PAINTER: Well, I do have an additional  
16 comment, and based on some of the things that were  
17 said about HIMP, and I've been involved with the  
18 process from the onset, and if we go to something  
19 like a HIMP, if that's the situation, you know,  
20 that's -- that process should meet the same standards  
21 other processes have to meet. We shouldn't change  
22 the standard. You shouldn't allow a plant to change

1 a critical control because they can't meet the  
2 guidelines where fecal wouldn't even be counted, you  
3 know. There should be certain standards as far as a  
4 line speed.

5 I know I worked for industry for a number  
6 of years, and I understand FSIS says, oh, we lost \$1  
7 million. No, you've projected you would make \$2  
8 million and you only made \$1 million. So you didn't  
9 lose \$1 million. You just didn't make as much as you  
10 thought you would make.

11 So, you know, we've got to look at the big  
12 picture here and the big picture is putting out a  
13 wholesome product with standards set at the current  
14 standards.

15 DR. DICKSON: I do want to wrap up this  
16 specific topic, and I appreciate what has been said  
17 here. From a broad sense, as I interpret this  
18 question, what are we missing? What has not been  
19 included in the public health risk-based inspection  
20 system other than the items already discussed. Is  
21 there anything else that needs to be brought to the  
22 attention of the Agency? I believe that's really

1 what's being asked here.

2 DR. HENRY: This is Craig Henry, GMA. No.  
3 The answer is no, we've got more on the table now  
4 than we say grace over. The data gaps need to be  
5 filled in. We need to look at what the impact is of  
6 the proposed program, and then let's go back to the  
7 analysis team. Okay. But for us to drum something  
8 up now, we've already gone well beyond where we had  
9 been a year ago, two years ago, or five years ago.  
10 We've also already injected the potential impact of  
11 serotype, the potential impact of enumeration, and  
12 the potential impact of lowered standards of  
13 performance or more aggressive standards of  
14 performance waiting on the new baseline. So until we  
15 get some more information, I think we're status quo.

16 DR. DICKSON: Okay. Thank you. Okay. I  
17 apologize to those sitting behind me. If you need to  
18 get my attention, just walk up and smack me on the  
19 back of the head.

20 (Laughter.)

21 DR. DICKSON: Our second charge here --

22 MR. PAINTER: I have something.

1 DR. DICKSON: Stan.

2 MR. PAINTER: Stan Painter, National Joint  
3 Council. If I could, I'd like to say that I agree  
4 with what Craig Henry just said but I'd like to add  
5 another piece to that.

6 The Agency needs to give everything to the  
7 Committee. It's hard to make a recommendation when  
8 you don't have the whole process in order to look at.  
9 So that would certainly be helpful.

10 DR. DICKSON: Okay. Our next questions --

11 MR. KOWALCYK: Pardon me, Jim, before you  
12 continue. This is Michael Kowalcyk. I would like to  
13 add to that in general I agree with Craig's comment  
14 about the level of information, and I very much agree  
15 with Stan's comment about the amount of information  
16 we've been charged with reviewing and providing  
17 recommendations to the Agency on.

18 I commend them for providing this level of  
19 detail to us. However, I was part of the Data  
20 Integration Subcommittee and we had numerous  
21 teleconferences and even those teleconferences, there  
22 were many issues that were discussed within that

1 Committee and that was also under a very tight time  
2 constraint with large amounts of information and --  
3 recommendations to the Agency, I feel that we need  
4 more lead time with the information we're going to be  
5 given, more advanced notice as to what Subcommittee  
6 memberships we belong to. In other words, had I  
7 known three weeks ago that these were the topics that  
8 I would be specifically charged to look at in a three  
9 hour session, it would have been really good to know  
10 these questions ahead of time because then we could  
11 have actually consulted with each other before we  
12 even got here, and this two hours could have been  
13 spent more efficiently.

14           And we're talking about issues here that  
15 are again changing for consumers, for the inspection  
16 force that the Agency has and for industry. So I  
17 think as stakeholders and to make responsible  
18 recommendations, we need more advance notice, and if  
19 that means more meetings, if that means narrow -- I  
20 mean we could have spent two days on one of these  
21 topics alone. And really, NACMCF in their  
22 involvement in this process as well I see is not

1 having enough involvement with respect to certain  
2 issues that are very much in line with performance  
3 standards and data analysis.

4 I think, you know, I understand some of the  
5 statistics and that part, but I don't understand the,  
6 you know, what happens and, you know, the inspection  
7 forum, those here that are in industry and  
8 inspection, they know how it, you know, how this  
9 really works where as NACMCF is more of that  
10 scientific base and it seems like we're getting a lot  
11 of the science questions and I don't know what  
12 they're getting. I know that's a lot. So --

13 DR. HENRY: This is Craig Henry. I agree  
14 with Michael on that and Stan. I think, you know, if  
15 you got that down, James, rather well.

16 I would also add in, and I think this will  
17 bridge us over to number 2 question a little bit, to  
18 think a little bit about this as a good segue,  
19 because number 2 wants to know of additional data  
20 sources or variables that the Agency should consider  
21 including data analysis. I would suggest strongly,  
22 you know, and again I will say again tomorrow, hats

1 off to the Agency for doing just a hell of a job, one  
2 responding to OIG in such a short timeframe, two,  
3 rolling out a tremendous analysis on a lot of  
4 different data, for risk-based inspection compared to  
5 what we were over a year ago. So they've done a good  
6 job.

7           However, it is now time to allow this  
8 amount of information to go through all stakeholders'  
9 hands in the months to come and allow those  
10 stakeholders of which there are numerous ones outside  
11 of this room and outside of this meeting, that can  
12 provide additional, good solid, science-based  
13 information and recommendations to fulfill many of  
14 the questions we're asking here, but this thing needs  
15 to be analyzed.

16           Meanwhile, the Agency should be tasked with  
17 completing their baseline studies, completing their  
18 other risk assessments, et cetera, et cetera, and  
19 getting that data out of here as rapidly as possible  
20 so that we can determine what the true impact is of  
21 this program should it be implemented at any point in  
22 time.

1 DR. DICKSON: Thank you, Craig. And Jim  
2 Dickson. This is a general thought, and I guess I'm  
3 not soliciting a whole lot of comment on this. Would  
4 the Subcommittee here think there would be any value  
5 to a joint meeting with NACMCF? I have mixed  
6 feelings myself but I thought it was worth throwing  
7 out.

8 DR. HENRY: This is Craig Henry, GMA. I  
9 would say not at this particular time. My vote would  
10 be to formulate the right questions for the NACMCF  
11 and make sure they work commensurate with this  
12 program because we raise -- well, Carol is  
13 evidently -- questions about the micro side, but to  
14 get us together, we can spend a lot of time, you  
15 know, conveying our concerns but I think it should be  
16 captured after this meeting and moved on but I'm --  
17 not that I wouldn't do it. I'm just thinking in the  
18 interest of time, I'd rather see what their first cut  
19 is -- and see how that's changed, the direction that  
20 FSIS foresees going.

21 DR. DICKSON: Okay. Our second charge is  
22 are there additional sources or variables that FSIS

1 should consider for data analyses supporting the  
2 public health risk-based inspection system? Are  
3 there additional analyses that the Agency should  
4 consider performing to enhance the development of the  
5 proposed system?

6 MR. KOWALCYK: Michael Kowalcyk. I think  
7 for starters, one, and, you know, I'd like to commend  
8 the Agency in their work and the work that Dr. Disney  
9 has done on the risk assessment.

10 In our session, it was stated that there  
11 are certain data issues that they're currently  
12 working through. I would certainly make the  
13 recommendation that these studies that are either  
14 being reviewed or refined should be then completed  
15 and then brought back to this Committee. Because I  
16 feel very much that while these, what could be near  
17 complete products, there still is some refinement  
18 that needs to occur and I feel as someone on a  
19 Committee, I'm at a bit of a disadvantage making  
20 recommendations on what variables they should look  
21 at, and really this may change substantially more so  
22 than what we're anticipating and until we see a final

1 product, it's very difficult to make explanations.

2           So I certainly would, you know, I would  
3 advocate for this Committee recommending that all  
4 peer reviews that are currently underway be completed  
5 and communicated to stakeholders and this Committee  
6 as well as any refinement to the analysis that's  
7 currently under way.

8           DR. DICKSON: Additional comments from the  
9 Subcommittee?

10           DR. HENRY: This is Craig Henry. You heard  
11 mine earlier. And I'll agree with Michael's  
12 statement.

13           DR. DICKSON: Do we have a general  
14 consensus that what Michael's saying is supported by  
15 the Subcommittee about completing the ongoing work  
16 and bringing it to the Subcommittee in general? Am I  
17 generally seeing everybody nodding their head yes?  
18 Okay.

19           Additional data analyses or additional data  
20 sources, this is just a little bit different from the  
21 previous question but along the same vein. As I  
22 interpret this question, is there anything that the

1 Agency is currently overlooking that might be  
2 available in their database?

3 MS. CONTI: This is Kibbe Conti. Do you  
4 know in your literature review look at international  
5 studies, too, that are being done over in Europe and  
6 published over there?

7 DR. CATLIN: Michelle Catlin. The  
8 literature was -- they weren't just limited to the  
9 U.S.

10 MS. CONTI: Okay.

11 DR. ENGELJOHN: And I would just add --  
12 this is Engeljohn. From the Agency's perspective, we  
13 do have individuals who are well informed because of  
14 equivalency process, what occurs in other countries,  
15 and we do have interaction with other countries as to  
16 how they control their operations and to be fair,  
17 most other countries regulate different than FSIS  
18 with regards to poultry slaughter in that  
19 interventions are not allowed during the slaughter  
20 operation, but they occur on the farm. So there's --  
21 anything that happens, happens on the farm and the  
22 interventions that are applied in the slaughter, do

1 not include decontamination methods, so do not  
2 contain antimicrobials. So there is a considerable  
3 difference in other countries around the world versus  
4 the U.S. system.

5 MS. CONTI: Okay.

6 DR. DICKSON: And I would throw this out to  
7 first off the FSIS personnel. I'll get to you in  
8 just a second. FSIS personnel, is there anything  
9 that you folks would like to see that you don't  
10 currently have? Perhaps Dr. Disney would like to  
11 comment on that. Is there anything you'd like to  
12 have to do your risk assessment that you don't  
13 currently have?

14 DR. DISNEY: This is Dr. Terry Disney. The  
15 things that we talked about this morning, especially  
16 being able to incorporate line speed data into the  
17 risk assessment as it exists now, the facilities --  
18 but heretofore we did not have the data to do that.  
19 So we've been talking about it within FSIS in terms  
20 of getting line speed data.

21

22 In terms of the procedures data, Michael,

1 the issue that came up this morning, I think that we  
2 will as Dan mentioned, the new system hopefully will  
3 be able to distinguish at what point along the line  
4 these procedures are taking place. That will be very  
5 useful in terms of separating out those procedures  
6 that take place before the microbial sample is taken  
7 versus those procedures that take place after the  
8 microbial sample takes place.

9 Another issue that we're working on is  
10 being able to serotype these things. The model has  
11 capabilities now to, to look at various serotypes and  
12 define relationships between the serotypes. All we  
13 need is the data. Basically we have a model in  
14 place. It's a good model. It's been peer reviewed,  
15 but we're limited to the data that we can actually  
16 put into the model. So we have lots of data needs.

17 DR. DICKSON: Okay. There's a comment over  
18 here. I didn't mean to --

19 MS. KRUSHINSKIE: That's okay. Beth  
20 Krushinskie, Mountaire Farms. I guess one concern I  
21 had was with the NR, the correlation between NRs and  
22 *Salmonella* levels I think it was. I guess I would

1 like to suggest that that relationship between NRs at  
2 the plant and foodborne pathogen levels be reexamined  
3 and perhaps evaluate it with a different approach. I  
4 don't have a suggestion for approach but --

5 DR. DICKSON: And I apologize, but we  
6 discussed this in great detail yesterday afternoon,  
7 and I think the consensus of the Committee was, yes,  
8 we'd like to see that analyzed in more detail.

9 MS. KRUSHINSKIE: Okay.

10 DR. DICKSON: Joe, go ahead.

11 DR. HARRIS: Joe Harris. I'd just like to  
12 touch on your comment earlier, but I think it's  
13 pertinent to the second question as well, and that is  
14 I would like to see whatever additional work can be  
15 done relative to actually linking the inspection  
16 system with the reduction in foodborne illnesses. I  
17 mean that still is the -- that's the big hole in the  
18 system that we have trouble -- I'm like you. I've  
19 not seen studies that show that direct correlation.  
20 You know, again, we have to think it's probably  
21 there. I would like to see it more clearly defined.

22 I don't know that the Agency has the -- I

1 think the Agency has done what it can relative to  
2 taking the attribution data that is out there but I  
3 do think that they need to continue in those efforts  
4 to better define that relationship.

5 DR. DICKSON: Jim Dickson here. Certainly  
6 not speaking for other groups, other than myself, but  
7 my understanding from my colleagues at CDC is that  
8 they don't feel like they have the data to make that  
9 link either. So we may be looking for something that  
10 simply isn't there and maybe that's the challenge to  
11 all of us is to come up with a way of doing that.  
12 Ms. Nestor.

13 MS. NESTOR: Felicia Nestor, Food and Water  
14 Watch. I just want to underscore what Michael was  
15 saying and I want everybody to be clear that what  
16 the -- the Agency associated inspection tasks with  
17 reductions in *Salmonella* and they do not know what  
18 percentage of those tasks were done in the processing  
19 end of the plant and what were done in the slaughter  
20 end of the plant, before the *Salmonella* set was  
21 taken. So I just want -- I just hope everybody  
22 understands that.

1           The other thing is, just in trying to  
2 understand the risk assessment, and I just found out  
3 today, how you can have an unscheduled sampling test,  
4 you know, and why the Agency is presenting its, you  
5 know, routine *Salmonella* sampling as an unscheduled  
6 test. So I think in later iterations of these  
7 things, you know, maybe if we could all come to  
8 agreement on what a term means. They were talking  
9 about an unscheduled task being one that an inspector  
10 might do if he or she notices a problem in the  
11 plant -- that it's discretionary for the inspector.  
12 But that is not the *Salmonella* test. They are not  
13 discretionary.

14           DR. DICKSON: Okay.

15           MS. NESTOR: Sorry. One other point. I  
16 think the way the Agency did its analysis, picking  
17 these -- because they don't know whether these tasks  
18 are done because an inspector is there or not there,  
19 you know, they can't say that increased sanitation  
20 tasks were the only thing that caused that *Salmonella*  
21 reduction. It could be that the increased  
22 *Salmonella* -- sanitation tests are an indication that

1 you had an inspector in the plant who was not pulled  
2 to the line because sanitation is one of the priority  
3 tasks. So if you see sanitation tasks going up, it  
4 may just be that all of a sudden the inspector is not  
5 pulled to the line all the time and can actually do  
6 some inspection.

7 So, you know, there may be a whole systemic  
8 thing that's leading to that reduction, not the  
9 individual sanitation tasks.

10 DR. DICKSON: Other comments? Did you have  
11 any comments?

12 DR. DISNEY: No. I'll respond briefly to  
13 that. I think that's pretty much why. I mean we  
14 don't make that -- like I said this morning, we don't  
15 make that cause and effect relationship between what  
16 we observe and the microbial outcome. But I think  
17 you're right on track. I mean it could simply show  
18 that the inspector was allowed to do his duty as  
19 normal and that's associated with a decreased flow in  
20 the plant which is good information. I mean, I don't  
21 see anything wrong with that.

22 DR. HENRY: This is Craig Henry, GMA. I'd

1 like to make a comment.

2 I think that goes back to the issue we  
3 discussed yesterday. I don't care which one of the  
4 data points we're going to pull out of here for the  
5 entire proposed system. No one of them tells a story  
6 about how good a plant is doing or not doing its job.  
7 Whether we take line speeds, whether we take how many  
8 inspectors are in the plant, whether we take how many  
9 scheduled or unscheduled tasks are done. Nobody here  
10 could sit here and do that.

11 To truly evaluate how well that plant is  
12 running requires a team effort, and that's why HACCP  
13 was based on a team, and a team, by the way, includes  
14 FSIS. Every HACCP plan in place today in every  
15 facility was approved by the Agency.

16 Now the key is to make sure that the  
17 program is executed appropriately and to also be able  
18 to measure other things that have changed that may  
19 make it less efficacious.

20 Now in the situation that we spoke of just  
21 a minute ago, which Stan brought up, Dr. Dickson  
22 brought up, and now -- Joe did, I think that we

1 certainly need to have a little what if scenario put  
2 forth.

3           We know that between 2006 and 2007, correct  
4 me, FSIS, if I'm wrong, there was a very significant  
5 reduction in *Salmonella* incidence for all poultry  
6 plants. Is that not true?

7           So that being the case, I mean, let's pick  
8 a year, can we show any correlation to improve or  
9 shall we say, reduce Salmonellosis in the human  
10 population as a result of foodborne illnesses? I  
11 mean there's going to be a lot of effort, a lot of  
12 resources that are going to go in just in  
13 implementing this program on both sides of the fence,  
14 both between FSIS as well as industry just to begin  
15 to implement.

16           We need to know can we see and I have to go  
17 back to this, cause and effect relationship. The  
18 model is useless. That risk assessment is useless if  
19 we don't show cause and effect. I mean we're trying  
20 to get down to and that's effectively where we are  
21 here and, you know, I'm talking about a very general  
22 term here. We're trying to say if we do X, we want

1 to get Y. And I'm saying today why is 2006 versus  
2 2007, not a fair year to look at. How many years do  
3 you need? How many months do we need?

4 DR. DICKSON: Jim Dickson here. This gets  
5 back to the public health issue and the effect of  
6 *Salmonella*. I have a colleague who says somewhat  
7 facetiously that trying to link these two is  
8 something like trying to do a case control study on  
9 the effectiveness of parachutes for controlled  
10 descent of humans from airplanes. Who are you going  
11 to get be the controller? Stan.

12 MR. PAINTER: I'd like to comment, Stan  
13 Painter, on what was just said regarding the HACCP  
14 plan. As an inspector, I don't approve the plans,  
15 HACCP plans. I try to see that it meets the  
16 guidelines set forth in the regulations, and that's  
17 not getting my approval. That's not giving my  
18 blessings. As an inspector, that means it meets the  
19 regulatory guidelines.

20 So there's not an approval per se by an  
21 inspector, and regarding the team concept portion of  
22 it, I think that an inspector should work with a

1 plant in order to achieve regulatory compliance when  
2 there's a possibility to do so. There's times that,  
3 you know, the inspector may have to draw the line and  
4 say, yeah, I've got to take a stand here and the  
5 plant may have an opposing view but, you know, the  
6 whole goal between both parties is to achieve  
7 regulatory compliance and put out a product that  
8 is safe--

9 MR. RICE: John Rice, Sanders Farms. It's  
10 been my experience based on looking at plants that  
11 have a low instance of *Salmonella* that going back and  
12 doing -- with numbers following these samples, that  
13 you come out with a very, very low number of  
14 *Salmonella* per ml. And there's data out there with  
15 different species of *Salmonella* to say what the  
16 effective dose is and number of *Salmonella* cells that  
17 one would need to become infected.

18 There's data out there for *Campylobacter*  
19 which Norman Stern has put together at the ARS Lab  
20 down in Athens, and USDA is proposing a quantitative  
21 standard for *Campylobacter*.

22 And I think that we need to consider if

1 we're down below 10 percent, look at the numbers of  
2 *Salmonella* that are in those samples. We may be at a  
3 point where we don't have an infected dose and going  
4 further and further down is not going to have any  
5 benefit on public health.

6 DR. HENRY: This is Craig Henry, GMA. I  
7 concur with John Rice because, you know, even though  
8 we try to run away from the enumeration issue, I  
9 think it's very much in front of us, and I would  
10 suggest that at least this Subcommittee consider a  
11 recommendation to the Agency to establish an  
12 appropriate sampling and enumeration technique for  
13 *Salmonella*. We kicked that around on our Data  
14 Subcommittee calls a couple of times, but that needs  
15 to be brought to bear, so that we do have the  
16 appropriate numbers here if we get closer and closer  
17 to a serotype performance standard. But what Johnny  
18 says is correct. It's a fair evaluation to say, how  
19 long can you go because effectively you could be  
20 chasing zeros and on an incident levels, that's very  
21 much different. That's apples and oranges when  
22 you're looking at a true enumeration basis.

1           MR. RICE: This is John Rice again. As an  
2 example, it's very common for me to have a four young  
3 male aliquot of samples that comes up positive for  
4 *Salmonella*. But when I go back and do an enumeration  
5 with a MPN and do the 9G pollution, none of those  
6 chickens may come up positive.

7           DR. DICKSON: Shelton.

8           DR. MURINDA: Just to add to what they are  
9 saying, the technique that you use for enumeration  
10 has a bearing on whether you come out with positives  
11 or not. The MPN test is not the most sensitive.  
12 Current tests that target for DNA sequences are  
13 highly sensitive but they still have problems in the  
14 sense that they just pick up DNA. They don't tell  
15 you whether it's really alive or not in some  
16 instances.

17           MR. RICE: With the MPN test you're always  
18 looking for live organisms.

19           DR. MURINDA: Yeah, you are looking for  
20 live organisms but using a probabilistic approach.  
21 So it doesn't really give you numbers. If you  
22 compare that say to colony forming units, vis-à-vis

1 DNA based, that might pick out the live organisms.  
2 They give you different aspects of numbers actually.

3 MR. RICE: In any event, we need to be  
4 looking at numbers with a method that is reliable.

5 DR. MURINDA: Quite right. And the  
6 liability of most of these methods is correlated to  
7 conventional methods where you actually isolate that  
8 organism.

9 MS. KRUSHINSKIE: This is Beth Krushinskie.  
10 I just want to clarify that MPN, we do most commonly  
11 in the poultry industry, is using a serial dilution  
12 type or a dilution of the rinse aid, and then PEs and  
13 PCRs to determine whether *Salmonella* is present or  
14 absent and then calculating the most probably number  
15 because there's so few colony forming units you can't  
16 do a direct plating.

17 DR. DICKSON: Ms. Nestor, yes.

18 MS. NESTOR: Felicia Nestor, Food and Water  
19 Watch. I have a question on this enumeration issue.  
20 What happens in distribution? I mean is it the case  
21 that if the bird leaves with very little *Salmonella*  
22 that there's little chance that it's going to grow

1 out if there's temperature abuse in distribution or  
2 what? I mean it still could multiply in transit,  
3 correct?

4 MS. KRUSHINSKIE: It's dependent on  
5 temperature, the growth associated with temperature  
6 and warmer temperatures it multiples faster.

7 MS. NESTOR: So even if you have a low  
8 enumeration, it still could grow given abuse of  
9 temperature.

10 MS. KRUSHINSKIE: We maintain a goal chain,  
11 however, though from production through consumer. So  
12 the --

13 MS. NESTOR: That's not fool proof. I mean  
14 consumers know about temperature violations all the  
15 time.

16 COURT REPORTER: I'm sorry. One at a time.

17 DR. DICKSON: One at a time please.

18 MR. PRETANIK: Steve Pretanik, National  
19 Chicken Council.

20 Felicia, to answer your question, with  
21 respect to *Campylobacter*, that would be true.  
22 Whatever level you have when leaving the plant, that

1 level is going to decrease on distribution. It's a  
2 very fragile organism. Not true with *Salmonella* but  
3 with *Campylobacter*, that is true.

4 MS. NESTOR: Thank you.

5 MR. PRETANIK: I just wanted to point that  
6 out.

7 MS. NESTOR: Thank you.

8 DR. DICKSON: Any other -- yes, sir.

9 MR. RICE: John Rice again. The other  
10 thing I want to point out, there is also additional  
11 data on a pathogen modeling program, that was  
12 developed by ARS on the Eastern Shore which looks at  
13 the affect of temperature on *Salmonella* growth and  
14 you've got to get above 55 degrees for more than 8  
15 hours to get any significant growth. So you've  
16 really got to have some, some pretty bad ignorance of  
17 sanitation and temperature in order to get a  
18 significant growth in *Salmonella*.

19 MS. NESTOR: Thank you.

20 DR. DICKSON: Okay. I'd kind of like to  
21 wrap this up here. Are there final comments from the  
22 Subcommittee because we're losing our Subcommittee as

1 we speak. Final comments from the Subcommittee from  
2 those of you at the table on any of these issues or  
3 anything for the general good of the cause. Yes,  
4 Michael.

5 MR. KOWALCYK: Michael Kowalcyk. I think  
6 since we're talking about across the whole public  
7 health-based inspection system, I think one thing  
8 that -- one additional set of analyses that can be  
9 done, and it was I believe touched on a little bit in  
10 our discussion about the case studies yesterday, is  
11 to really look at and Craig mentioned this in our  
12 Subcommittee meeting yesterday, what would this  
13 system tell us, with the data we have now, of an  
14 event that happened in the past.

15 There are case studies, to beat up Topps  
16 again and talk about that example. What happened  
17 under the current regime, identify where the  
18 management fallacies occurred, then go back and look  
19 at this plant in this new proposed environment, how  
20 would that have been managed differently. And in the  
21 case that was just talked about, well, this could  
22 have been prevented. Well, how could it have been

1 prevented? What prompts would have triggered what  
2 actions and how could they?

3 One question I have about the system is I  
4 don't see a fail safe in here for, yes, an  
5 establishment has interventions. Well, how do you  
6 verify that? And if a continual yes occurs and then  
7 the same type of NR keeps occurring over a set and  
8 timeframe. Is there something else that's occurring  
9 that is being missed? And I think now is a really  
10 good time for those case studies to be kind of, you  
11 know, dug into with more detail to really see, how  
12 would this affect the Agency's actions? And  
13 secondly, how would that impact the resources that  
14 you currently have?

15 I'm assuming that no incremental resources  
16 would be given in the way of humans to actually do  
17 the work and I'm hoping that there's additional IT  
18 resources that would facilitate more timely execution  
19 of these plans.

20 And I just think that analysis needs to be  
21 out there because you are changing the way you're  
22 managing your inspection force.

1 DR. DICKSON: Dr. Henry.

2 DR. HENRY: Craig Henry, GMA. I think  
3 coming back to that analysis, too, Michael, the thing  
4 that I threw out a minute ago, relative to 2006,  
5 2007, I think FSIS should consider the analysis of  
6 how they will correlate any improvement in plant with  
7 the public health incidence rank because, you know,  
8 we kind of forget this a little bit. The last time I  
9 checked on give and take, a five or six year lag  
10 phase before we get anything out of CDC on real  
11 numbers especially relative to attribution. So, you  
12 know, we can be putting things together next year and  
13 we're going to be into 2010 plus before we get the  
14 data back out to say, oh, yeah, that's six years ago.  
15 I think we changed X, Y and Z, and look what we did  
16 over here.

17 So I would suggest that FSIS figure out how  
18 we are going to show a reasonable cause and effect  
19 relationship and if there is going to be a lag in  
20 making that connection because if there is, we've got  
21 a whole other issue on our hands I think.

22 DR. DICKSON: Jim Dickson here. A general

1 comment, this is again I'm more than willing to  
2 discuss this in detail, given that we don't have the  
3 cause and effect relationship and given that it's  
4 unlikely to be able to conclusively demonstrate cause  
5 and effect, at least in short term, is there anyone,  
6 and I'm not asking this of ridiculousness, is there  
7 anyone fundamentally opposed to lowering the  
8 *Salmonella* levels in poultry, broilers, as a  
9 Subcommittee? Anyone fundamentally opposed to that?  
10 And so a system, whatever it is, however it proceeds,  
11 it fundamentally lowers *Salmonella* levels,  
12 *Campylobacter* levels in broilers would be generally  
13 endorsed by the Subcommittee? Brian.

14 MR. COVINGTON: I would agree with that,  
15 just a science based -- whatever the standard becomes  
16 that it's based on science.

17 DR. DICKSON: Okay.

18 DR. BRATCHER: And pathogens of concern or  
19 just pathogens.

20 DR. DICKSON: *Campylobacter* and whatever  
21 else comes along.

22 MR. KOWALCYK: This is Michael Kowalcyk. I

1 think there were good points raised about, I mean  
2 regression analysis can't show cause and effect but  
3 we can show that there's a good amount of evidence  
4 there are certain interventions or lack of effective  
5 interventions that do relate to these higher  
6 incidence of certain types of organisms that have  
7 shown to be indicators of pathogenic organisms.

8 I think we need to be very careful in  
9 taking that lightly because what can the Agency do?  
10 Well, the Agency can affect how a plant operates and  
11 how they manage their critical controls.

12 Will we ever eliminate these pathogens  
13 completely? Probably not. But I think the Agency is  
14 taking a science based approach and trying to  
15 understand what are significant NRs that result, and  
16 there is some additional analysis to do there. What  
17 type of interventions do impact lower incidence  
18 levels and I think enumeration is something important  
19 to be looking at. I mean if you look at -- there has  
20 been a leveling off of the *Salmonella* and it may be  
21 that there are more plants in the Category 1 in  
22 meeting the current performance standards. That

1 could be a symptom of how the testing is done because  
2 the testing is in what would be deemed as a purely  
3 quality control sampling methodology. There's  
4 limitations to that. And the enumeration could be an  
5 issue that there may be less positives but the ones  
6 that are positive have a higher load. It was stated  
7 that some have a low load that would not cause  
8 infection but there could be the opposite going on in  
9 certain cases, and I think enumeration would be an  
10 important factor to look at because the positive  
11 level might not move but then you get into, well,  
12 what can you do to affect the actual level of the  
13 pathogen?

14 DR. HENRY: This is Craig Henry. I'll  
15 chime in on relative to reducing that number, I think  
16 we do need to qualify that from the standpoint of  
17 chasing the wrong zero because we can continue to go  
18 down that line. Dr. Engeljohn already made note that  
19 at least overseas, and I think there's a higher  
20 desirability here to get into the live production  
21 farms and try to provide interventions there.

22 Dr. Rice and others have already made note

1 and at previous meetings, some three years ago now,  
2 that FSIS held relative to pre-harvest interventions,  
3 you know, we're really talking about vaccine  
4 interventions out on the farm. Vaccines, this is  
5 very analogous to influenza. You've got to pick the  
6 right serotype if you want to get the right efficacy  
7 out of the vaccine.

8           So I think we need to be cautious as to who  
9 low we try to go for a given zero relative to  
10 incidence and that we need to be smarter about  
11 targeting the correct pathogen attributable to the  
12 product in question.

13           And lastly, we should refer FSIS back to  
14 our recommendation in October, the Subcommittee that  
15 we had, talking about enumeration serotyping and pre-  
16 harvest interventions and appropriate funding because  
17 funding is hot right now since the budgets are  
18 rolling in.

19           MR. RICE: James --

20           DR. DICKSON: I'm sorry.

21           MR. RICE: -- John Rice. There's plants  
22 out there, if they are failing the performance

1 standard, the goal should be to reduce the incidence,  
2 but I'm also aware that there's an awful lot of  
3 plants out there right now that are less than 10  
4 percent and there's a lot of them that's 5 percent or  
5 less incidence and short of -- such as irradiation, I  
6 don't know if you're going to be able to get any  
7 lower in those plants.

8 DR. DICKSON: Real quick to wrap up here,  
9 anything else from those at the table first?

10 (No response.)

11 DR. DICKSON: Any comments from the FSIS  
12 staff present? Ms. Nestor.

13 MS. NESTOR: Felicia Nestor, Food and Water  
14 Watch. Just in terms of future meetings and future  
15 discussions about these things, I think the Agency  
16 should be more transparent in the limitations of the  
17 data that it's presenting. I don't know how many  
18 people when they first read the risk assessment  
19 understood that the Agency hadn't, you know,  
20 separated the processing tasks from the slaughter  
21 tasks and, for instance, in the HIMP program, the  
22 samples that the federal inspectors look at are

1 marked at the top of the line. So as the pork  
2 carcass is going down the line, all of the company  
3 employees working on the carcass on that end know  
4 which of the 24 carcasses out of the 8,000 that they  
5 do that day are going to be looked at by FSIS. And  
6 the workers say -- the inspectors say, it's very  
7 evident that the workers treat those carcasses  
8 differently.

9           So whenever FSIS comes to the public and  
10 makes these statements about this is what the data  
11 is, you know, we just feel like we're being  
12 hornswoggled if you're not explicit about what the  
13 limitations are.

14           DR. DICKSON: Anything else from the  
15 audience?

16           MS. KAUSE: This is Janell Kause with FSIS.  
17 In response to a previous comment. We will continue  
18 to try and put everything in the risk assessment. I  
19 do recognize our documents are long. We did put all  
20 the procedure codes in every table. So the entire  
21 risk assessment is documented. But we're still  
22 looking maybe for some -- ways to communicate these

1 complicated analyses in a way that they're  
2 streamlined. And we realize we're starting to move  
3 now towards something that's really short and then  
4 all the appendices. But we're still finding that we  
5 hear this word transparency, whether or not we're  
6 transparent or not, and when you go and look at it,  
7 you'll find that everything is in there but maybe  
8 it's just a matter of finding another way of  
9 communicating it so that everyone is seeing it  
10 readily.

11 DR. CATLIN: Michelle Catlin. I would like  
12 to reiterate that we did make a real effort to try  
13 and provide probably an overwhelming amount of  
14 information in this case, and one other thing I would  
15 like to say is if you look in the processing  
16 report, specifically not -- the slaughter team didn't  
17 want it, the poultry slaughter team, they wanted to  
18 put it in a different place, but there is actually,  
19 and I can't remember the appendix, and it might be  
20 Appendix E, but my memory might fail me, an entire  
21 chapter describing all the data sources that we used.  
22 So we did get -- in our defense, we did try and make

1 an effort -- to be very transparent.

2 DR. DICKSON: If there are no further  
3 comments, from those of you in the Subcommittee,  
4 please give me your edits, suggestions and comments  
5 on yesterday's report. I'll get that edited first so  
6 that Mr. Tynan will let me go home today.

7 (Laughter.)

8 DR. DICKSON: And then I'll summarize what  
9 we've got here in our report today. Okay. Thank  
10 you.

11 (Whereupon, the meeting was concluded.)

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C E R T I F I C A T E

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

NATIONAL ADVISORY COMMITTEE ON  
MEAT AND POULTRY INSPECTION

SUBCOMMITTEE 2

Arlington, Virginia

February 6, 2008

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

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SEAN WILLIAMS, Reporter

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