

# UNITED STATES DEPARTMENT OF AGRICULTURE

EMERGING EGG AND EGG )  
PRODUCTS STRATEGY )

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THE UNITED STATES DEPARTMENT OF AGRICULTURE

EMERGING EGG AND EGG )  
PRODUCTS STRATEGY )

Holiday Inn Capitol  
550 C Street, S.W.  
Washington, D.C.

Tuesday,  
June 5, 2001

The hearing in the above-entitled matter was  
convened, pursuant to notice, at 7:03 p.m.

P R O C E E D I N G S

(7:03 a.m.)

1  
2  
3 MR. MORSE: My name's Dale Morse. I'm from the  
4 New York State Department of Health. Why don't we just  
5 go around to the left.

6 MS. JOHNSON: Alice Johnson, National Food  
7 Processors.

8 MS. KASTER: Collette Schultz Kaster, Premium  
9 Standard Farms.

10 MR. JAN: Lee Jan, Texas Department of Health.

11 MS. ESKIN: Sandra Eskin. I'm with AARP and  
12 I'm taking the place of Nancy Connelly.

13 MS. RIGGINS: Judy Riggins, Office of Policy,  
14 FSIS.

15 MS. LOGUE: Catherine Logue, North Dakota State  
16 University.

17 MR. MORSE: Sure. Go ahead.

18 MS. TANNER: Susan Tanner. I'll be trying to  
19 capture your main points.

20 MR. MORSE: All right.

21 MR. MADELEY: Julian Madeley, United Egg  
22 Producers.

23 MR. GREEN: Randy Green, United Egg Producers.

24  
25 MR. WOOD: Richard Wood, with FAC Trust and  
26 Savings.

1 MS. WALLACE: Una Wallace, FSIS. I'm going to  
2 translate.

3 MS. CANNON: I'm Lorraine Cannon and I'm --

4 MS. LEVINE: I'm Vicki Levine, colloquially  
5 known as the "Egg Lady."

6 (Laughter.)

7 Also, FSIS.

8 MR. MORSE: Okay.

9 MR. MERCER: Ron Mercer.

10 MR. MORSE: Okay. Now when people are talking  
11 do they need to speak into the mikes or how do you?

12 THE COURT REPORTER: Well, anyone at the table  
13 I'll be able to pick up. The people on the other side of  
14 the room I'll have a little problem with.

15 MR. MORSE: Okay.

16 THE COURT REPORTER: But if I am having a  
17 problem I'll just raise my hand.

18 MR. MORSE: Okay.

19 A PARTICIPANT: And you don't need us to say  
20 our names when we speak since you know who's sitting  
21 where or is that easier for you if we do it?

22 THE COURT REPORTER: You can --

23 A PARTICIPANT: Okay.

24 THE COURT REPORTER: -- but I do have a name  
25 list so I will know who's speaking from the table, but on  
26 the outside it could be a little difficult for the first  
27 10 minutes or so. Okay.

1           MR. MORSE: And we have basically the followup  
2 discussion on the egg and egg products strategy. What I  
3 think I'll -- we'll talk about -- Judith, maybe -- are  
4 there any other points, introduction, you want to make?

5           MS. RIGGINS: No. I really think what Vicki  
6 said she's the Egg Lady. The reason she said that is  
7 because she's our chief drafter of the documents of our  
8 proposals, so, she can add a lot to the substance of the  
9 discussion.

10           But I think it probably would be -- if you have  
11 questions that you want to ask, clarifications on the  
12 presentation that I gave this morning, the issues that  
13 aren't clear to you I can try to answer those. But I  
14 think, you know, probably as you work your way through  
15 the questions these issues may also emerge, you know, as  
16 you discuss it. So I'm at your disposal, whichever you  
17 want.

18           I mean I basically laid out all of the current  
19 thinking this morning. But if there are areas that, you  
20 know, I wasn't clear on or questions that you have I'll  
21 be happy to answer.

22           MS. JOHNSON: Mr. Morse, can we ask for some  
23 clarification?

24           MR. MORSE: Sure.

25           MS. JOHNSON: Alice Johnson with the National  
26 Food Processors. Maybe this is to the Egg Lady.

27           (Laughter.)

1           But where FSIS is already working or there is a  
2 proposed rule drafted, is that right? There's a proposal  
3 that is in its second draft or third draft.

4           MS. LEVINE: Well, the third draft -- it's  
5 actually the millionth draft but --

6           MS. JOHNSON: Yeah.

7           MS. LEVINE: -- but it's actually in its second  
8 draft.

9           MS. JOHNSON: Okay. And where within the  
10 Agency?

11           MS. RIGGINS: It's currently in our General  
12 Counsel's office --

13           MS. JOHNSON: Okay.

14           MS. RIGGINS: -- for review.

15           MS. JOHNSON: Do you know where the FDA rule  
16 is? Is it --

17           MS. RIGGINS: The FDA rule has been cleared by  
18 their General Counsel and has gone to their department  
19 and is in clearance in their department.

20           MS. JOHNSON: Thank you.

21           MR. JAN: Can you give us a line to FSIS.

22           MS. JOHNSON: Thank you.

23           (Laughter.)

24           MR. JAN: Okay.

25           MS. RIGGINS: A line?

26           A PARTICIPANT: Ditto.

27           MR. JAN: Like jurisdiction?

1 A PARTICIPANT: Jurisdictional.

2 A PARTICIPANT: The way it's divided currently?

3 MS. RIGGINS: On the farm the FDA has  
4 jurisdiction under the Federal Food Drug and Cosmetic Act  
5 for all production animals including laying hens.

6 MS. ESKIN: So on the farm is FDA?

7 MS. RIGGINS: On the farm is FDA. I should  
8 also add that APHIS has authority on the farm for all  
9 issues related to animal production and animal diseases.  
10 So, you know, that's an overlapping authority.

11 But FDA's focus is production animals for use  
12 as food by humans and, therefore, the human health  
13 consequences of production practices on the farm.  
14 Whereas, APHIS focuses on production practices as it  
15 relates to animal health and the ability of animals to  
16 thrive, you know, as agricultural commodities.

17 MS. ESKIN: Again, FDA has authority over the  
18 eggs themselves, that is the product, and also over the  
19 feed?

20 MS. RIGGINS: The FDA has jurisdiction.

21 MS. ESKIN: Over the feed that's fed to the --

22 MS. RIGGINS: To the hens.

23 MS. ESKIN: -- hens.

24 MS. LOGUE: But APHIS is responsible then for  
25 animal health and interventions to ensure the health of  
26 the animal by --

27 MS. RIGGINS: Yes.

1 MS. LOGUE: -- drugs and stuff like that.

2 A PARTICIPANT: How about molting?

3 MS. RIGGINS: No. Well, no, not animal drugs.

4 A PARTICIPANT: No. That's FDA, right?

5 MS. RIGGINS: That's FDA.

6 A PARTICIPANT: That's FDA.

7 MS. RIGGINS: APHIS has responsibility for  
8 biologics, vaccines and serums for animals.

9 MS. LOGUE: Animal health issues?

10 A PARTICIPANT: Right.

11 MS. RIGGINS: Yeah. That's under the serum --  
12 vaccine, serum, I can't remember, and something else.  
13 APHIS has responsibility for biologics, serums and  
14 vaccines. FDA has responsibility for all other drugs  
15 that are used in animals.

16 A PARTICIPANT: Okay.

17 MR. WOOD: Can people on the edge ask questions  
18 or not?

19 MS. RIGGINS: Sure.

20 MR. WOOD: I'm always on the edge but --

21 (Laughter.)

22 -- sometimes over the edge. I'm Richard Wood  
23 with FAC.

24 MS. RIGGINS: Right.

25 MR. WOOD: In the -- and, by the way, like the  
26 vaccine for SE, Salmonella enteriditis, is an FDA-  
27 regulated question and not an APHIS question. Okay.



1 Will -- maybe you can say or maybe you can't say -- but  
2 does the proposed rule coming from USDA address any on-  
3 the-farm questions --

4 MS. RIGGINS: No.

5 MR. WOOD: -- in terms of egg safety?

6 MS. RIGGINS: No. Our proposals will only  
7 address egg packers and egg pasteurization --

8 MS. ESKIN: Right.

9 MS. RIGGINS: -- practices.

10 MS. ESKIN: Egg products.

11 MS. RIGGINS: Egg products.

12 MR. WOOD: Okay.

13 MR. JAN: So once it leaves the chicken it goes  
14 to FSIS?

15 MS. ESKIN: Once it leaves the farm --

16 MR. JAN: The farm.

17 MS. ESKIN: -- once the shell is cracked.

18 (Laughter.)

19 (Multiple voices.)

20 MS. ESKIN: Leaves the farm, right?

21 MS. RIGGINS: Once the whole egg leaves the  
22 farm.

23 MR. JAN: But if you have a packer on the farm  
24 --

25 A PARTICIPANT: Yeah.

26 A PARTICIPANT: Yeah.

27 A PARTICIPANT: Yeah.

1 MS. RIGGINS: Well, we've talked about that.  
2 Those are companies or, you know, concerns that are going  
3 to be under dual jurisdiction and we're going to work out  
4 an arrangement given that we planned to work through  
5 contracts with the states to make sure that the  
6 requirements that FSIS has in place and the requirements  
7 that FDA has in place are verified but that we're not  
8 sending two and three people on to one farm.

9 So we'll make sure that the verification  
10 responsibilities are carried out by one person who will  
11 be an agent of both FDA and FSIS.

12 MS. JOHNSON: So you wouldn't have FDA if  
13 you're, as Dr. James said, you have a farm with a  
14 processing facility right there; there would never be a  
15 time when you'd have somebody from FDA and somebody from  
16 USDA in the same spot.

17 MS. RIGGINS: We'll make sure that we are  
18 coordinating it.

19 MS. JOHNSON: Mm-hmm.

20 MS. RIGGINS: Because one of the goals of the  
21 egg safety action plan is to use our resources  
22 efficiently. So, you know, it would be -- not be cost-  
23 effective for us to have, you know, more than one person  
24 going to actually do the verification.

25 MS. ESKIN: I just want to clarify, too. This  
26 distinction is one that's based in the laws or one that's

1       been sort of an agreement between the two agencies as to  
2       who will handle what?

3               MS. RIGGINS:   At the time that we worked  
4       through all the issues in the egg safety action plan we  
5       looked at the authorities that are currently in our  
6       statutes --

7               MS. ESKIN:   Mm-hmm.

8               MS. RIGGINS:   -- and we made decisions based on  
9       those authorities that we currently have and we did not  
10      go beyond those authorities.

11              Now there are -- as Joe Levitt talked about,  
12      FDA has not exerted a lot of authority on the farm  
13      because they haven't had the resources.  We also have not  
14      exerted authority at egg packers, although the authority  
15      has been in the EPIA since, you know, its inception.  So  
16      there are areas that were untapped in each of the  
17      statutes and we are using them, maximizing them.  I'm  
18      sorry.  Randy?

19              MR. GREEN:   No, No.  I didn't mean to  
20      interrupt.

21              MS. RIGGINS:   Yeah.

22              MR. GREEN:   Well -- Randy Green, United Egg  
23      Producers.  Maybe just as a point of information, one of  
24      the reasons that this topic you raised is so important is  
25      that it is today more the norm than the exception that a  
26      commercial egg operation has both henhouses and a packing

1 plant. These are called in-line operations as opposed to  
2 offline operations where the egg is transported --

3 A PARTICIPANT: From someplace else.

4 MR. GREEN: From the henhouse to --

5 A PARTICIPANT: Mm-hmm.

6 MR. GREEN: -- to a central packing facility.

7 So, obviously, one of the concerns that we've  
8 consistently heard from producers, the questions is, will  
9 we, in fact, have sort of duplicative regulation? This  
10 is why we're so gratified when Judy says things like she  
11 just did because, obviously, they would like to see  
12 regulation made consistent and not duplicative.

13 The only other point of information I was going  
14 to add on this subject is that another agency, the  
15 Agricultural Marketing Service, presently does have  
16 responsibility for what's called a quarterly showing  
17 surveillance program. This also is impacting houses. So  
18 they're there --

19 MS. ESKIN: Is that generally a quality  
20 control?

21 MR. GREEN: It has -- I think it's fair to say  
22 that it would have both quality and food safety --

23 MS. ESKIN: No, I understand that.

24 MR. GREEN: They also, they also in about a  
25 third of the operations do voluntary grading, which is  
26 more oriented towards quality.

27 MS. ESKIN: Toward quality, right.

1           MR. GREEN: To have some, some safety  
2 implications because it regulates things like the  
3 temperature --

4           MS. ESKIN: The temperature.

5           MR. GREEN: -- in the wash water.

6           MS. JOHNSON: Judy, does the FDA currently have  
7 statutory authority to go on the farm? I know Joe today  
8 was talking about going to Congress and trying to expand  
9 their statutory authority but I didn't quite understand -  
10 -

11          MS. RIGGINS: No. They currently have  
12 authority to go on the farm.

13          MS. JOHNSON: They just don't have any money.  
14 (Multiple voices.)

15          MS. RIGGINS: Yeah. It's money that really --

16          MS. ESKIN: Okay. I'm sorry. I didn't --

17          MS. RIGGINS: Yeah. He has the authority.

18          MS. ESKIN: And obviously, this whole issue  
19 does show what the scope of what we will talk about  
20 because, obviously, in this situation it kind of brings  
21 to light this issue of resources between agencies and  
22 priorities and everything else. I assume that we're  
23 going to discuss only FSIS' role and we won't touch on  
24 FDA's role? Or we would be able to discuss all of it?

25          MR. MORSE: I think we can cover that. For  
26 example, number 2 would probably have the second question  
27 relate to communication and interaction.

1 MS. ESKIN: Okay.

2 MR. MORSE: So that might be a good point to  
3 bring that up.

4 MS. ESKIN: Mm-hmm.

5 MR. MORSE: I guess I'll -- it's just a  
6 question of clarification again because we really have  
7 the two page general statement. I mean you get a lot  
8 more information in your presentation but it isn't like  
9 we have a proposed rule to comment on because that's not  
10 available.

11 So to a certain extent the questions seem very  
12 general, but not having seen the rule, right, we're just  
13 sort of asked to comment and make some general comments  
14 regarding these questions but -- rather than reacting to  
15 the rule at this point because that's not available.

16 MS. RIGGINS: Right. You'll have an  
17 opportunity to comment and we will also have a public,  
18 more public meetings because I'm sure that there are  
19 going to be issues that will emerge as ones that we need  
20 to have both general meetings on and then technical  
21 meetings just as we do with the meat and poultry HACCP.

22 There were a number of technical issues that  
23 had to -- that had enough substance that they were the  
24 subject of a meeting, you know, by themselves. So we had  
25 a number of meetings. So, yes, you'll have an  
26 opportunity to comment on all of the issues related to  
27 the program.

1 MS. JOHNSON: When you talk about publishing a  
2 proposed rule and having several meetings I think that  
3 would be really good when we do the HACCP rule from doing  
4 cultures. Are you looking at doing this in conjunction  
5 with FDA so that the proposed rule will be published  
6 close to the same time?

7 MS. RIGGINS: Right. They're going to be  
8 published as a package.

9 MS. JOHNSON: Okay.

10 MS. RIGGINS: We have already briefed on the --  
11 when was it? August? August when we did our public  
12 meeting?

13 A PARTICIPANT: Yes.

14 MS. RIGGINS: Our last public meeting on  
15 current thinking. Prior to that August meeting we went  
16 to OMB and presented the framework.

17 MS. JOHNSON: FSIS --

18 MS. RIGGINS: And OMB.

19 MS. JOHNSON: Okay.

20 MS. RIGGINS: And our understanding with OMB is  
21 that the four components, FDA's two proposals and our two  
22 proposals, will publish as a package. We would, in  
23 conjunction with FDA, have public meetings so that all of  
24 the components could be discussed and we will get, you  
25 know, comprehensive comments about all of the proposals.

26 MS. JOHNSON: Okay.

1 MS. RIGGINS: Because they -- you know, they  
2 fit together.

3 MS. JOHNSON: I think that the committee should  
4 -- whether we do it through a recommendation or support,  
5 but I think that's a good way to do it, to allow the  
6 commenters to have both -- do it as a package and to have  
7 both rules and everything to comment at once. I would  
8 hope that the committee would come forth with their  
9 support for that or something. Chairperson Morse?

10 MR. MORSE: Yeah. I think that's a good  
11 comment but I guess I sort of related -- we can only make  
12 these general comments --

13 MS. JOHNSON: Yeah.

14 MR. MORSE: -- on three questions --

15 MS. RIGGINS: Right.

16 MR. MORSE: -- without having seen the draft  
17 rules. So I think, to be honest, it's going to be  
18 somewhat general because I think we're going to have to  
19 review those to comment and also GAO's report. It does  
20 have a flow diagram trying to explain responsibilities,  
21 but I don't know if it may have changed a little bit in  
22 terms of trying to define because it has USDA and FDA  
23 overlap in a number of places --

24 MS. JOHNSON: Right.

25 MR. MORSE: -- on the boxes. So --

26 MS. ESKIN: But it does flag lots of issues.



1           MR. MORSE: Right. Right. But I guess tonight  
2 we were only supposed to address the three questions in  
3 general.

4           MS. RIGGINS: But if they're, but if they're  
5 issues, yes. I mean to focus on the questions whether  
6 they're issues that are in the report that you believe  
7 are germane to these questions then I don't think there  
8 is anything to preclude you from including those concerns  
9 or comments or recommendations.

10           I mean you have the -- you know, the authority  
11 to decide how broad your comments are going to be. I  
12 mean we're looking to get your best thinking so it's up  
13 to you.

14           A PARTICIPANT: Is it safe to say that the  
15 proposed rule addresses a lot of what are in these  
16 reports as far as the points of concern that were brought  
17 up in the GAO report?

18           MS. RIGGINS: To the extent that we are working  
19 to maximize the use of our collective statutory  
20 authorities in a coordinated way and that with each  
21 initiative, this one being one, this theory being an  
22 example of another, that we are learning to address the  
23 issues in a comprehensive way understanding that the --  
24 that they're not specific to meat and poultry but they  
25 also apply, you know, to fresh fruits and vegetables and  
26 game animals and cheeses and, you know, dairy products  
27 and seafood.

1           This has become a model for us. I mean I don't  
2 see us changing the way that we do our work, you know.  
3 Going back to the way that we used to do our work. I  
4 think that we worked on a model that is helping us to  
5 work through the problems because they're too complex for  
6 just one agency to deal with.

7           No one agency has enough resources. No one  
8 agency actually has all of the expertise in one place.  
9 So sharing across agency lines is certainly, you know,  
10 what I see us doing, you know, over the -- over the next,  
11 you know, 10 or 20 years until there's some better  
12 information that will allow us to, you know, to change  
13 again to improve on what we're doing.

14           But I'm not sure what you mean by, does it  
15 address every one of the issues. I don't think it  
16 addresses every one of the issues that is in the GAO.  
17 With respect to eggs from farm to table, this is our best  
18 thinking at this time.

19           MR. MORSE: Okay.

20           MS. LEVINE: I seem to recall that one big  
21 issue at GAO kept referring to back to this question of  
22 jurisdiction. Not only does no one agency have the  
23 expertise, but no one agency has the legislative power --

24           MS. ESKIN: Currently, right.

25           MS. LEVINE: -- to do this. Therefore, until  
26 some type of --

27           MS. ESKIN: Consolidation?

1 MS. LEVINE: Changes are made to the laws we  
2 can't, even though GAO repeatedly says, why is it like  
3 this? You should change it. Well, we can't change it --

4 MR. MORSE: Right.

5 MS. LEVINE: -- so until that happens this is  
6 the only way to deal with that issue.

7 MR. MORSE: Okay.

8 MS. LEVINE: That was a big concern.

9 MR. MORSE: Right. Okay. Well, any other  
10 clarifications, comments?

11 MR. WOOD: Well, just one and I think it's  
12 germane and it's looking way down the pike, but at what  
13 point in the rulemaking process or once the rule is  
14 complete does the appropriation process begin? Are we  
15 looking at -- which fiscal year for that which is a very  
16 important part of this whole puzzle, I would think?

17 MS. RIGGINS: Right. Well, right now we're in  
18 --

19 A PARTICIPANT: Just about it.

20 MS. RIGGINS: -- we're just finishing 2002.  
21 We've received our marks from the department and the  
22 formulation for 2003 will begin very soon. I'm not --  
23 part of it has to do with the fact that we don't have  
24 politicals in place. We don't have an undersecretary in  
25 place. But the formulation for 2003 would -- will begin  
26 very soon.

27 What we anticipate is that we currently have

1     \$2 million in the budget that was allocated for this year  
2     to use to actually develop the rule. So we have a number  
3     of issues that we are working now, contracts for  
4     gathering information for the cost benefit analysis of  
5     the final rule working on the egg baseline, which is a  
6     study to determine the number of pathogens in eggs before  
7     breaking and after -- I mean after breaking but before  
8     pasteurization.

9             MR. WOOD: Before pasteurization.

10            MS. RIGGINS: Developing a pilot protocol or a  
11     plan for standard sanitation SOPs for egg-packing. So we  
12     have a number of activities that are going on.

13            We anticipate that we will again ask for the  
14     \$2 million in 2002 to continue these efforts and to begin  
15     to look at the development of training because we know  
16     that training is going to be the next big, big initiative  
17     for us because we're planning to train all FDA, FSIS,  
18     AMS, APHIS and state inspectors, you know, as a group.

19            So Fiscal Year 2002 will likely be that year of  
20     developing the training materials. In 2003 then, we will  
21     have -- when we formulate 2003 we will have to ask them  
22     for money because we will anticipate having gone to a  
23     final rule and we'll then be asking for money for  
24     contracts with the states because that would be the first  
25     year, if I've got it right, of actually working through  
26     the verification activities doing the education effort,  
27     you know, with all of the producers and egg packers and

1 egg processing plants. So 2003 would be the first year  
2 that we would ask for money for contracts with the  
3 states.

4 MR. WOOD: Okay. Thanks.

5 MR. MORSE: Okay. We can ask for  
6 clarifications as we go on. Why don't we start  
7 approaching the question and then we'll ask for  
8 clarification.

9 The clarification helps but I guess we're  
10 struggling in terms of approaching the first question and  
11 my understanding is that, for example, the GAO report  
12 recommended that to enhance safety protections in egg  
13 products processing plants we recommend that the  
14 Secretary of Agriculture develop regulations to require  
15 these plants to implement HACCP systems.

16 From the two pages we have, look on the first  
17 bullet, "So FSIS intends to propose to require egg  
18 packers and egg-product producers to develop and  
19 implement hazard analysis and critical control point  
20 systems for the prevention of biological chemical and  
21 physical food safety hazards.

22 If I understand the first question, we're asked  
23 to comment based on experience with HACCP what comments  
24 or suggestions we would have on the implementation of a  
25 proposed FSS egg food safety plan, the limitation being  
26 we haven't officially seen the proposed plan.

27 MS. ESKIN: Right.

1           MR. MORSE: So that's why it seems like our  
2 discussion has to be general, if the Agency's going ahead  
3 with the proposed HACCP on what suggestions we have on  
4 how that's implemented not knowing the total plan.

5           MS. ESKIN: Can I --

6           MR. MORSE: Yeah.

7           MS. ESKIN: -- I hate to keep asking for  
8 clarification but this specifically relates to HACCP  
9 which again is mentioned in this short two-page outline  
10 and it's mentioned in GAO. How does the, how does the --  
11 as best you can say it, how does the HACCP idea as  
12 currently developing for eggs relate to the kind of  
13 systems you have in states like Pennsylvania? I mean  
14 those are called something else. Those aren't called --  
15 I might have mischaracterized -- they're not really  
16 called like a HACCP program, they're quality assurance  
17 programs?

18           MR. WOOD: They usually call it quality  
19 assurance.

20           MS. ESKIN: How do they compare? How do they  
21 relate? Do they have similar features? It is a totally  
22 different approach?

23           MS. RIGGINS: Well, to clarify, the program  
24 that is in place in Pennsylvania and one in California,  
25 for instance, are quality assurance programs on the farm.

26           MS. ESKIN: Right. Relating only to --

1 MS. RIGGINS: So those -- yeah. And what FDA's  
2 planning to do is take the best management practices from  
3 those quality assurance programs and to propose to  
4 require those across all 50 states.

5 MS. ESKIN: Right. At that point on the farm  
6 and then when you --

7 MS. RIGGINS: ON the farm.

8 MS. ESKIN: -- get to processing which may, in  
9 fact, be on the farm, but the actual processing --

10 MS. RIGGINS: When you hit the --

11 MS. ESKIN: -- piece of it.

12 MS. RIGGINS: -- packing --

13 MS. ESKIN: Packing. Sorry.

14 MS. RIGGINS: -- which is shell eggs being  
15 washed and sanitized and put into cartons --

16 MS. ESKIN: Right.

17 MS. RIGGINS: -- for consumer use, then we are  
18 proposing HACCP and sanitation standard operating  
19 procedures. Likewise, we are also proposing HACCP and  
20 sanitation operating procedures for --

21 MS. ESKIN: Processing.

22 MS. RIGGINS: -- breaking and pasteurization.

23 So that is the -- but it is not HACCP on the farm --

24 MS. ESKIN: Yeah, it's --

25 MS. RIGGINS: -- it's quality assurance --

26 MS. ESKIN: -- quality assurance.

27 MS. RIGGINS: -- requirements.

1 MS. ESKIN: Right.

2 MR. MORSE: And so question 1 based back again,  
3 you want our comments on the implementation of HACCP  
4 SOP's in a packaging processing plant? That's -- and I  
5 guess it has to be general without seeing the specifics,  
6 right?

7 MS. LEVINE: Well, basically what we've done in  
8 meat and poultry plants is what we would like to do in  
9 packing and processing. So the regs that are already on  
10 the books for meat and poultry --

11 MR. MORSE: Right.

12 MS. LEVINE: -- would in general be the regs  
13 that we would like to apply.

14 MS. ESKIN: Right. Although then that leads to  
15 another question which is from your perspective what  
16 makes the egg-packing and processing different? Now  
17 there's obviously lots of different steps in meat and  
18 poultry. In principle, you'd have a lot of the same  
19 structure in terms of -- but let me ask it a different  
20 way. What particular safety issues do eggs raise that  
21 aren't raised in these other FSIS-regulated areas?

22 MS. RIGGINS: You mean with regard to --

23 MS. ESKIN: Well, I mean --

24 MS. RIGGINS: -- with regard to the specific  
25 pathogens --

26 MS. ESKIN: Well, yeah, I mean --

27 MS. RIGGINS: -- are concerned?



1 MS. ESKIN: -- salmonella is obviously the one  
2 --

3 MS. RIGGINS: Salmonella is the primary for  
4 shell eggs.

5 MS. ESKIN: Right.

6 MS. RIGGINS: Vicki, do you want to talk about  
7 the information that we received about other pathogens in  
8 shell --

9 MS. ESKIN: Mm-hmm.

10 MS. RIGGINS: -- on or in shell eggs or in  
11 pasteurized eggs?

12 MS. LEVINE: So far salmonella is, of course,  
13 the big one.

14 MS. ESKIN: Right.

15 MS. LEVINE: The only other one -- well,  
16 proscilla seros (phonetic) is a question mark. There has  
17 been a report or two that it was found in pasteurized egg  
18 products. However, it's never really been confirmed that  
19 that was the case.

20 MS. ESKIN: Okay.

21 MS. LEVINE: So that remains a bit of a  
22 question. There are questions about, for example,  
23 listeria, DT104. But there's not a lot of research out  
24 there that says yea or nay. Actually, it tends to be  
25 towards the nay side.

26 MS. ESKIN: Mm-hmm.

1 MS. LEVINE: But we are looking -- we keep on  
2 looking for research that's done, anything that can help  
3 us try to figure out what is really out there.

4 MS. ESKIN: Right. And again, certainly at the  
5 point before you reach processing. I mean you have an  
6 egg.

7 MS. LEVINE: Mm-hmm.

8 MS. ESKIN: Is there any contamination at all  
9 that can occur on the shell or inside the eggs.

10 MS. LEVINE: Right.

11 MS. ESKIN: So --

12 MS. RIGGINS: So you'd have the same chemical  
13 and physical hazards --

14 MS. ESKIN: Right.

15 MS. RIGGINS: -- that you have with, you know,  
16 with meat and poultry and other foods, you know.  
17 Pesticides would be an issue, of course.

18 MS. ESKIN: Mm-hmm.

19 MS. RIGGINS: I mean there are some issues that  
20 are cross-cutting for, you know --

21 MS. ESKIN: Right.

22 MS. RIGGINS: -- for most foods that are  
23 processed.

24 MS. KASTER: So you would still take the  
25 approach of the three types of contaminants which you've  
26 just described.

27 MS. RIGGINS: Right.

1 MS. KASTER: Physical, chemical and biological.

2 MS. ESKIN: And there's no difference? I mean

3 --

4 MS. KASTER: Well, they're categorically as how  
5 from --

6 MS. ESKIN: Sure.

7 MS. KASTER: -- developing the HACCP plan for  
8 those that -- just like there would be differences in how  
9 you'd approach turkey versus pork or --

10 MS. ESKIN: Sure.

11 MS. KASTER: -- or beef versus ground beef  
12 versus --

13 MS. KASTER: And certainly if you took the  
14 whole range of possible contaminants and you ranked them,  
15 you know, in terms of those other contaminants may be  
16 pretty --

17 MS. ESKIN: Relative to risk.

18 MS. KASTER: -- yeah, relative to risk is  
19 pretty remote as compared to SE.

20 MS. JOHNSON: We keep -- we just mentioned  
21 risk, but I have to bring this up. But if the Agency is  
22 proceeding with a HACCP role and one of the questions is  
23 on the -- what's the experience on the implementation of  
24 HACCP? All I have to judge it on is meat and poultry.

25 Have you -- it seems a little unusual that the  
26 Agency's moving ahead with proposing a HACCP role on  
27 another product until some of the implementation issues

1 on meat and poultry have been resolved. That looks like  
2 it's a little unfair. Are you proceeding in the egg role  
3 to make the HACCP concept consistent with the 1997 paper?

4 Are you -- you know, there are a lot of issues  
5 in meat and poultry that still need to be resolved that  
6 the Agency is working through. Are you --

7 MS. RIGGINS: Well, to the extent --

8 MS. JOHNSON: How does this all fit?

9 MS. RIGGINS: -- to the extent that we are --  
10 we have lessons learned from meat and poultry we will not  
11 --

12 MS. JOHNSON: To date, obviously.

13 MS. RIGGINS: -- we will not make those  
14 mistakes again with eggs and egg products. So any of the  
15 improvements that we make with regard to HACCP and meat  
16 and poultry will automatically be adopted for eggs.

17 In other words, we're not going to go back to  
18 1996. We will, you know, take benefit off all that we've  
19 learned. But when you said that you think that it's  
20 unusual that we're going forward --

21 MS. JOHNSON: Well, you have a petition from  
22 the meat and poultry industry.

23 MS. RIGGINS: Right.

24 MS. JOHNSON: And so we need to talk about is  
25 this --

26 MS. RIGGINS: Right.

27 MS. JOHNSON: -- related to --

1 MS. RIGGINS: Right.

2 MS. JOHNSON: -- HACCP and the way FSIS  
3 implemented it and the interpretation of the HACCP  
4 regulation. I'm just wondering if the committee would --  
5 I don't know how we do this. Do we formally say -- do we  
6 want a recommendation that these issues be looked at and  
7 tried --

8 MS. ESKIN: Are you saying to wait then to do  
9 it in April?

10 MS. JOHNSON: Well, not necessarily wait. It's  
11 still in the proposed rule stage.

12 MS. ESKIN: Right. Right.

13 MS. RIGGINS: It's not even in the proposal.

14 MS. ESKIN: Yeah. Just understand where they  
15 are relative to --

16 MS. JOHNSON: No. I understand that. I mean  
17 it looks like because if there are changes to the meat  
18 and poultry regulation then it looks like you could save  
19 a lot of --

20 MS. RIGGINS: Yeah.

21 MS. JOHNSON: -- time and energy. As you were  
22 talking about today in jobs, talking about the smaller  
23 guys, is it fair to subject them to this and this and  
24 this?

25 I'm not saying, you know, propose, but as part  
26 of the proposal, you know, solicit comments on some of  
27 the issues that are still out there with the petition

1 because it looks like to move forward without addressing  
2 some of the issues in the petition is kind of ignoring  
3 some of the new progress that has been made.

4 MR. MORSE: Maybe we could list some of these.  
5 Okay. Since we still don't have the rule, in the  
6 development stage --

7 MS. JOHNSON: Yeah.

8 MR. MORSE: -- things that we would recommend  
9 they do at this point. So one would be to, you know, to  
10 review and learn lessons from --

11 MS. JOHNSON: To resolve. To come to some  
12 resolution with some of the implementation issues, you  
13 know, like on the training and on -- you know, do you  
14 look at the 1997 paper? Is that what you base your HACCP  
15 system on? You know, a whole lot of the training of the  
16 inspectors I think would be a big issue, too.

17 MS. LEVINE: On an issue like that, for  
18 example, we already know that there were some problems  
19 with that.

20 MS. JOHNSON: Sure.

21 MS. JOHNSON: You know, so we already have  
22 changed the approach to how that's going to happen  
23 because we know it was not successful the first time.

24 MS. RIGGINS: That doesn't preclude the group  
25 from giving us that recommendation.

26 MS. ESKIN: Sure, yeah.

1 MS. JOHNSON: Well, now this gets into what Dr.  
2 Morse was saying --

3 MS. ESKIN: Yeah.

4 MS. JOHNSON: -- we don't have the role but you  
5 heard the discussion today --

6 MS. ESKIN: Oh, sure.

7 MS. JOHNSON: -- on prerequisite programs, you  
8 know. I mean here I know the meat and poultry industry  
9 is going round and round and round about that within my  
10 own member companies as well as there's disagreement and  
11 there's disagreement within the Agency, between the  
12 industry and the Agency.

13 MR. MORSE: Right.

14 MS. JOHNSON: And it looks like for there to be  
15 some resolution to that might be beneficial to the egg  
16 industry.

17 MS. LEVINE: There are significant differences  
18 between meat and poultry --

19 MS. ESKIN: And eggs.

20 MS. JOHNSON: -- and eggs in that arena, you  
21 know what I'm saying.

22 MS. ESKIN: There is

23 MS. JOHNSON: Of the approximately 620  
24 something egg products -- egg packers that would fall  
25 under this rule maybe 150 of them have any type of  
26 regulatory presence right now. The rest of them see an  
27 AMS inspector once a quarter and that's it.

1 MS. ESKIN: But you're still implementing a  
2 HACCP or somewhere in the next two or three years --

3 MS. JOHNSON: Right. Absolutely.

4 MS. ESKIN: -- you'll be implementing that  
5 HACCP rule.

6 MS. ESKIN: That's the idea, but they don't --  
7 I like to look at it from the perspective of they don't  
8 already have prerequisite programs.

9 MS. KASTER: Exactly.

10 MS. ESKIN: They don't have --

11 MS. KASTER: Anything.

12 MS. ESKIN: -- anything. So this is not for  
13 them a change in -- yes, it's a change in thinking but -

14 MS. KASTER: It's something new.

15 MS. ESKIN: -- it's totally new.

16 MS. JOHNSON: Well, talk about half of the  
17 prerequisite programs that the meat and poultry companies  
18 have are not regulated programs.

19 MS. KASTER: That's right, yeah.

20 MS. JOHNSON: So do you know what they actually  
21 have, they have some sort of sanitation --

22 MS. KASTER: Right, right, right, right.

23 MR. JAN: -- you know.

24 MS. ESKIN: I mean I agree with your -- I  
25 understand your point, Alice, but again I have the same  
26 reaction which is HACCP has certain similarities across  
27 HACCP systems. I could be wrong here, but this does seem



1 in many ways a different -- present lots of different  
2 issues, perhaps less complicated issues than a lot of the  
3 meat and poultry HACCP issues.

4 It is a significant public health concern,  
5 certainly salmonella is. Certainly for the people at  
6 AARP and, you know, it is a clearly identified public  
7 health problem that has arisen in the last whatever  
8 period of time.

9 I agree, we shouldn't make the same mistakes  
10 twice but I think there's -- it's fair to acknowledge  
11 that there's other things going on that need to be  
12 considered, but I don't think it should in any way slow  
13 down what already is, from many people's point of view,  
14 too slow.

15 I mean the reality is actually if we could  
16 really open this up we should be focusing on-farm -- and  
17 that's not even HACCP, but all the on-farm --

18 MS. JOHNSON: I'm not saying to slow down.

19 MS. ESKIN: No. I know. But --

20 MS. JOHNSON: The meat and poultry --

21 MS. ESKIN: -- I want to make sure --

22 MS. JOHNSON: -- industry petition the Agency  
23 to go for HACCP like five years before they actually did  
24 it.

25 I'm just saying is there not a need to do some  
26 benchmarking with what we're already done and to resolve

1 some of the issues before you? Because it's going to  
2 cost these people.

3 It's going to -- it's not going to slow  
4 anything down, it's just going to -- you know, look at  
5 these issues as we go through the proposed rule and say,  
6 "This is something that's not resolved in the -- you  
7 know, if it's an issue for the larger companies how's it  
8 going to be in with the smaller guys that aren't used to  
9 --

10 MS. ESKIN: Right. But theoretically, very  
11 theoretically, assume that you've got these tracks going  
12 and the egg -- FSIS's egg proposal comes out. And let's  
13 say that some of these issues have yet to be resolved in  
14 the meat and poultry context, that stuff we talked about  
15 today, then what happens? Theoretically, that might --

16 MR. JAN: It's coming out as a proposed rule.  
17 It won't be finalized probably for another three years.

18 MR. MORSE: Maybe we can ask our industry  
19 observers to be with the group. We'd ask the industry  
20 observers are there like prerequisite programs that are  
21 in the industry now?

22 MR. GREEN: There are a number of programs.  
23 One of them -- one of the things I was going to offer was  
24 maybe like just a couple of points structurally about the  
25 industry as well.

26 But in the processing side, and we are  
27 fortunate enough to represent both producers and

1 processors, the processing side these are further egg  
2 products, liquid eggs --

3 MS. ESKIN: Right.

4 MR. GREEN: -- and so on.

5 MS. ESKIN: Eggbeaters.

6 MR. GREEN: A significant number -- I dare say  
7 a majority of companies there have HACCP plants. They  
8 have them --

9 MS. ESKIN: Okay.

10 MR. GREEN: -- because their customers expect  
11 it.

12 MS. ESKIN: Mm-hmm.

13 MR. GREEN: I don't know that that's a majority  
14 but I believe it is.

15 MS. ESKIN: You think it is?

16 MR. GREEN: But I think it is. In the packing  
17 side, which as I said earlier, is largely -- it's now  
18 with the producer side. Okay. To my knowledge they  
19 generally are not HACCP programs, per se. However, the  
20 majority of the producers have these quality assurance  
21 programs. As we have discussed, those have implications  
22 in the packing plant, as well.

23 APHIS did a study called Layers '99 by the  
24 National Animal Health Monitoring Service, but it's a  
25 survey, a statistically valid survey, of the whole egg  
26 laying industry, very interesting stuff, quite relevant  
27 to what you're talking about here.

1 I don't remember the exact percentage, but on  
2 the order of 60 percent of the number of operations which  
3 we translate into a substantially higher portion of total  
4 production had quality assurance programs of some type or  
5 other --

6 MS. ESKIN: Is there --

7 MR. GREEN: -- since 1999.

8 MS. ESKIN: I'm sorry. These are --

9 MR. GREEN: These were production sites so I  
10 believe this would include both -- somebody that knows  
11 the study better than I should correct me -- but I  
12 believe this would include both operations which are in-  
13 line which would be both packers and producers as well as  
14 offline production operations.

15 That's partly by way of saying my guess is that  
16 all of this is actually implemented -- there might be --

17 (Away from microphone.)

18 MS. ESKIN: -- did that study, the APHIS study?

19 MR. GREEN: The Animal Plant Health Inspection  
20 Service, APHIS.

21 MS. ESKIN: APHIS. Okay. Yeah.

22 MR. GREEN: And, specifically, their national  
23 animal health monitoring service, NAHMS system, yes.

24 MR. GREEN: That's on the Internet. You can --

25 MS. ESKIN: That's why they knew every species.

26 MR. GREEN: It's a very -- it's a highly  
27 respected -- I mean they do a very great job --

1 MS. ESKIN: Great. Great.

2 MR. GREEN: -- to protect the sources and so  
3 they have statistically --

4 MS. ESKIN: Great.

5 MR. GREEN: -- (inaudible).

6 MS. JOHNSON: I'm not asking that we postpone  
7 anything but what I'm saying is in the preamble in the  
8 proposal should you solicit comments on the same type of  
9 issues that we have in the meat and poultry and try to  
10 come to some resolution before you get a final rule? I  
11 mean, you know, we know we have the industry petition has  
12 caused a lot of problems in implementation --

13 MR. GREEN: Right.

14 MR. JAN: -- from what my members are saying  
15 but I don't know -- you see, the proposal whether you've  
16 addressed --

17 MS. ESKIN: Yeah.

18 MS. JOHNSON: -- you've asked for specific  
19 comments, you know, here's what we heard from the meat  
20 and poultry industry, would the egg guys like to comment?

21 MS. ESKIN: Yeah.

22 MS. JOHNSON: Would somebody like to say, do  
23 you think this will be an issue?

24 MS. ESKIN: Right. For you? Right.

25 MS. JOHNSON: Yeah.

26 MS. ESKIN: You're saying just open it up and  
27 say if there's anything --

1 MS. JOHNSON: And be sure that the proposal so  
2 that you can -- you know, if you don't have it resolved  
3 in meat and poultry then you can solicit more input and  
4 maybe even ask for specific data on, you know, what type  
5 of prerequisites are out there, you know. What's  
6 available. What issues do we need to be concerned with  
7 before we go back and do a final rule.

8 (Multiple voices.)

9 MS. LEVINE: I believe we have nothing.

10 MR. MORSE: I was going to say how --

11 MS. LEVINE: We have said that the petition is  
12 out there and let's do comments on it.

13 MR. MORSE: Maybe I think they should just do  
14 some general principles, like I've jotted down three  
15 that, you know, since we have the rule to comment, there  
16 are some general --

17 (Laughter.)

18 -- things that we recommend that you put in the  
19 discussion. So, for example --

20 MS. JOHNSON: That's what I'm saying here.

21 MR. MORSE: -- one, use lessons learned. Use  
22 different wording. Use lessons learned from the meat and  
23 poultry --

24 MS. JOHNSON: Yeah.

25 MR. MORSE: -- HACCP limitation --

26 MR. JAN: That's relevant.

27 MR. MORSE: Right.

1 MS. ESKIN: Or is this relevant?

2 MR. MORSE: Developing the rule, that's one.  
3 Second, review and consider -- I can't read my own  
4 writing.

5 MS. ESKIN: Is this it?

6 MR. MORSE: Yeah. Consider merits of existing  
7 prerequisite programs and HACCP programs because we're  
8 hearing that some of these are already --

9 MS. ESKIN: And also quality assurance  
10 programs, right? That's the term and word.

11 MR. WOOD: Can I make a comment on number 2 or  
12 number 3? Oh, you want to say 3 first?

13 MR. MORSE: Well, just run through whether the  
14 group wants some general principles then we can -- maybe  
15 we should work on those. What they should do because the  
16 next thing is are the rules going to be out and how  
17 you're going to implement it. But it seems like the  
18 group -- there's been a lot of discussion that some  
19 things should be taken into consideration before you get  
20 there.

21 The third was, you know, something about asking  
22 for comments on implementations of the HACCP before it's  
23 released as a draft rule. So I guess the sense of the  
24 group, do you want to have some general principles of  
25 things that we --

1           MR. JAN: Before we get there, it seems to me  
2 that the 416 and 417 are generic enough that they could  
3 apply to the egg business and then --

4           MS. ESKIN: Like 416 is the SOPs.

5           MR. JAN: That's the SOPs.

6           MS. ESKIN: And 417 is HACCP.

7           MR. JAN: And 417 is HACCP.

8           MS. ESKIN: Planned development and stuff.

9           MR. JAN: Yeah. If you instead of coming up  
10 with a separate rule why not incorporate egg products and  
11 make the 416 and 417 apply to that? If 415 comes about  
12 and it works then we have 415; 416 and 417 are the only  
13 -- and 500 now -- but 416 and 417 are the only rules that  
14 apply both to meat and poultry.

15           At one time we said, well, because we have meat  
16 laws on this one, so we have to make some meat rules --

17           MS. ESKIN: Right. Right.

18           MR. JAN: -- but now they're moving to combine  
19 that and under that same thinking it seems to me that we  
20 could say, well, we could -- this HACCP and SSOPs is the  
21 generic issue and then the plants, the inspection, will  
22 be different. But that's --

23           MS. ESKIN: Yeah.

24           MR. JAN: -- that's going to be developed based  
25 on -- not on rules. You do that on policy or the egg  
26 inspection people will develop there, how often they  
27 inspect and how they write their documents and things.



1 MS. ESKIN: Mm-hmm.

2 MR. JAN: But it seems to me that that would be  
3 a simple way to go.

4 MS. ESKIN: But now I'm confused. We're still  
5 in the proposed rules stage, right? You're working on a  
6 proposed rule.

7 A PARTICIPANT: We're working on a proposed  
8 rule.

9 MS. JOHNSON: Okay. So there is no draft final  
10 rule or anything?

11 MS. LEVINE: No. All you've had is thinking  
12 papers.

13 MR. JAN: Yeah. Try to get it through the  
14 system.

15 MS. ESKIN: Thinking papers.

16 MR. JAN: Thinking -- thinking papers.

17 MS. ESKIN: I like that.

18 MR. JAN: But, you know, I think some of the  
19 issues that we've had in implementation have been 417 and  
20 maybe more --

21 MR. JAN: Sure.

22 MS. JOHNSON: -- the interpretation. I think  
23 that's something that should go into any kind of preamble  
24 when you talk about, you know, here's what's going on in  
25 meat and poultry and here's the issues that they -- we've  
26 seen an implementation there.

1           I also think it's real important that we hit on  
2 the training of the inspectors and getting people up to  
3 speed and, you know, if the Agency hasn't started  
4 thinking about that now then, you know, there's maybe a  
5 need to get the egg guys into, you know, meat and poultry  
6 plants and get the experience up so that once the final  
7 rule is -- it won't be like starting from ground zero.

8           MS. ESKIN: In response to what you just said,  
9 I don't know if you can tell us this but is the current  
10 thinking that you're going to have another set of C.F.R.  
11 rules that are just going to apply to eggs or this idea  
12 of trying to use this as a model?

13           MS. LEVINE: Correct me if I'm wrong, Judy, but  
14 I think we have been pretty clear in saying 416 and 417  
15 will apply to --

16           MS. ESKIN: Okay. That helps. Thanks.

17           MR. WOOD: Could I make just one comment?

18           MR. MORSE: Sure.

19           MR. WOOD: My organization has not only  
20 orientation of fact for consumers, but also we do have 14  
21 farms, but -- program in Pennsylvania on the East Coast.

22           We are in that nonstudy or in the industry  
23 study. The processors that we work with and packers  
24 there's one that has their HACCP program in-line and  
25 there's another one that is moving that way kicking and  
26 screaming.

1           If -- Judy, the numbers you said are 628  
2 packers nationwide and 150 -- only 150 under regulatory  
3 presence?

4           MS. LEVINE: They -- those 150 participate in  
5 AMS' volunteer regrading program.

6           MR. WOOD: Right. Have the others?

7           MS. LEVINE: (Shaking head.)

8           MR. WOOD: Right. And so my point is that I'm  
9 not sure how this compares to meat and poultry but I  
10 would caution, I would caution the process in developing  
11 rules to be sensitive to the uniqueness of the egg  
12 industry and there may need to be -- and also because of  
13 the inspectors being much more present in meat and  
14 poultry than they are with the egg processing industry.

15           Particular attention may need to be paid to  
16 training and education as opposed to simply getting  
17 enough inspectors trained and online but that training  
18 and inspection that would precede any -- even precede any  
19 rule coming down the pike I think would be very important  
20 to helping all these processors and packinghouses to  
21 respond faithfully.

22           MR. GREEN: Mr. Chairman, could I just agree  
23 with Rich's point for possibly slightly different  
24 reasons? I am not at all an expert on part 416. I did  
25 though attend the April meeting of the National Egg  
26 Regulatory Officials organization, which is the state-  
27 level regulators.

1           I recall a concern was raised there about  
2 whether part 416 may, since it is written for the meat  
3 and poultry sector, not necessarily be all that  
4 applicable to the egg and egg products industry in every  
5 case and that it may be better to sort of have something  
6 separate for eggs as opposed to trying to anticipate  
7 every situation that could come up where the existing  
8 regulation might need to be changed.

9           For example, in the egg products sector every  
10 egg that goes in further processing has to be pasteurized  
11 which is a good thing. But that's kind of a difference  
12 with the processing of these other products.

13           Another difference that I had begun to allude  
14 to earlier is that at the packing level most of these  
15 places don't have HACCP plans now. I don't know enough  
16 about HACCP to know how simple it's going to be for them  
17 to get them even where there's something like SSOP's and  
18 good manufacturing practices might --

19           MS. LEVINE: Yeah.

20           MR. GREEN: But there are some -- there are  
21 some differences and I know at least at that meeting that  
22 there were questions raised whether part 416 itself could  
23 be applied to the egg industry without change. I don't  
24 know that we have a real strong view on that but it's at  
25 least a question in our minds, as well.

26           MR. MORSE: Could that be viewed as another,  
27 you know, instead of what we've been doing discussing --

1       instead of going ahead and talking about implementation  
2       we're talking about a number of steps that I think  
3       (inaudible) the development of the proposed rule.

4                 MS. KASTER:   The HACCP -- mm-hmm.

5                 MR. MORSE:   There are a number of things that  
6       could be done.  So that could fit in as a fourth bullet  
7       if --- and somebody else can articulate it .

8                 It sounds like since a lot of the egg packers  
9       and processors or whatever aren't familiar with this does  
10       the group think that they actually should start educating  
11       them that this rule's coming, it's going to -- ASOP and  
12       SOP -- so that they can become familiar with what that  
13       might mean for them in the industry so that they could  
14       comment?

15                MR. JAN:    Certainly they need to have education  
16       but, you know, that can be made available through the  
17       HACCP alliance just like it was for meat and poultry  
18       plants.  I don't see that they need to have it -- you  
19       know, that the government was supposed to be required to  
20       provide the education.

21                MS. KASTER:  417 will cover training, anyway.  
22       It would be a requirement that's already in there that  
23       they'll be required to have sent somebody out for  
24       training anyway.

25                MS. RIGGINS:  This morning in the presentation  
26       I mentioned the fact that we are going to have an  
27       education effort for the egg producers and egg packers

1 that is similar to the one that we had for very small  
2 plants. If you'll recall, we prepared a kit.

3 MR. JAN: Right.

4 MS. RIGGINS: And for the purposes of meeting  
5 the requirements of 417 for training that kit was  
6 considered to be sufficient to meet that. So I mean we  
7 do intend to have a very aggressive education effort for  
8 egg producers and packers.

9 MS. KASTER: And egg processors?

10 MS. RIGGINS: We know that egg packers are  
11 going to be of particular concern because of what Vicki  
12 said. Very few of them have ever had anyone from a  
13 regulatory agency walk into their facility. So this is  
14 going to be very, very new.

15 A PARTICIPANT: A rude awakening.

16 A PARTICIPANT: Yeah.

17 (Multiple voices.)

18 MS. JOHNSON: Maybe they should start going  
19 into plants and just introducing themselves.

20 A PARTICIPANT: Right.

21 MR. JAN: I don't think they'll take advantage  
22 or any significant amount would take advantage of any  
23 training up until it becomes mandatory, and right at the  
24 deadline they're going to start scrambling for this  
25 training. I mean that's just from experience.

26 MS. JOHNSON: Human nature.

1           MR. JAN: They're not going to voluntarily get  
2           educated enough to make comments I don't believe. Now  
3           some of the associations might be able to but I don't  
4           think the packers and those people that are in the  
5           business. We didn't see that in the small meat and  
6           poultry people. They waited and they thought it was  
7           going to go away. They felt if they ignored it --

8           MS. JOHNSON: Right. You know, I can say that  
9           to some degree but I think -- and, Judy, no disrespect  
10          for the Agency -- but in the proposed rule the way they  
11          implemented the implementation in the proposed rule was  
12          different than the final rule. I think that was just  
13          because the smaller guys did start realizing, oh, my  
14          gosh, what's this going to do for us? They did have some  
15          impact there.

16          But I agree with you and I think the meat and  
17          poultry showed that, that the small guys didn't really  
18          get concerned about it until December.

19          MS. ESKIN: That was right --

20          MS. JOHNSON: And there was just a couple of --

21          MS. ESKIN: -- up against the deadline.

22          MS. JOHNSON: In January, yeah. I know you  
23          guys were sending to the circuit to do everything  
24          possible to get word out. So I don't, you know --

25          MR. MORSE: So in terms of recommendations to  
26          the Agency would we recommend that they start, you know,

1 some education in advance or do they wait until the  
2 proposed rule is --

3 MR. JAN: Well, they need to try to --

4 MS. RIGGINS: One of the things we did do for  
5 the very smallest we monitored the very smallest. We had  
6 --

7 MR. JAN: In that last year though.

8 MS. RIGGINS: Yeah, in that last year.

9 A PARTICIPANT: Are you saying you had all  
10 year?

11 A PARTICIPANT: Yeah.

12 MS. RIGGINS: There was a program in place  
13 where we determined how many had started working on their  
14 HACCP plans and we monitored them right up to the, you  
15 know, January 25th so that we were sure that we knew the  
16 majority of plants had HACCP plans already drafted.

17 You know, there were a few that, you know, that  
18 were still remaining on the effective date but I think  
19 without that effort we would have had a larger number.  
20 So, you know, I don't know to what extent we will be able  
21 to do that in this instance because we knew where they  
22 were.

23 (Laughter.)

24 Our hope is that we will have a better  
25 understanding of how -- what the universe of plants are  
26 because right now there are only a finite number that  
27 actually registered with AMS. We have to go out and seek



1 out the others, too. We need to find out where they are  
2 to register.

3 MS. JOHNSON: Even with the proposed rule  
4 didn't you guys go out across the country and, you know,  
5 did some things that I thought was wonderful to let, you  
6 know, people that normally -- yeah, the people --

7 MR. JAN: Here?

8 MS. JOHNSON: Yeah.

9 MR. JAN: Public meetings?

10 MS. JOHNSON: Public meetings.

11 A PARTICIPANT: Public meetings.

12 MS. JOHNSON: I went to one in Missouri.

13 A PARTICIPANT: Right.

14 MS. JOHNSON: They got word out and the small  
15 guys got there and they understood --

16 A PARTICIPANT: Field meetings.

17 MS. JOHNSON: Yeah. They understood, yeah,  
18 this is a proposal and it's coming and we need to know  
19 what's coming and we need to -- which maybe we should  
20 recommend that you follow that because I think that did -  
21 -

22 MR. JAN: Right.

23 MS. JOHNSON: -- have a big impact. A lot of  
24 you state guys got word out.

25 MR. JAN: I think that was the big difference  
26 is that because we have the state -- this is a state-

1 inspected program, basically. In fact, that meeting I  
2 think was in Kansas City you're talking about.

3 MS. JOHNSON: Yeah.

4 MR. JAN: And I think it was for -- primarily  
5 for state-inspected plants and I think the reason -- I  
6 mean the Federal plants, too, but the very small ones.  
7 But it's a very small plant deal.

8 But I think the reason they got interested or  
9 were so aware of it was because we in the state  
10 inspection program were telling them all along and also  
11 sharing some of their concerns and bringing those to the  
12 FSIS because we saw that as a killer for very small  
13 plants. So once we got, you know, then they started  
14 saying -- and, yeah, they did start getting in there.

15 MS. JOHNSON: Yeah.

16 MR. JAN: In those meetings so some kind of  
17 education effort or some kind of awareness effort --

18 MS. JOHNSON: Even on the proposal stage.

19 MR. JAN: Right. On the proposal. And I don't  
20 know how you get that kind of interest at the packer or  
21 produce -- packer and shell -- broken shell people since  
22 we don't have people in there all the time. I don't know  
23 how many are members of associations. You know, how  
24 would they, you know, get the work to them in some kind  
25 of way?

1 MS. JOHNSON: Maybe we should make a  
2 recommendation on the communication part that they do the  
3 town meetings like they -- during the --

4 A PARTICIPANT: Yeah.

5 MS. JOHNSON: -- proposal stage. Don't wait  
6 until the final rule's out, do it during the proposal  
7 stage and start getting them prepared. But now how do  
8 they get word out?

9 MS. ESKIN: You can do it here actually.  
10 Actually, because that communication --

11 MS. JOHNSON: Yeah.

12 (Static in sound system.)

13 MS. ESKIN: -- the way it's characterized here  
14 is just between all the regulators.

15 MS. JOHNSON: Well, we're expanding.

16 MS. ESKIN: Yeah, no.

17 MR. MORSE: Well, but we could also. Vicki?

18 MS. LEVINE: Meeting with everybody. I would  
19 like to take just a minute to explain how we've gotten to  
20 this point. We know that we have a lot to learn about  
21 egg packers. Because we know that there's been -- the  
22 main small group of people who have been working on this  
23 rule we've been going out now for a while and visiting  
24 packers.

25 Everyplace we go we tell them that this is  
26 what's coming down the line or what we think is coming  
27 down the line. We've had some people who don't really

1 react and we've had some people who are real smart  
2 cookies and they immediately, you know, you can just see  
3 everything work. Okay.

4 We are also going to be doing this packing  
5 pilot that's been mentioned once or twice where we will  
6 be going into facilities and actually trying out  
7 verification tasks to see if they're the right kind of  
8 tasks for packers. Okay. Maybe they are or maybe they  
9 aren't.

10 Now this is -- we've been working with A&S and  
11 the members of states to do this. We also have had an  
12 ongoing dialogue with NERO, as Randy mentioned. The  
13 state people have an incredible wealth of knowledge that  
14 we are trying to suck up like a sponge.

15 When I tell you this is the only rule I work on  
16 40 hours a week I'm not kidding. Because we are aware of  
17 how much has to be done, how far we have to move and how  
18 far the industry may have to move.

19 So, you know, while meat and poultry is sort of  
20 a slapdash job we're trying very hard to make this not be  
21 a slapdash job. We are also aware that we will come out  
22 with a proposal and we will get comments and we will most  
23 likely have to make changes in the final rule and we know  
24 that.

25 So we're not going in -- we're going in with a  
26 basic framework that has to be fleshed out. We know that  
27 and we expect that to happen during this process. So I

1 just wanted everybody to understand this is -- well, I  
2 say not the old FSIS --

3 (Laughter.)

4 -- but I mean the people I'm working with to  
5 make this happen we all really seem to care about this.  
6 So I hope maybe that makes people feel better.

7 MR. GREEN: Mr. Chairman, if I could add to  
8 that?

9 MR. MORSE: Sure.

10 MR. GREEN: Sort of a quasi-public setting  
11 coming in, Julian and others in FSIS because Vicki's  
12 absolutely right because of the outreach effort they have  
13 made to us and to others in industry. We have  
14 appreciated it. I mean that doesn't mean we necessarily  
15 agree with everything they all come out with but they  
16 have been quite inclusive without denying the realities  
17 of human nature. Because I understand a lot of these  
18 guys won't focus on it until it comes down the pike.

19 Nonetheless, there has been an awful lot of  
20 sensitization, if that's a word, on the part of producers  
21 and processors in the last couple of years just because  
22 there's been so much public discussion. But these are  
23 fairly sophisticated business operators, at least in my  
24 experience with them.

25 Our organization would like to be helpful in  
26 any cornfed appropriate way we could in helping with the  
27 education process, meetings, whatever. Again that's, you

1 know, not necessarily with respect to the merits of any  
2 particular part of the proposal, but whatever it is it's  
3 going to be very important to our membership to  
4 understand it and to comment on it which is a separate  
5 process but they've got to understand it.

6 MS. JOHNSON: Well, do we want to -- I feel  
7 like we need to come up with some recommendations or  
8 we're going to look pretty bad.

9 MR. MORSE: Right.

10 MS. JOHNSON: When the other groups get in  
11 there.

12 MR. MORSE: Well, I guess the question is --  
13 (Multiple voices.)

14 MS. JOHNSON: Do we want to recommend? Is  
15 there a need to do like outreach across the country once  
16 the proposal's out? Randy, are you saying that that's  
17 already been done or you guys -- I mean is there a need  
18 to continue --

19 MR. GREEN: Well, I wouldn't want to tell you  
20 what to recommend. But in terms of outreach certainly  
21 there's been education on the issue but the producers and  
22 the processors don't know what the proposal is.

23 MS. ESKIN: Nor do we.

24 (Laughter.)

25 MR. GREEN: Nor do you. So once they're public  
26 it would seem to me that there certainly is a need for --

27 MS. JOHNSON: Okay.

1 MR. GREEN: -- outreach and education.

2 MR. MORSE: Could we be supportive of FSIS if  
3 we, if we're still in this development? I would put this  
4 as a fifth development and continue outreach --

5 MS. ESKIN: It's really critical.

6 MR. MORSE: -- efforts to visit and seek input  
7 from packers and processors --

8 MS. ESKIN: And it's just --

9 MR. MORSE: -- all before the proposed rule is  
10 released. So I don't know. So we have like potentially,  
11 you know --

12 MS. ESKIN: Right.

13 MR. MORSE: -- a group of at least five  
14 principles that we're asking them to do.

15 MS. ESKIN: And obviously, that one comes right  
16 from the first question which is --

17 MS. JOHNSON: Yeah.

18 MS. ESKIN: -- what you've learned from  
19 implementing meat and poultry?

20 MS. JOHNSON: But do we want to --

21 MR. MORSE: But now we should probably list  
22 some things that they should do. I don't know if you  
23 want to go -- do you want to go as far as implementation  
24 or --

25 MS. ESKIN: Well, we --

1           MR. MORSE:  -- then we've mentioned a couple of  
2 things once -- so then you're going to come out with a  
3 proposed rule?

4           MS. ESKIN:  But there are other things about  
5 the proposed rule that we haven't even talked about.

6           MR. MORSE:  Right.

7           MS. ESKIN:  I mean --

8           MR. WOOD:  She's got the list right here.

9           MS. ESKIN:  Of what?

10          MR. WOOD:  Right here.

11          (Laughter.)

12          MS. ESKIN:  Oh, that's just a probable -- we  
13 haven't talked about the specifics of the rule --

14          MR. MORSE:  It's in development.

15          MS. ESKIN:  -- though itself.

16          MR. MORSE:  Right.  Well, that's sort of the  
17 next --

18          MS. ESKIN:  We haven't talked about --

19          MR. MORSE:  -- well, I guess that would be the  
20 next --

21          MS. ESKIN:  Right.

22          MR. MORSE:  -- next -- so maybe we should move  
23 on to that?  But I don't know if you want to go back  
24 through these or come back to the end?  Okay.  So then I  
25 guess we've made some comments about the proposed rule.  
26 I mean is this -- do you have --



1 MR. JAN: Don't make the same mistake of  
2 expecting the packers to eliminate salmonella from eggs  
3 that come in with salmonella unless you're going to go --

4 MS. LEVINE: They can't do that unless they  
5 pasteurize it, right?

6 MR. JAN: Right. And that's what FSIS expected  
7 grinders to do.

8 MS. LEVINE: Well --

9 MR. JAN: That's what I'm saying, don't make  
10 that mistake. So keep that in mind, that that is one  
11 thing that they can't do unless we require  
12 pasteurization. In some shell eggs -- I mean shell eggs  
13 are not all pasteurized when they're sold. If they are  
14 or they can be then that's great. But I don't think that  
15 that's --

16 MS. LEVINE: I don't think we want to --

17 MR. JAN: I don't think --

18 MS. LEVINE: -- require that.

19 MR. JAN: I don't think you do.

20 MS. LEVINE: By any stretch of the imagination.

21 MR. JAN: So I'm just saying be mindful of that  
22 -- things that packers can't address and we need to know  
23 about that or need to keep that in mind. Can't expect  
24 them to have less salmonella than is delivered to them  
25 from the producer side.

26 MS. LEVINE: See, now that's one of the  
27 differences I think between meat and poultry and eggs.

1 You can get an egg that has SE in it, okay, and you don't  
2 know it and you haven't done anything. You can handle  
3 that egg properly and there may still be this chance that  
4 at the other end --

5 MR. JAN: You've got SE.

6 MS. LEVINE: -- you've got it and if the  
7 consumer doesn't handle it properly there's going to be  
8 an illness. We're saying what we're asking you to do is  
9 to make sure that you handle it in such a way that if  
10 it's in there you're not going to make it any worse with  
11 anything you do do.

12 MR. JAN: I agree with that. That's not what  
13 FSIS --

14 MS. JOHNSON: That's exactly the same as the --

15 MS. LEVINE: Well, yeah, but --

16 MR. JAN: You've got it right. You're right.  
17 Exactly what you're talking about is what it seems to me.

18 MS. LEVINE: But I was -- I didn't preface all  
19 of this with the statement that SE has not been -- let's  
20 see, what word do I want? Legally --

21 MR. JAN: Is it adulterant?

22 MS. LEVINE: -- called an adulterant.

23 MR. JAN: Nor has salmonella.

24 MS. JOHNSON: Salmonella, yeah.

25 A PARTICIPANT: No.

26 MS. LEVINE: But E. coli was.

27 MR. JAN: E. coli was.

1 A PARTICIPANT: E. coli.

2 MR. JAN: That's not the one that causes all  
3 the trouble.

4 MS. LEVINE: Yeah.

5 A PARTICIPANT: Apparently.

6 A PARTICIPANT: Right.

7 MR. JAN: I mean as far as political trouble or  
8 --

9 A PARTICIPANT: Legal trouble.

10 MS. LEVINE: I understand that.

11 MR. JAN: Right.

12 MS. LEVINE: I understand that.

13 (Multiple voices.)

14 MS. RIGGINS: Let me clarify. Under FDA's  
15 statute SE in a raw egg is an adulterant. It is an  
16 adulterant. FDA has interpreted adulteration a little  
17 differently than FSIS has. So SE in a raw egg is an  
18 adulterant.

19 MS. ESKIN: But does that have any bearing once  
20 it is outside of FSA's control, so to speak? I mean once  
21 it's at a point where --

22 MR. JAN: Well --

23 MS. ESKIN: -- FSIS --

24 MR. JAN: -- you can't know every egg that goes  
25 into your processing plant is plus or minus --

26 MS. RIGGINS: Right.

27 MR. JAN: -- unless you --

1 MS. RIGGINS: -- unless you --

2 MR. JAN: -- sample it and then you don't have  
3 anything left.

4 MS. RIGGINS: Right. Right. And under the  
5 FSNC Act FDA has to find a positive analysis, through  
6 analysis has to find a positive result of SE in order to  
7 deem that product or that lot --

8 MS. ESKIN: Adulterated.

9 MS. RIGGINS: -- that's represented by that  
10 sample as adulterated. But I'm just saying don't think  
11 of it in terms of the way that FSIS has interpreted  
12 adulteration and only E. coli 057:H7 in ground beef is  
13 considered to be an adulterant.

14 MS. ESKIN: By FSIS?

15 MS. RIGGINS: By FSIS.

16 MS. ESKIN: I guess that's true.

17 MS. RIGGINS: Under FDA's rules, under FDA's  
18 laws, a pathogen in a raw product or a pathogen in a  
19 cooked product is considered to be an adulterant.

20 MS. ESKIN: What bearing does that have though  
21 for purposes of what we're discussing here? I'm asking a  
22 question.

23 MS. RIGGINS: Once that what we are operating  
24 under is the definition of adulteration under the FD&C  
25 Act because if it gets into the chicken or the egg and  
26 all of that --

1           MR. JAN: It causes me some concern that if  
2 we're going to -- if you're going to move to performance  
3 standards and you say, okay, we're going to have a set of  
4 performance standards for SE and it is an adulterant then  
5 the performance standard has to be zero.

6           I don't know how you're going to be able to  
7 require or produce a packer that has no control over the  
8 layers to make his eggs that he produces at the end zero  
9 for Salmonella enteritidis if that's not happening on the  
10 farm.

11           I agree your goal should be to eliminate that  
12 pathogen or any other pathogens --

13           MS. ESKIN: Before it reaches the packers.

14           MR. JAN: -- before it ever reaches that. But  
15 if you put in and say, we're going to -- you're going to  
16 have to meet this standard.

17           MS. RIGGINS: Right. But you realize at any  
18 point where testing is done and the egg or the lot is  
19 found to be SE-positive that lot would be --

20           MS. ESKIN: Diverted.

21           MS. RIGGINS: -- diverted to pasteurization.

22           MR. JAN: Right.

23           MS. ESKIN: At the point where it enters the  
24 packer?

25           MR. JAN: Do all packers do pasteurization? Do  
26 they all have the capability of doing pasteurization?

1 Are some packers only packing shell eggs and that's all  
2 they can do and now they --

3 MR. GREEN: No. They -- I think what Judy's  
4 saying is that in that situation in which under -- I  
5 think under FDA's plan would occur an environmental  
6 policy followed by a positive egg test then the producer  
7 or the packer as it may be would be required to send his  
8 eggs or sell his eggs to a further processor.

9 MS. ESKIN: He wouldn't have to do it himself.

10 MR. GREEN: The further processor again by law  
11 or by --

12 MS. ESKIN: Right.

13 MR. GREEN: -- regulation must pasteurize those  
14 eggs whereas pasteurization in the shell, although there  
15 are two companies that are trying it and it's not really  
16 a developed technology yet, one of these days it may be.

17 MS. JOHNSON: But what -- for the purpose of  
18 the committee right now I think, you know, the discussion  
19 is good but we're not looking at performance standards  
20 right now. We're looking at basically the HACCP concept.  
21 I'm assuming, you know, in meat and poultry we have the  
22 pathogen reduction HACCP but --

23 MS. ESKIN: Right.

24 MS. JOHNSON: -- what we're being asked to  
25 discuss now is the HACCP concept and not necessarily  
26 pathogen reduction. So I think we maybe kind of strayed  
27 a little bit on that.

1 MS. ESKIN: How should --

2 MS. JOHNSON: I assume that's why we're here --

3 A PARTICIPANT: No, that's all --

4 MR. JAN: Well, I tried to make that point  
5 early on with the meat program about not holding the  
6 grinder and I thought if that wasn't early enough --

7 MS. JOHNSON: Okay. But that was --

8 MR. JAN: -- maybe we'll try --

9 MR. MORSE: But this is -- this is slightly  
10 different because it's eggs and if the packers and the  
11 processors can, you know, have enough labeling. So if  
12 the labeling was adequate enough because they can tell  
13 what farm it came from so we can do trace-backs which on  
14 the part of E. coli in beef there wasn't always -- you  
15 couldn't tell which animal it came from necessarily and  
16 which farm.

17 Well, in this case with proper labeling they  
18 should be able to tell which farm it came from and all  
19 the trace-backs that were done in the late '80s and '90s  
20 100 percent of them were able to go back when there was  
21 an outbreak to a farm to find a positive flock.

22 So I mean it seems like if there's good  
23 labeling, if you have a packer that doesn't have proper  
24 labeling and can't tell where he got the eggs then he  
25 probably is at risk, then he is responsible.

26 MR. WOOD: Well, and another difference -- and  
27 we trace back -- while the facts support trace-backs,

1 it's sometimes counterproductive as a primary focus and I  
2 hope that in any kind of work at that point the primary  
3 focus would be on the farm, you know, strong quality  
4 assurance --

5 MS. ESKIN: Quality assurance measures.

6 MR. WOOD: -- testing programs.

7 MS. ESKIN: Yeah, definitely.

8 MR. WOOD: Because, you know, some eggs will  
9 get through and others don't. The ones that just don't  
10 happen to get through that farm gets the trace-back and  
11 all those others get through. But the other difference  
12 may be -- and I may be all wet here but with E. coli if  
13 there's a positive, the hamburger is condemned, it's not  
14 made into the stroganoff.

15 With eggs if there's a positive it becomes a  
16 cooked product. You don't get as good a price for a  
17 cooked product but if you come -- I mean it goes to the  
18 breakers, am I wrong?

19 MR. JAN: With E. coli -- I mean E. coli in  
20 ground beef can be cooked.

21 MR. WOOD: Even after you've determined --

22 MR. JAN: Right.

23 MR. WOOD: -- after a packing facility has  
24 found E. coli in their processing plant?

25 MR. JAN: It can be cooked but it has to be  
26 cooked under inspection --

27 MR. WOOD: All right. Well, then -- all right.



1 MR. JAN: -- so that it meets that --

2 MR. WOOD: I didn't know that.

3 MS. ESKIN: Very, very strict.

4 MR. JAN: But most of them end up condemning  
5 it.

6 MR. WOOD: Right.

7 MR. JAN: But, more importantly, what I was  
8 trying to get at -- and, of course, that's -- you know,  
9 farm standards is not the issue but just, we need to know  
10 that there are things that HACCP can't control and that  
11 if salmonella comes in with the egg HACCP is not going to  
12 eliminate it.

13 But I agree that it can control it from getting  
14 worse and, you know, you get your temperatures and those  
15 type things to make the -- to keep it from increasing  
16 within the egg, but you can't take it out of the egg.

17 MS. ESKIN: Unless you --

18 MR. JAN: Unless you do pasteurize it or --

19 MS. ESKIN: Right.

20 MR. JAN: -- they do a kill --

21 MS. ESKIN: Right. If you just --

22 MR. JAN: But if you're selling --

23 MS. ESKIN: -- the packer there and you're just  
24 --

25 MR. JAN: Yeah. The egg --

26 MS. ESKIN: -- take an egg and washing it and  
27 packing it.

1 MR. JAN: Yeah.

2 MS. ESKIN: You're not doing anything to the  
3 egg.

4 MR. JAN: Now washing it possibly you could  
5 contaminate and those are I think --

6 MS. ESKIN: Right.

7 MR. JAN: -- and I'm not in the egg business,  
8 but any time you're removing -- if you've got any checks  
9 or anything like that you could introduce something and  
10 that should be considered in the HACCP plan, you know.

11 MS. ESKIN: Right.

12 MR. JAN: But SE from the chicken --

13 MS. LEVINE: Well, but your checks should be  
14 diverted.

15 MR. JAN: Well, yeah, agreed. That would be --  
16 I think it would be addressed in the HACCP plan.

17 MS. LEVINE: One of the interesting questions  
18 has been how many CCPs are there in a HACCP plan for a  
19 packer?

20 MS. ESKIN: For a packer, right.

21 MS. LEVINE: And we've had people tell us none.

22 (Laughter.)

23 MS. ESKIN: Right.

24 MS. LEVINE: And we've had people who we think  
25 probably know what they're talking about tell us one or  
26 two. Initially we were like, no, it can't be just two.

27 A PARTICIPANT: Oh, is that a secret? Sorry.

1 MS. LEVINE: No. Where are they? Let me think  
2 about this.

3 (Pause.)

4 Well, but actually maybe at the end, the  
5 refrigeration might be. But my point is that these are  
6 interesting questions and we're interested in talking to  
7 people and learning about these things.

8 MS. KASTER: Just -- and this is totally out of  
9 curiosity, but along with what you're saying. What  
10 proportion of SE contamination is an exterior versus the  
11 interior of the egg?

12 MS. LEVINE: Well, when we say it's 20,000 for  
13 interior one in 20,000 eggs has --

14 MR. GREEN: That's the overall.

15 MS. LEVINE: Yeah.

16 MS. KASTER: Overall.

17 MS. LEVINE: So I guess the rest of it would be  
18 -- well, I don't know.

19 MR. GREEN: No. I think -- my impression is  
20 that one in 20,000 would comprise --

21 MS. KASTER: Both.

22 MR. GREEN: -- eggs that are contaminated in  
23 the interior and on the exterior.

24 MS. LEVINE: No. I thought the --

25 MR. GREEN: But maybe I'm wrong.

26 MR. MORSE: -- I thought the one in 20,000 was  
27 transovarian infection.

1           MR. GREEN: That's not my understanding but I  
2 may be wrong.

3           MS. KASTER: I guess I was just thinking all  
4 the lines of your development of the CCP and what  
5 proportionately is environmental versus -- but that is  
6 not  
7 --

8           MS. LEVINE: Now that's --

9           MS. KASTER: -- that's totally academic. I'm  
10 sorry.

11          MS. LEVINE: Well, but it's a question we're  
12 interested in and that we were thinking of asking, the  
13 microbiological.

14          MS. KASTER: I guess because one way you have  
15 some CCPs and the other way your CCP list gets pretty  
16 restricted pretty fast.

17          MS. LEVINE: Yeah.

18          MS. KASTER: Is because when you started  
19 talking about that I kept thinking of environmental and I  
20 was like, oh, yeah, you know, there's some pretty  
21 reasonable dispute but then if there's -- if it's  
22 interovarian --

23          MS. LEVINE: Well --

24          MS. KASTER: -- is that what you said?

25          MS. LEVINE: Transovarian.

26          MS. KASTER: Transovarian. I'm learning new  
27 things.

1           MR. JAN: Well, you check when you're on the  
2 farm but there's no harm in packing --

3           MS. KASTER: Right. The stuff could -- to the  
4 farm -- I mean to the packing --

5           MS. LEVINE: He is washing the CCP.

6           MS. KASTER: Well, if it's on the exterior it's  
7 a logical one that --

8           MS. LEVINE: Well, some people say it is and  
9 some people say it isn't. Of course, you know what we  
10 say.

11          MS. KASTER: Just have the CCP.

12          MS. LEVINE: We don't --

13          (Laughter.)

14          MS. KASTER: Sorry.

15          (Laughter.)

16          MS. LEVINE: Look at your hazard analysis and  
17 make the appropriate determination.

18          A PARTICIPANT: On your own circumstance.

19          MS. KASTER: Or?

20          MS. LEVINE: On your own -- based on your  
21 hazard analysis.

22          A PARTICIPANT: That's right.

23          (Multiple voices.)

24          MS. RIGGINS: You've got to have documentation  
25 for that decision.

26          MS. LEVINE: Yeah. You've got to have  
27 documentation.

1           MR. JAN:  Are chickens considered a plant?  
2  Eggplant?

3           A PARTICIPANT:  Oh.  Good point.  Good point.

4           MR. MORSE:  Let's get back so we have something  
5  in writing.  I guess --

6           (Laughter.)

7           -- not being an egg expert here, but are there  
8  some principles that we want to say about development of  
9  the rule itself so --

10          MS. KASTER:  Or some aspects of the rule that  
11  we think are really essential?

12          MR. MORSE:  Right.  So I've got notes but I  
13  don't have anything to -- I mean things like don't hold  
14  packers responsible for eggs which come in infected,  
15  maintain labeling so eggs can be traced back to source.

16                 Is there anything we want to comment on  
17  microbiologic testing or hazard analysis?  Use hazard  
18  analysis to define --

19          MS. LOGUE:  But there is already bacteria for  
20  microbiological testing, isn't there?

21          MR. MORSE:  In the packing -- in the packing  
22  plants?  In the processing plants?

23          MS. KASTER:  In both?

24          MR. MORSE:  There are on the quality assurance  
25  on the farms but are there in --

26          MS. LOGUE:  That's on the farm.

27          MR. MORSE:  -- are there any --

1 MS. RIGGINS: There is not -- to my knowledge  
2 there is not testing for -- existing testing for  
3 pathogens for packers.

4 MS. JOHNSON: How about processors?

5 MS. RIGGINS: Processors are -- we're working  
6 on the baseline study so that the processors will know  
7 what the incoming -- or at least have a better idea of  
8 what the incoming pathogens would be.

9 But, of course, times and temperatures for  
10 pasteurization will then be adjusted to accommodate the  
11 pathogen load depending on where they know they are  
12 getting their eggs from.

13 If they know that they're being -- that they  
14 are from a diverted lot then they will, you know, make  
15 decisions about the times and temperatures for  
16 pasteurization to accommodate the higher pathogens.

17 MS. JOHNSON: Can we make a recommendation that  
18 USDA develop the HACCP proposal based on the HACCP  
19 criteria outlined by the microbiological criteria for  
20 foods? Just so that we have some type of -- because  
21 that's what they did with --

22 MS. ESKIN: Is that that seven-step?

23 MS. JOHNSON: Yeah.

24 MS. ESKIN: It includes microtesting and  
25 verification.

26 MS. JOHNSON: Yeah. You have the seven  
27 principles. I mean I'm assuming that's what it is but --

1 MS. ESKIN: Right.

2 MS. JOHNSON: -- maybe we should make that  
3 recommendation that they follow the 1997 national  
4 advisory  
5 -- microbiological criteria for this committee.

6 MR. MORSE: Is there anything the group wants  
7 to comment about to come up with a plan in terms of it's  
8 being rolled out? Is there a difference in size of  
9 these? The other was rolled out with a large --

10 MS. ESKIN: Well, that's --

11 MR. MORSE: -- with a large first and --

12 MS. JOHNSON: Phase in?

13 MR. MORSE: Phase in. Is there -- are the  
14 packers and processors of different sizes so that -- is  
15 that the case or is there a variation that they're all  
16 large that shouldn't be an issue?

17 MR. JAN: Well, one of the things that was  
18 brought out today was the --

19 MS. ESKIN: The exception, yeah.

20 MR. JAN: And I don't know if that's --

21 A PARTICIPANT: That's probably --

22 MR. JAN: -- legislative or --

23 MS. ESKIN: You had said it was based in the --

24 MS. RIGGINS: It's in the -- it's in the egg  
25 products inspection manual do you want to expound on  
26 that, please?

27 MS. ESKIN: Yeah. What exactly does it say?



1 MS. RIGGINS: Well, it basically says --

2 MS. LEVINE: Well, it basically says if you  
3 have 3,000 -- well, it's actually less than --

4 MS. ESKIN: It's less than 3,000.

5 MS. LEVINE: -- 3,000 birds and you only pack  
6 production from your own flock then you are exempt from,  
7 actually, the surveillance requirements. So --

8 MS. ESKIN: But is the HACCP system developed  
9 under that?

10 MS. LEVINE: Well, what -- since those -- and  
11 those people -- we don't know how many of them are out  
12 there, they don't have to register with AMS. So we don't  
13 know who they are.

14 MS. ESKIN: You can't get them, anyway.

15 MS. LEVINE: So -- well, it's -- what we've  
16 done for now -- and this is directly addressed in the  
17 preamble -- it said, "We're going to continue with this  
18 exemption and apply it for our regs so that" --

19 MS. ESKIN: But are you saying that it's  
20 required by the statute or that's just a judgment call?

21 MS. LEVINE: Yes. It's a judgment call.

22 MS. ESKIN: Call. So --

23 MS. LEVINE: It is not --

24 MS. ESKIN: It's not mandated?

25 MS. LEVINE: It's not mandated by the statute,  
26 no, but the way it's written one could easily think that.

1 MS. RIGGINS: There is not an analogous  
2 exemption --

3 MS. ESKIN: Right.

4 MS. RIGGINS: -- in the Food, Drug and Cosmetic  
5 Act. So that means that all producers --

6 MS. ESKIN: Will be subject to on farm.

7 MS. RIGGINS: -- will be subject to the on-farm  
8 quality assurance --

9 MS. ESKIN: And there's --

10 MS. RIGGINS: -- you know, requirements.

11 MS. ESKIN: -- I mean what percentage are we  
12 talking about? Was it one percent? I don't remember  
13 what you said. How many -- are there a lot of producers  
14 out there that have less than 3,000?

15 MR. GREEN: There is a very large number  
16 compared to the number of commercial operations. Their  
17 egg production is very small.

18 MS. ESKIN: Okay.

19 MR. GREEN: But I believe the '97 census of Ag  
20 would show you that it might be in excess of 50,000 farms  
21 that produce some eggs. Then if you then subtract out  
22 from that as -- exception of those that have fewer than  
23 50 layers, which is sort of backyard flocks, a number  
24 between 50 and 3,000 layers --

25 MS. ESKIN: Right.

26 MR. GREEN: -- which is in most cases not large  
27 enough to be a commercial operation.

1 MS. ESKIN: Right. Right.

2 MR. GREEN: As I understand it they would be  
3 exempt under the Agency's current thinking. Our view is  
4 just they should not be because --

5 MS. ESKIN: Should not be exempt?

6 MR. GREEN: Should not be exempt.

7 MS. ESKIN: Well, there's no --

8 MR. GREEN: The same rules should apply to  
9 everybody.

10 MS. ESKIN: -- there's no public -- I mean is  
11 there a public health basis for the exemption?

12 MS. LEVINE: Well, what we've said --

13 MS. ESKIN: I mean that's what it's coming down  
14 to, right?

15 A PARTICIPANT: Yeah.

16 MS. LEVINE: -- what we've said for now --

17 MS. ESKIN: We'll help them do their plan.

18 MS. LEVINE: -- is since everybody else  
19 accounts for 98 to 99 percent of all of the commercial  
20 production that, in fact, there may not be a public  
21 health risk with these other guys. However -

22 MS. ESKIN: But there's no justification -- on  
23 the other hand --

24 MS. LEVINE: -- we very clearly say --

25 MS. ESKIN: -- there's no justification.

26 MS. LEVINE: -- "We want comments on this  
27 including data."

1 MS. LOGUE: Well, wait a second. If they're  
2 producing something and they're putting it into commerce  
3 --

4 MS. ESKIN: That's public --

5 MS. LOGUE: -- and it's on the shelf,  
6 therefore, then it has to be covered by something.

7 MS. ESKIN: Yeah.

8 MS. LOGUE: You cannot have some guy with 3,000  
9 chickens and he's suddenly, you know, he's selling it to  
10 the local --

11 MS. ESKIN: How do I know going in the grocery  
12 store?

13 MS. LOGUE: -- grocery store and there's like  
14 100 people in the village buying these eggs.

15 MS. ESKIN: And 80 of them --

16 MS. LOGUE: It has to be covered by something  
17 and you're telling me it's not.

18 MS. LEVINE: That's what I'm telling you.

19 MS. LOGUE: You can't do that though.

20 MR. MORSE: But you're also --

21 MS. LOGUE: It would be different if he had 50  
22 chickens and he only fed them to his wife and kids.

23 MS. LEVINE: Right.

24 MS. LOGUE: But not if it's on a shelf. Then  
25 it has to be --

26 (Multiple voices.)

1 MS. LEVINE: But not all of these guys sell  
2 them on the shelf. So these guys can take them down to  
3 the farmer's market.

4 MS. LOGUE: Yeah.

5 MS. LEVINE: They sell them right out the front  
6 door, you know. But that's why we're asking for comment  
7 on it because when --

8 (Multiple voices.)

9 MS. LOGUE: He said no matter whether it's  
10 between 50 and 3,000 layers there has to be something.

11 MS. ESKIN: Right.

12 A PARTICIPANT: And the issue is is maybe their  
13 HACCP plan is sufficient, but I would strongly recommend  
14 that we don't endorse the idea.

15 MS. LOGUE: If I could just make a comment  
16 here.

17 A PARTICIPANT: Phase in is fine.

18 MR. MORSE: But just a clarification.

19 MS. LOGUE: Just a comment here. This goes  
20 back to where I'm from and I'm -- I'm European. But the  
21 point of it is though in Ireland they introduced if you  
22 had a small backyard kind of bakery or kitchen you  
23 eventually got to the point where you had to have a HACCP  
24 plan for your little production line. Why can't the same  
25 apply to these egg producers who only have three dozen  
26 chickens or --

27 A PARTICIPANT: Absolutely.

1 MS. LOGUE: -- 201 chickens? I mean surely he  
2 can still develop some kind of a miniature HACCP plan for  
3 them that -- it doesn't have to be rocket science, but  
4 they have some way of tracking and keeping an eye on what  
5 goes on? I mean you say that --

6 MS. LEVINE: They sell them.

7 MS. LOGUE: -- you say they don't have to be  
8 registered with the AM or whatever it was.

9 MS. LEVINE: Yes.

10 MS. LOGUE: But that's -- surely there must a  
11 local vet who knows about it or somebody else that has  
12 some information.

13 MS. LEVINE: Well, we've talked to the states.

14 MS. LOGUE: Yeah.

15 MS. LEVINE: And we've said to the states, do  
16 you know how many? Some states say, oh, sure, there are  
17 five of them. Some states say there aren't any. Some  
18 states say, oh, there might be a few. We don't know.

19 MS. LOGUE: There must be some kind of -- in  
20 principle there should not be an exemption.

21 MS. LEVINE: Exactly. That's good in  
22 principle.

23 MS. LOGUE: There should not be an exception.

24 MS. LEVINE: I'm not saying that maybe this  
25 isn't something that should be changed. But it's  
26 something we need comment on and if people, you know, can  
27 say, this is a bad idea, this is why and this is

1 something else you can do in place of, you know, that's  
2 stuff we're going to consider.

3 In fact, one of the things we've also talked  
4 about is even though they might not be subject to the  
5 rules --

6 MS. LOGUE: But they're subject to something.

7 MS. LEVINE: -- they're still going to have to  
8 at least undergo an education.

9 MS. LOGUE: Oh, yeah.

10 MS. LEVINE: We talked about that, too. So  
11 these are -- you know, those are the kinds of  
12 recommendations and comments we could really use.

13 MS. LOGUE: Oh, yeah.

14 MR. WOOD: In reference to what you said -- the  
15 Chair said about the diversity of packers, I mean I  
16 guess, you know, a majority are large packers and easily  
17 identifiable but we don't -- I mean Judy just said that  
18 you're not even sure how many packers are out there.

19 I think perhaps one of the tasks in preparing  
20 for this rule is to identify, you know, who is out there  
21 and then to determine whether different kinds of training  
22 needs to take place and what kinds of inspection  
23 protocols need to take place. I don't know if we can say  
24 that at the get-go.

25 Another piece of this in terms of addressing  
26 the whole range of producers from the 3,000 on up and

1       there's a vast difference in terms of 3,000 and in terms  
2       of the eggs that we produce on 14 small farms.

3               MS. LEVINE:   Mm-hmm.

4               MR. WOOD:   And we're well above that on an  
5       hourly basis.  But it is to take a look at another piece  
6       of the continuum which USDA does not have jurisdiction  
7       over and that's the retail end.

8               MS. ESKIN:   Retail.

9               MR. WOOD:   Retailers, right.

10              MS. ESKIN:   Right.

11              MR. WOOD:   And the retailers -- I mean that  
12       gets everybody's attention when they say, "you know, you  
13       have to meet these HACCP requirements --

14              MS. ESKIN:   Or I won't sell your product.

15              MR. WOOD:   -- before we accept your product.  
16       That is another part of the whole puzzle.

17              MR. MORSE:   What I'm going to suggest is I  
18       don't feel too bad about the first question because not  
19       having seen the rule I mean we've listed some general  
20       principles which I think a small group, as we'll try to  
21       articulate later.

22              What I'd suggest is that we go into the second  
23       question because I think we can sort of maybe go on with  
24       it -- we could sort of 2 and 3 we could answer quick  
25       --

26              MS. JOHNSON:  You think we could get some  
27       answers?



1 MR. MORSE: Well, at least we could just sort  
2 of rattle off a number of things that -- maybe could make  
3 lists of things that could be done quicker and then we'll  
4 come back to 1, because otherwise, we're going to run out  
5 of time.

6 So if that's okay with everybody I suggest that  
7 we -- so is that all right, anybody? Everybody?

8 So what is the second question? What is the  
9 best way to achieve effective interaction and  
10 communication among the Federal, state and local agencies  
11 involved? What I would suggest is that we just sort of  
12 like free association of how this could be done.

13 MS. ESKIN: Townhall meetings --

14 A PARTICIPANT: Yeah. I'd say quarterly.

15 MS. ESKIN: -- across the country.

16 A PARTICIPANT: Some sort of regular meeting.

17 MR. MORSE: One at a time. One at a time. One  
18 at a time.

19 MS. ESKIN: Meetings among Federal and state  
20 regulators to share on a regular basis, regular meetings.

21 MR. MORSE: So have regular meetings. We're  
22 just getting --

23 MS. ESKIN: We're just talking about process.  
24 That's --

25 MR. MORSE: Process.

26 MS. ESKIN: So state and Federal regulators.

1 MS. JOHNSON: Okay. And then townhall meetings  
2 with egg producers, the local guys --

3 MS. ESKIN: Packers.

4 MS. JOHNSON: -- to get them involved as much  
5 as possible.

6 MS. ESKIN: Right.

7 MS. JOHNSON: What about training packets? You  
8 know about training packets?

9 MR. WOOD: Involved consumers is --

10 MS. LOGUE: What about --

11 MR. WOOD: -- a term we use.

12 MS. LOGUE: -- what about you said --

13 A PARTICIPANT: Training packets.

14 MS. LOGUE: You mentioned the processors, that  
15 some of them have regulated personnel and others just  
16 meet with some authorities on a quarterly basis. What  
17 about using that visitor, that person that does that?

18 MS. LEVINE: Well --

19 MS. LOGUE: Making the connection there? I  
20 don't know who it is. What did you say it was?

21 MS. LEVINE: AMS.

22 MS. LOGUE: AMS.

23 MS. LEVINE: Agricultural Marketing Service.

24 MS. LOGUE: Why not use that as well then? Is  
25 that a possibility?

26 MS. LEVINE: Yes.

1           MR. MORSE: So disseminate information through  
2 what do you call it? Extension? What do they call it?

3           (Multiple voices.)

4           A PARTICIPANT: Shell egg surveillance program.

5           MS. LEVINE: Yeah, sure.

6           MR. MORSE: So disseminate --

7           A PARTICIPANT: Shell egg surveillance program.

8           MR. MORSE: -- shell eggs -- Okay. Disseminate  
9 through --

10          A PARTICIPANT: Existing programs.

11          MS. JOHNSON: And the Extension people did a  
12 lot with the smaller guys, didn't they, Judy, in the meat  
13 and poultry? They sent out through Extension.

14          (Multiple voices.)

15          MS. JOHNSON: Yeah. The little plan kits they  
16 sent you when I was trying to get everybody together.

17          A PARTICIPANT: They used the Extension  
18 offices.

19          MR. MORSE: They use the Extension Service.

20          A PARTICIPANT: Offices.

21          MR. MORSE: -- offices.

22          MS. RIGGINS: We also have contracts with the  
23 schools, agricultural schools.

24          MS. ESKIN: And, obviously, the trade  
25 associations --

26          MS. RIGGINS: Yeah.

1 MS. ESKIN: -- are critical here. Trade  
2 associations are critical because they, obviously know  
3 who's affected.

4 MS. JOHNSON: But you know, I imagine there are  
5 some really small meat and poultry guys out there that  
6 have yet to understand --

7 (Multiple voices.)

8 MR. MORSE: Trade associations.

9 MS. JOHNSON: -- that are selling something to  
10 somebody somewhere.

11 MR. MORSE: Should there be -- is there any  
12 kind of posting on the Web or mailings that go out that  
13 would reach a lot of people?

14 MS. ESKIN: Certainly whether it's the agencies  
15 or the --

16 MR. MORSE: Well, just the agencies.

17 MS. ESKIN: -- or trade associations. I mean  
18 there's lots of ways you can get the information out --

19 MS. JOHNSON: If you have a townhall --

20 MS. ESKIN: -- electronically.

21 MS. JOHNSON: -- if you have a townhall meeting  
22 you can put it in the local paper which, you know, most  
23 of the people would read.

24 MS. ESKIN: The agricultural newspapers.

25 MS. JOHNSON: Yeah. Agricultural newspapers.

26 MS. ESKIN: Or trade magazines.

1           MR. JAN: Well, the townhall meetings need to  
2 be where the egg producers are located.

3           MS. ESKIN: Oh, yeah.

4           MS. JOHNSON: Yeah.

5           MR. JAN: Not in Washington, D.C.

6           (Multiple voices.)

7           MR. WOOD: There are also -- there are also  
8 each year two or three major trade shows --

9           MS. ESKIN: Yes.

10          MR. WOOD: -- that most people in the industry  
11 go to.

12          MS. ESKIN: That's a great idea.

13          MR. WOOD: There's one in Atlanta and one in  
14 the Midwest. There's what's called a Kerner-Barry  
15 Conference which is put on by a private firm and most of  
16 the participants in the industry go to one or more of  
17 those.

18          MS. ESKIN: So trade conferences.

19          MR. WOOD: Trade shows.

20          MS. ESKIN: Trade shows. That's right.

21          MS. LOGUE: Suppliers. How about suppliers to  
22 these egg producers? You've got feed suppliers, you've  
23 got people who supply the packaging materials for the  
24 boxes?

25          MS. JOHNSON: And the retailers.

26          MS. ESKIN: And the retailers.

27          MS. LOGUE: And the retailers.

1 MS. JOHNSON: I'm kind of twisting to get this  
2 point in but when we talk about effective interaction and  
3 communication should we say recommend that we support the  
4 Agency's current thinking on rolling this thing all out  
5 together with the FDA and FSIS so that you can get the  
6 most interaction and people can comment together?

7 MS. ESKIN: Parallel rulemaking?

8 MS. JOHNSON: Yeah.

9 A PARTICIPANT: Parallel rulemaking.

10 MR. MORSE: Maybe that's even a separate --

11 A PARTICIPANT: Conjoined.

12 MR. MORSE: -- these are all -- the first ones  
13 are the --

14 A PARTICIPANT: Yeah.

15 MR. MORSE: -- and this is like a separate main  
16 point.

17 MS. ESKIN: With this FDA/USDA.

18 MR. MORSE: Under this heading.

19 MS. ESKIN: APHIS.

20 MR. MORSE: I mean one way to ensure effective  
21 interaction is to have either the same regulation or that  
22 they're equal or equivalent or consistent with no  
23 disparities, right? Because you've got two different  
24 agencies. So I guess this has a rolling amount at the  
25 same time or you could make them the same if --

26 MS. ESKIN: They're not the same.

1           MR. JAN: They'd have to have a joint  
2 regulation.

3           MS. ESKIN: They have a joint safety plan and a  
4 joint risk assessment. But they each do regularly  
5 different parts of the --

6           MR. JAN: They have the same regulation but --  
7 yeah, whoever happens to be -- have jurisdiction over it  
8 to implement or apply that part of the regulation.

9           MS. ESKIN: A particular piece of that. Like  
10 you said, some do both and some --

11          MR. JAN: Right. Some do both and you have one  
12 --

13          MS. JOHNSON: Yeah. Or not together it's  
14 understood that it's a --

15          MR. MORSE: Okay. So we have communication and  
16 we have --

17          MS. ESKIN: Particular right.

18          MR. MORSE: -- the packing of rulemaking with  
19 FDA.

20          MS. ESKIN: Right.

21          MR. MORSE: Any other major points or --

22          MS. ESKIN: Under 2?

23               (Pause.)

24          MR. GREEN: It may be related to the last point  
25 that was made but one of the -- even if it isn't possible  
26 to have a joint regulation on those points the industry

1 has made it's desirable to the maximum extent feasible to  
2 have the same people carrying out -- this plan out.

3 I think Judy has said that as well that if that  
4 is a state agency that's under contract --

5 MS. ESKIN: Oh, that actually does the --

6 MR. GREEN: -- the AMS that is actually in the  
7 plan however frequently that might be an effective play  
8 of actually implementing it as opposed to having two or  
9 three agencies come in at different times.

10 MS. JOHNSON: We've talked a lot about how to -  
11 - I'm sorry.

12 MR. MORSE: So can we articulate that in our  
13 points. I'm sorry. So this is a coordinated --

14 MS. ESKIN: The Federal presence or the Federal  
15 -- government presence because it's either --

16 MR. MORSE: Yeah, it's felt in states.

17 MS. ESKIN: Implementation at the state level  
18 should be coordinated between FSIS and FDA or something  
19 like that.

20 MR. MORSE: So is that going to be a "C?" I  
21 guess that's --

22 MS. ESKIN: Mm-hmm.

23 MR. MORSE: Utilize existing onsite personnel -  
24 -

25 MS. ESKIN: Right. Feasible. Don't -- you  
26 know, no overkill. Are you done with the two?

27 (Increasing static in sound system.)



1           MR. MORSE: Just -- there's one other point I  
2 wanted to raise to the group if I haven't forgotten it, I  
3 think I wrote it down. I guess around -- should there be  
4 anything about training? So, for example, does it help  
5 to have the same training session at the Federal, state  
6 and local groups and even the industry would attend the  
7 same training sessions that the group would be  
8 distributing.

9           MS. JOHNSON: Joint training.

10          MR. MORSE: Is that beneficial so you don't  
11 have, you know, the regulators separate training for --

12          MS. ESKIN: Well, for what it's worth --

13          MR. MORSE: -- does that help foster  
14 communication?

15          MS. ESKIN: -- for what it's worth, I mean  
16 you're thinking in the meat context. Do you have  
17 training of people working in slaughterhouses rather than  
18 in processing? I mean those are treated separately?

19          MS. JOHNSON: No.

20          MS. ESKIN: Then I'm asking --

21          MS. JOHNSON: Everybody goes.

22          MS. ESKIN: I'm asking. I don't know.

23          MS. JOHNSON: No. Everybody goes. There's a  
24 three-day session on point.

25          MS. ESKIN: Okay.

26          MS. JOHNSON: And, you know --

27          MS. ESKIN: Then that makes sense.

1 MS. JOHNSON: -- yeah, it's understandable that  
2 there will be a different component as far as the  
3 regulatory of how you write this --

4 MS. ESKIN: Sure.

5 MS. JOHNSON: But the basic science HACCP  
6 principles.

7 MS. ESKIN: Okay. That seems reasonable.

8 MS. JOHNSON: Sit down and do it. We've talked  
9 a lot about communicating with the egg processors but I  
10 think one thing that FSIS -- and not being critical but  
11 sort of being critical -- you've got to communicate with  
12 your inspectors because a lot of times I think that's --  
13 everybody gets so busy working on a role and going  
14 forward that there gets to be a lot of apprehension in  
15 the field over what does this mean? What could happen?

16 MS. ESKIN: How do I -- how do I do this?

17 MS. JOHNSON: Yeah. And you know, as much  
18 communication as you can with your inspectors it kind of  
19 alleviates the fear of this is a new program. I'm going  
20 to not --

21 MR. MORSE: So do we put --

22 MS. JOHNSON: -- I'm going to --

23 MR. MORSE: -- do we put this in some -- is  
24 this a joint training session for --

25 MS. ESKIN: Yeah.

26 MR. MORSE: -- government and industry? How do  
27 you want to -- how do you want to --

1 MS. ESKIN: Joint training sessions for  
2 industry really and then --

3 MR. MORSE: Well, then why --

4 MS. ESKIN: -- the issue -- and the second  
5 point is the Agency should communicate with the  
6 inspectors in the whole rule development process --

7 MS. JOHNSON: Yeah. But a joint --

8 MS. ESKIN: -- is what we're saying.

9 MS. JOHNSON: -- you know, the joint training  
10 is what -- between industry and Agency personnel on  
11 scientific issues.

12 MS. ESKIN: Got it.

13 MS. JOHNSON: And then --

14 MR. MORSE: Could you --

15 MS. ESKIN: Personnel. Industry.

16 MS. JOHNSON: And then the next thing I'd like  
17 to see happen is, you know, communication between  
18 headquarters and the field over what's happening, whether  
19 it's just in your newsletters and, you know, you've got -  
20 -

21 MS. ESKIN: In the development of the rule and  
22 obviously and the implementation? You're saying both?

23 MS. JOHNSON: It doesn't -- and it doesn't have  
24 to be real detailed about the development of the rule.  
25 It just has to say here's what we're doing, you know, so  
26 a person can understand, you know, to get into too much  
27 detail during rulemaking.

1 MS. ESKIN: Headquarters. Headquarters.

2 MS. LOGUE: Well, you know, once you've got a  
3 route for this communication you go way back to the  
4 beginning where you have a list of all possible ways you  
5 could do it.

6 MS. ESKIN: Right.

7 MS. LOGUE: You know, pick out the training  
8 people that you could use there.

9 MS. JOHNSON: Yeah. That's right.

10 MS. LOGUE: Once they're there.

11 MR. MORSE: So do you want to add some  
12 qualifier to this?

13 MS. ESKIN: No.

14 MR. MORSE: No?

15 MS. LOGUE: Well, no. Just list it back to the  
16 very first one.

17 (Multiple voices.)

18 MS. LOGUE: We had the really long list here.

19 MS. JOHNSON: Yeah. You could say that applies  
20 for FSIS as well as --

21 MS. LOGUE: Yeah. It could apply to both  
22 places.

23 MS. JOHNSON: -- in the field.

24 MS. ESKIN: Well, it's just --

25 MS. LOGUE: Well, you'll get some points --

26 MS. ESKIN: Right.

27 MS. LOGUE: -- on this.

1 MS. ESKIN: Right. Right.

2 MS. LOGUE: You don't have to take them all.

3 MS. ESKIN: Whatever.

4 MS. LOGUE: I mean this one Extension offices  
5 would be a good source for us.

6 MR. JAN: There might need to be somewhere in  
7 there probably under bullet 2 or question 2, a  
8 correlation or review or some standardization from state  
9 to state on implementation which would be communication I  
10 guess.

11 But we heard today how some states have no egg  
12 regulations and some have and some have different places,  
13 but will have one set -- one rule but that still doesn't  
14 mean that it will -- each state's going to carry it out  
15 the same. There should be some Federal oversight to  
16 ensure that there's consistency --

17 MS. ESKIN: That it's consistent from state to  
18 state.

19 MR. JAN: And you know, with the rest of its  
20 problems can still be shipped in interstate commerce.

21 MR. WOOD: And related to that raises the  
22 numbers in question 3 in terms of these -- in terms of  
23 allocation and resources to where there may be a real  
24 void and a vacuum in terms of any existing quality  
25 assurance programs or whatever that may require more  
26 resources than other states that are already behind it.

1           MR. MORSE: So is that consistency in  
2 implementation or consistency --

3           MS. ESKIN: Both.

4           MR. MORSE: Ensure consistency?

5           MR. JAN: Yeah. Ensure consistency.

6           MS. ESKIN: Does it have a plan and --

7           MR. MORSE: Implementation --

8           MR. JAN: The plan is going to -- I mean --

9           MR. MORSE: -- between states.

10          MR. JAN: Yeah. Each -- all the states.

11          MR. MORSE: Different jurisdictions.

12          MR. JAN: And states carry it out the same way  
13 across the --

14          MR. MORSE: Mm-hmm.

15          MS. ESKIN: The Agency in Texas or --

16          MR. JAN: Right.

17          MS. ESKIN: -- in California.

18          MS. JOHNSON: Between states in implementation  
19 of the regulation.

20          MR. JAN: Right.

21          MS. JOHNSON: That's going to --

22          MS. ESKIN: And implementation.

23          MS. JOHNSON: -- the way it jumps but if you do  
24 something like the HACCP hotline that they did at the  
25 Tech Center.

26          MS. ESKIN: Mm-hmm.

1 MR. MORSE: Should we start -- start up with  
2 some kind of verb, to "maintain" or "ensure?"

3 MR. JAN: Correlates. Correlates.

4 MS. ESKIN: Ensure. Ensure.

5 MR. JAN: Correlates.

6 (Multiple voices.)

7 MS. ESKIN: I think "ensure consistency."

8 MR. MORSE: Before just --

9 MS. ESKIN: Ensure.

10 MR. MORSE: Ensure.

11 MS. ESKIN: To say "ensure consistency."

12 MR. MORSE: Before. Just the first --

13 MS. ESKIN: In the front of the above, yeah.

14 MR. MORSE: Ensure consistency.

15 MS. ESKIN: Ensure.

16 MR. MORSE: Ensure.

17 MR. GREEN: At the risk of complicating that  
18 further, it not only states -- although that's absolutely  
19 right, but Federal personnel meaning FSIS personnel have  
20 to implement consistently the same rules the same way --

21 MS. ESKIN: Wherever they are.

22 MR. GREEN: -- and that is perhaps the most  
23 commonplace.

24 MS. JOHNSON: How about consistency between the  
25 regulators and implementation. That way you can state if  
26 FSIS --

27 MR. ARNOLD: Or between states and Federal?

1 MR. JAN: I thought maybe --

2 MS. ESKIN: Well, yeah, because that --

3 MR. MORSE: So ensure consistency between  
4 regulators.

5 MS. ESKIN: Let's do separate for state and  
6 Federal. It's going to get confusing, no?

7 MR. MORSE: Meaning?

8 MS. ESKIN: Just say their point was -- your  
9 point. Randy was --

10 MR. GREEN: Consistent to that. Consistent  
11 application of --

12 MS. ESKIN: There we go.

13 MR. GREEN: -- rules by Federal --

14 MS. ESKIN: By Federal authorities, right.

15 MR. MORSE: As a separate bullet?

16 MS. ESKIN: I think so.

17 MR. MORSE: All right.

18 MR. JAN: Ensure consistency between states and  
19 Federal -- Federal --

20 MS. ESKIN: Yeah. But that sounds like you  
21 want the states to be consistent with each other. This  
22 way you're saying it's all the states and then all the  
23 Federal. It's slightly -- said slightly differently.

24 MR. GREEN: Federal personnel.

25 MR. JAN: Just don't use the word "equal to."

26 MS. ESKIN: We're the same. All we're missing  
27 is --



1 (Multiple voices.)

2 MS. JOHNSON: The same thing as --

3 MS. ESKIN: Yeah. All we're missing in Federal  
4 interaction is endorsing the GAO's suggestion that there  
5 be one Federal agency. That's the only thing that's not  
6 there.

7 MR. MORSE: Yes.

8 MS. ESKIN: Go ahead.

9 MR. MORSE: Okay. We'll go on to the third --  
10 which --

11 MS. JOHNSON: Is it --

12 MR. MORSE: -- (inaudible) --

13 MS. ESKIN: It's lucky we've got 10 minutes.

14 MR. MORSE: Okay. Which area is it in? Well,  
15 we have to go back and write these up. Which is the --

16 (Multiple voices.)

17 A PARTICIPANT: I have to go home.

18 MR. MORSE: Somebody that has more knowledge of  
19 the egg rules and regulations. In which area in the egg  
20 food safety plan should FSA concentrate its limited  
21 resources?

22 MS. ESKIN: I mean it really has a very  
23 distinct piece of the whole process, right? I mean  
24 packing and processing.

25 MR. MORSE: Up on the farm.

26 MS. ESKIN: Well, that's -- we only touched  
27 that.

1 MR. MORSE: Right.

2 MS. ESKIN: So it seems to me that we've got to  
3 choose between --

4 MS. JOHNSON: Education. Let's throw out some  
5 things. What -- education.

6 MS. ESKIN: Risk-based.

7 MS. JOHNSON: Risk-based.

8 MS. ESKIN: That's always a good one.

9 MS. JOHNSON: Sounds like --

10 MR. MORSE: Risk-based. Science-based.

11 MS. ESKIN: Risk analysis.

12 MR. MORSE: It's free association here.

13 MS. ESKIN: Your talking about, you know, the  
14 whole continuum of --

15 MR. MORSE: Risk-based.

16 MS. ESKIN: -- I guess the whole principle,  
17 whether it's going to vary from plant to plant.

18 MR. MORSE: Try some things here.

19 MS. ESKIN: Right.

20 MR. MORSE: I'll put "science-based."

21 MS. ESKIN: Risk-based allocation of resources.

22 MS. JOHNSON: Issues of public health concern.

23 MS. ESKIN: Yes, public health.

24 A PARTICIPANT: Public health.

25 MS. JOHNSON: Make for someone if they want to  
26 be specific.

1 MS. ESKIN: Well, how can we know if they don't  
2 get --

3 MR. MORSE: Research.

4 A PARTICIPANT: Research.

5 MR. MORSE: Right. Yeah.

6 (Multiple voices.)

7 MR. JAN: That's the only way you're going to -  
8 -

9 MS. ESKIN: And is there a point -- Randy, is  
10 there a -- I mean where do the -- if we're talking about  
11 the minute an egg enters the packinghouse all the way  
12 through to if it's processed, you know, what are we  
13 talking about in terms of are there identifiable points  
14 where HACCP plans generally are going to focus?

15

16 MR. GREEN: Oh, I think --

17 MR. MORSE: Refrigeration.

18 MR. GREEN: -- there probably are, you know.

19 We talked about some of them.

20 MS. ESKIN: Refrigeration.

21 MR. GREEN: I actually read the question a  
22 little differently and I may have -- and I may have been  
23 mistaken because I thought it was saying what was the  
24 regulatory activity? Should FSIS focus limited resources  
25 on governmental oversight of this?

26 MS. JOHNSON: Verification.

1 MS. ESKIN: Well, it should -- yeah, what -- I  
2 see what you're saying. Should they focus on HACCP plan  
3 development or monitoring or testing for verification  
4 versus end decisions?

5 MR. GREEN: Did I understand Judy correctly for  
6 you to say during your presentation at some point earlier  
7 today that probably the Agency would make -- would have  
8 contracts with the states and is that the way that you  
9 intend to implement what you're doing at the packer  
10 level?

11 In a sense, is that your way of addressing part  
12 of this question that you have limited inspection  
13 personnel so it's your intention to enter into a contract  
14 with states. I guess from our standpoint that seems --

15 MS. RIGGINS: Yeah. Is that a good idea?

16 MR. GREEN: -- a reasonable way to do it.

17 MS. RIGGINS: Is that not a good idea? You  
18 know, should we -- you know, we have to do continuous  
19 inspection in egg-processing plants and the  
20 pasteurization plants. So we have people in place there  
21 but we don't have any additional resources.

22 So the question is then how do we cover egg-  
23 packing facilities? FDA does not have inspection  
24 resources to cover the farms at all, they're not there  
25 now.

26 MS. ESKIN: Currently?

1 MS. RIGGINS: Yeah. So the question is how do  
2 we cover these two segments of, you know, of the  
3 continuum? Do you think that state contracts are, you  
4 know, the appropriate -- a good idea? Are there other  
5 ideas that you have that would be -- you know, that would  
6 -- that might be more cost-effective or efficient that  
7 would still be protective of public health?

8 MS. ESKIN: Well, it seems to me that if you're  
9 going to go -- to suggest, you know, state contracts  
10 which may be the pragmatic way to go we'd want to make  
11 sure that again you'd have uniform standards that would  
12 apply. So the Federal Government sets the standards and  
13 the state personnel --

14 MS. KASTER: Which we covered in number 2 three  
15 different ways, right?

16 MS. ESKIN: Right.

17 MS. KASTER: But I mean the FDA portion is  
18 going to be contracted?

19 MS. ESKIN: Right. I mean --

20 (Multiple voices.)

21 MS. KASTER: And so --

22 MS. ESKIN: Both of them.

23 MS. KASTER: -- then if you're going to combine  
24 the two -- if FDA just by the nature that they do things  
25 particularly at this level is going to be contracting  
26 them, wouldn't it make the most sense to recommend that -  
27 - again going back to all the communication things we

1 said on number 2 -- that they be jointly done on a  
2 contract basis.

3 MS. ESKIN: Sure.

4 MS. KASTER: And then allocated according to  
5 risk?

6 MS. ESKIN: With -- yeah, with Federal  
7 standards.

8 MR. MORSE: Is that under state contract or is  
9 that just a bigger point, just uniform standards,  
10 developing uniform standards that can be used by  
11 regulators?

12 MS. KASTER: Sure.

13 MR. MORSE: So it's a big -- whether it's  
14 contracted or whether it's --

15 MS. KASTER: Develop standards which can be  
16 readily implemented by contract.

17 MS. ESKIN: I want to make sure that they're --  
18 we're not talking about third-party contractors. I want  
19 to make sure that's clear. We're talking about other  
20 government officials, in this case state or local --

21 MS. KASTER: Right.

22 MS. ESKIN: -- agencies.

23 MS. KASTER: Right.

24 MS. ESKIN: I just want to make sure that's  
25 quite clear.

26 MS. KASTER: Right.

1 MS. ESKIN: It's not talking about a third  
2 party.

3 MS. KASTER: Well, a little bit in that. If  
4 you would incorporate that AMS aspect of things.

5 MS. ESKIN: That raises a lot of concerns.

6 MR. JAN: There's, there's some local health  
7 departments that contract out private.

8 MS. ESKIN: Where?

9 MR. JAN: Down in San Antonio there's -- I know  
10 there's a guy that's got about eight cities that he's  
11 contracted. He does all of their public health work. So  
12 it could --

13 MS. ESKIN: Do you consider --

14 MR. JAN: -- but you would probably pay more  
15 for that than you would the state.

16 MS. ESKIN: Oh, very much so.

17 (Multiple voices.)

18 MS. KASTER: You would pay --

19 MR. JAN: You probably would.

20 A PARTICIPANT: Yeah.

21 A PARTICIPANT: Yeah.

22 MS. KASTER: Oh, APHIS I would for sure but AMS  
23 with some of their --

24 MS. RIGGINS: No. AMS is very -- has very  
25 rigorous requirements.

26 (Multiple voices.)

1 MR. MORSE: Does somebody have a way of wording  
2 this?

3 A PARTICIPANT: I understand.

4 MR. MORSE: We're talking about the standards,  
5 uniform standards.

6 MS. RIGGINS: Yeah. I realize it's, you know -  
7 -

8 MS. ESKIN: Exactly.

9 MR. WOOD: And could there also be a  
10 qualification that these inspectors with whom they are  
11 contracting have training in this, somewhere out there to  
12 inspect for the quality --

13 MS. ESKIN: Right. They have to have --

14 MR. WOOD: -- of the egg and the safety of the  
15 egg and --

16 MS. ESKIN: Qualified contractors.

17 (Multiple voices.)

18 MR. WOOD: Food safety.

19 MS. ESKIN: Keep going. Keep going. Standards  
20 for qualified statement.

21 (Multiple voices.)

22 MR. MORSE: Training is a new bullet? I mean  
23 education might -- okay. We've listed -- any -- we're  
24 listed -- free-associated a number of things that we want  
25 to prioritize these in some way. Because if they have  
26 limited resources they may not -- are they going to be



1 able to do all of these? Do you want to prioritize them  
2 or just list them?

3 (Pause.)

4 MR. WOOD: I suggest that there's a lag time  
5 that you just listed.

6 MR. MORSE: Okay.

7 MS. ESKIN: Or another option would be the  
8 point that's there, resources. The real practical  
9 suggestion is that one which is resources. All those  
10 things we say above are nice but they don't have  
11 specifics in them.

12 What we're talking about from a pragmatic point  
13 of view is knowing that there's limited resources.  
14 Here's the basic construct. We're talking about Federal  
15 regulation standards that are then going to be actually  
16 implemented by state --

17 A PARTICIPANT: Regulators.

18 MS. ESKIN: -- regulators.

19 MR. JAN: Qualified contractors.

20 A PARTICIPANT: Yeah.

21 MR. MORSE: Okay. Now that we've gone -- we've  
22 got like five minutes. What I'm going to ask is it would  
23 help if we could have one or two people from the  
24 committee take each one of the three questions and help  
25 go back and sort of take -- go through them and try to  
26 make sure that they're in order. Because you haven't  
27 typed any of these up yet, right?

1 A PARTICIPANT: I've typed it all.

2 MR. MORSE: You've typed it all?

3 (Applause.)

4 MR. JAN: But all you've got to do is --

5 MS. KASTER: Yeah. But it needs to be boiled  
6 down.

7 A PARTICIPANT: Yeah.

8 MS. KASTER: You typed all the notes that she  
9 did, right?

10 A PARTICIPANT: Yes.

11 MS. KASTER: Yeah.

12 MR. MORSE: All the notes. This has to be sort  
13 of solidified into these three questions, right? The key  
14 points?

15 MS. KASTER: Yeah.

16 MR. MORSE: So are there any volunteers? I was  
17 going to suggest that we print them out like three  
18 different responses or we can take the pages from three  
19 different -- and have -- well, there's six of us. Isn't  
20 that convenient?

21 (Laughter.)

22 So I'd ask two members of the committee to  
23 review, you know, 1, 2 and 3 and that's going to be the  
24 most efficient I think.

25 MS. ESKIN: Yeah, that's true.

26 MR. MORSE: Is that --

1           A PARTICIPANT: Everybody takes a question  
2 right now.

3           MR. MORSE: Two people, okay. So we have --

4           MS. ESKIN: I'd volunteer to take it home and  
5 do it, but --

6           MS. KASTER: Well, because we have to have that  
7 paper ready when we leave here pretty fleshed out, right?

8           MR. MORSE: Right. Right. So the two --

9           A PARTICIPANT: Unless you want to get up  
10 really early in the morning --

11          MR. MORSE: Well, some of these are easy -- we  
12 can just -- who has to drive --

13          MS. ESKIN: So we'll do --

14          MR. MORSE: -- there are certain questions that  
15 are easier, like 2 and 3 are much shorter, right?

16          A PARTICIPANT: Mm-hmm.

17          MR. MORSE: So you can give your comment to  
18 your co-person. So how many people want to work on 1?  
19 Two?

20          A PARTICIPANT: Can we just work on 1?

21          A PARTICIPANT: I'll work on one.

22          MR. MORSE: Okay. Two.

23          MS. ESKIN: I'll do 3.

24          MR. MORSE: You want to work on 3? Okay.

25          MR. JAN: Okay. Did you say 3?

26          MR. MORSE: Well --

27          (Multiple voices.)

1 Do you want 3?

2 A PARTICIPANT: Three.

3 MR. MORSE: Three.

4 (Multiple voices.)

5 MR. MORSE: Three is one page. So --

6 MS. ESKIN: I know. That's why I volunteered.

7 (Laughter.)

8 MR. MORSE: Right. So does somebody want to  
9 work with Sandra?

10 MR. JAN: I'll work with her.

11 MR. MORSE: Okay. So then -- just so we get  
12 your comments.

13 MR. JAN: Yeah.

14 MR. MORSE: All right. You could just leave  
15 your comments with Jan and --

16 A PARTICIPANT: Sure.

17 MR. MORSE: -- get a little -- okay. One is --  
18 1 is the longest. So we have 2. Two, right?

19 (Multiple voices.)

20 Two is -- well, 2 is fairly short.

21 A PARTICIPANT: Yeah.

22 (Multiple voices.)

23 ALL: Thank you.

24 (Whereupon, at 8:55 p.m., the meeting was  
25 concluded.)

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CERTIFICATE OF REPORTER, TRANSCRIBER AND PROOFREADER

Emerging Egg and Egg Products Strategy

Name of Hearing or Event

N/A

Docket No.

Washington, D.C.

Place of Hearing

June 5, 2001

Date of Hearing

We, the undersigned, do hereby certify that the foregoing pages, numbers 1 through 110, inclusive, constitute the true, accurate and complete transcript prepared from the tapes and notes prepared and reported by Beth Roots, who was in attendance at the above identified hearing, in accordance with the applicable provisions of the current USDA contract, and have verified the accuracy of the transcript (1) by preparing the typewritten transcript from the reporting or recording accomplished at the hearing and (2) by comparing the final proofed typewritten transcript against the recording tapes and/or notes accomplished at the hearing.

6/5/01

Date

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Name and Signature of Transcriber  
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