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EGG SAFETY PUBLIC MEETING

Sponsored by: Food and Drug Administration (FDA)  
and Food Safety Inspection Service (FSIS)

MEMBERS PRESENT:

LOU CARSON  
JUDY RIGGINS

Held on:

Thursday, March 30, 2000

Location:

Hyatt Regency Hotel  
350 N. High Street  
Columbus, Ohio

MCCRERY REPORTING  
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TR 1

1                   LOU CARSON: I want to welcome you all here.  
2                   Thank you for your participation ahead of time. We  
3                   hope to have a very full and open public meeting and  
4                   hearing your comments. Today each one of you should  
5                   have picked up a green folder in the back which will  
6                   have the materials as well as the agenda. If you have  
7                   not, please pick one up in the back. We have  
8                   additional agendas out at the registration desk if you  
9                   need them. Today we're going to be starting here and  
10                  just now we are going to go over an introduction.  
11                  These are some of the administrative details that I'd  
12                  like to remind you about. When you do speak, when you  
13                  get up to speak and make a comment, if you would,  
14                  identify yourself by name and affiliation. And the  
15                  reason this is important is we have the two young  
16                  ladies over there on the side who are taking this down  
17                  as a transcript and we hope to have a transcript of  
18                  this meeting that will be displayed on our web site  
19                  in probably a few weeks. So it's important to hear  
20                  your name and your affiliation so that we can link up  
21                  to comment with that your person.

22                  Let me just quickly go through the agenda.  
23                  The agenda is laid out that we will have some brief  
24                  background remarks from Judy Riggins and myself. Then

1 we are going to go into a presentation from CDC on SE  
2 illness. And then we're going to go into the segments  
3 of the Egg Safety Action Plan. One thing that's  
4 changed from the agenda that you have before you, we  
5 will have a question and answer period right after the  
6 CDC presentation and I'd like you to note that there is  
7 a different speaker. Mary Evans will be speaking from  
8 CDC in that 8:45 slot. So immediately following her  
9 presentation, we will open the discussion for any  
10 questions or answers of the opening remarks and then  
11 the CDC presentation and then go into the next  
12 presentation. The way we're going to handle the  
13 presentations and the comments is that there will be a  
14 brief five to ten minute presentation of each segment  
15 such as on-farm production -- overview of the issues.  
16 And then we will ask our panelists to answer a few  
17 questions that we will have on the screen. And these  
18 questions were the ones that were in the federal  
19 registered document. That discussion period will be  
20 moderated by Marilyn Balmer in the morning, and Ms.  
21 Vicky Levine in the afternoon. And basically what they  
22 are going to be doing is trying to acknowledge people  
23 as they get to the microphone so that we don't have  
24 everyone trying to speak at the same time.

25 We will have a break around a little after  
26 10:00. Again, the sessions will be up to an hour. If

1           there are no other comments, then we will move on to  
2           the next section.   So we do not need to hold each  
3           session for an hour if there are not sufficient  
4           comments.   We will try to move the program forward.   We  
5           will break for lunch approximately at 11:35, return in  
6           approximately an hour and start the afternoon program  
7           and repeat.

8                       We have asked people if they wish to make a  
9           statement at the end of the meeting, to register.   And  
10          Linda Russell out at the registration desk is taking  
11          names so we can just acknowledge certain people in an  
12          orderly fashion so that you can make statements.   So if  
13          you wish to do so, please register out at the  
14          registration desk and then we'll acknowledge you after  
15          the meeting.

16                      And then finally, at around 4:30, we will try  
17          to make some closing remarks.   Those remarks will  
18          simply try to highlight those points that we've heard  
19          during the whole day of discussion.   Are there any  
20          questions on how the meeting will be run?   Okay.   Judy.

21                      JUDY RIGGINS:   Good morning.   You've met my  
22          colleague, Lou Carson, and I'm Judy Riggins from the  
23          U.S. Department of Agriculture in the office of policy.

24                      And I have a voice like Minnie Mouse so you'll have to  
25          bear with me here.   Lou and I appreciate the  
26          opportunity this morning to welcome you on behalf of

1 the Food Safety Council and the Task Force to our first  
2 of two public meetings.

3 The two departments, HHS and USDA are  
4 developing a farm-to-table approach to reduce the  
5 illnesses from salmonella enteritidis from shell egg  
6 and egg products. We appreciate the opportunity today  
7 to hear your thoughts, your concerns, and your comments  
8 on our current thinking for proposed rules for on-farm  
9 practices, shell-egg packing, and breaking and  
10 pasteurization facilities. Last year, the President's  
11 Food Safety Council initiated a process to develop a  
12 national strategic plan for food safety.

13 As a first step, the council identified egg  
14 safety as a public health issue that warranted  
15 immediate federal interagency action. The council  
16 established a Task Force that's co-chaired by Dr. Jane  
17 Haney, the commissioner of FDA, and Dr. Catherine  
18 Loteke the undersecretary for food safety at USDA.

19 Lou and I served as co-chairs for the Egg  
20 Working Group convened by the Task Force to draft an  
21 Egg Safety Action Plan which we published on December  
22 10, 1999. The overarching goal of the Action Plan is  
23 to eliminate SE illnesses associated with egg  
24 consumption by 2010. The interim goal is a 50 percent  
25 reduction in egg-associated SE illnesses by 2005. The  
26 action plan is based on the SE Risk Assessment that

1 indicated that multiple interventions can achieve a  
2 more substantial reduction in SE illnesses than using  
3 any one intervention alone. The Egg Safety Action Plan  
4 offers two equivalent SE reduction strategy to the  
5 industry each delivering eggs into distribution and to  
6 the consumer at an equivalent level of safety.

7 Egg producers and/or packer/processors will  
8 determine the point at which pathogen reduction steps  
9 will be taken. Pathogen reduction steps may be taken  
10 on the farm using SE testing and egg diversion and at  
11 the packer and/or processor with a "kill step" to  
12 eliminate SE. FSIS in cooperation with CDC, AMS,  
13 APHIS, and representatives from the states are drafting  
14 proposed regulations to address SE hazards on the farm  
15 at egg-packing facilities and in egg-pasteurization  
16 facilities. We published a March 21st Federal  
17 Registered Notice announcement of this meeting that  
18 requested comments on numerous questions related to our  
19 interagency coordinate egg rulemaking. We welcome your  
20 comments and request that you submit them to us by  
21 April 20th. Now Lou will talk to you in more detail  
22 about the Egg Safety Action Plan and it's two  
23 strategies.

24 LOU CARSON: The way the agenda is arranged  
25 is to try and give you the picture that the two  
26 strategies that Judy just talked about. One focuses on

1 the farm and putting in preventive control systems.  
2 The other strategy focuses at the egg-processing  
3 segment that would apply whatever technology that would  
4 provide a "kill step" whether it's pasteurization or  
5 other, they need to deliver to the distribution chain  
6 the same safe eggs regardless of which pathway has been  
7 taken. And what this really means is that the pathway  
8 for both strategies require renewed emphasis at the  
9 farm, at the packer/processor, at the retail, and at  
10 the consumer level. Each strategy is built on each one  
11 of those as an interval element to achieve this  
12 reduction by 2005. And so our agenda today is arranged  
13 so that we are covering each one of those segments from  
14 farm-to-table. We recognize that we can do better at  
15 each level. In the back of the room, for example, we  
16 have put up the Fight Back Campaign which Fight BAC! is  
17 really targeted at consumers, but we are also looking  
18 at educational efforts at the retail level, at the  
19 packer/processor level, and at the farm production  
20 level. So we can, I think, make people more aware of  
21 what are the potential hazards of each one of the steps  
22 and where we might be able to make a difference in  
23 achieving our reduction goal of 50 percent by 2005.

24 Today, what we are trying to present to you  
25 are some of those elements at each one of those  
26 segments which we believe have a contribution. What we

1 need to hear from each one of you is to what level you  
2 believe they can contribute and how best they can  
3 contribute. As Judy mentioned, we were charged by the  
4 Food Safety Council to come up with an Egg Safety  
5 Action Plan. This Action Plan required the  
6 coordination and cooperation of the agencies that Judy  
7 mentioned, APHIS, AMS, FSIS, CDC, and FDA. We continue  
8 to work together crafting our proposed rules, and we  
9 are working with a group of state officials that are  
10 assisting us in that regard. The time line that we  
11 have before us is this: We are charged with proposing  
12 rules by the end of this year and then allowing those  
13 for public comment, trying to finalize those rules the  
14 following year, and try to implement those standards in  
15 either 2002 or 2003. We would assume that there would  
16 be a phased-in approach so it would take more than one,  
17 probably one to two years to phase that in.

18 We need to achieve implementation by 2003 if  
19 we hope to be able to measure the success by 2005. So  
20 to measure whether we have achieved the goal of 50  
21 percent reduction, we will have to have a plan in  
22 place, allow it to perform to see if that program is  
23 really deriving the benefits that we're trying to  
24 achieve. The next speaker, is Mary Evans from the  
25 Centers for Disease Control. We mention in our Egg  
26 Safety Action Plan that we were going to be using the

1 baseline data from CDC as the starting point for trying  
2 to achieve our 50 percent reduction of SE illnesses.  
3 And what we would like for Mary to come up and talk a  
4 little bit about are those systems that we would be  
5 using to determine the incidence of SE illnesses and  
6 whether we are being successful.

7 MARY EVANS: Good morning. Today I would  
8 like to present an overview of the CDC surveillance  
9 data for salmonella serotype enteritidis infections in  
10 the United States. I'll begin with a short background  
11 about SE and continue with our laboratory-based active  
12 surveillance and SE-outbreak surveillance systems and  
13 then offer some short conclusions.

14 SE emerged in the Northeastern United States  
15 in the early 1980s and has since spread throughout the  
16 United States. Since 1993, SE has been the first or  
17 second most common salmonella serotype behind  
18 salmonella type venereum. Previous studies as well as  
19 outbreak investigations have shown that raw or  
20 undercooked eggs are the predominant vehicle of SE  
21 infection.

22 Culture-confirmed cases of salmonella are  
23 reported to CDC through the Public Health Laboratory  
24 Information System or what we call PHLIS. This slide  
25 shows the proportion of salmonella isolations from  
26 human sources that were SE between 1996 and 1998. As

1 you can see from the graph, the proportion of SE has  
2 dramatically increased from 1996 reaching a high of 26  
3 percent or approximately 98,000 on isolations in 1994.

4 Since then, the isolation rate has fallen to 18  
5 percent in 1998 representing approximately 6,000  
6 culture-confirmed cases. This slide shows the SE  
7 isolation rate by region of the United States. And as  
8 you can see, the New England region shown in yellow and  
9 the Mid-Atlantic region shown in blue have historically  
10 had the highest rate of SE infection.

11 Although in recent years, both of these  
12 regions have fallen dramatically. Conversely, the  
13 Pacific region which is shown in green, while it has  
14 historically had low rates of infection, dramatically  
15 increased in the 1990s, but, again, this region has  
16 also fallen in 1998. The Food-Borne Diseases Active  
17 Surveillance Network, or FoodNet, is collaboration  
18 between CDC, FDA, USDA, and selected sites around the  
19 United States. And the purpose of FoodNet is to  
20 conduct active surveillance for various bacterial and  
21 parasitic pathogens including SE. In 1999 there were  
22 eight FoodNet sites which represented about 25 million  
23 population that was under surveillance.

24 Now, as you can see from FoodNet data, the  
25 rate of SE was approximately 2.5 per hundred thousand  
26 in 1996 and 1997. However, in 1998, we again saw a

1 dramatic decline in the rates of SE in the FoodNet  
2 sites, about a 44 percent decline down to 1.4 per  
3 hundred thousand population. And as you can note from  
4 this slide, this graph is only based on the original  
5 FoodNet catchment area which was five sites.

6 Now, we know that for any culture-confirmed  
7 case of salmonella or any pathogen that's reported to  
8 CDC, many more cases go unreported. And this rate of  
9 under-reporting can be estimated and shown here by what  
10 we call the burden of foodborne illness pyramid. Along  
11 the base of the pyramid represents the general  
12 population. The next tier represents the people that  
13 actually become ill. Now a person may or may not  
14 decide to seek care for their illness. Their health  
15 care provider may or may not order a specimen to be  
16 tested. The lab to which the specimen is submitted may  
17 or may not test for all potential bacterial pathogens.

18 A proportion of the specimens that are submitted will  
19 actually yield a pathogen and then a proportion of  
20 these culture-confirmed cases will actually be  
21 reported.

22 So FoodNet is unique in that it allows us  
23 through the act of surveillance and through the various  
24 surveys listed here, the laboratory survey, physician  
25 and population survey, to estimate the number of cases  
26 that occur along each level of the pyramid. From this

1 we can create a multiplier that helps us to estimate  
2 the number of SE cases in the entire country. And the  
3 FoodNet multiplier that has been derived is 38. That  
4 is, for every one culture-confirmed case that you see  
5 at the top of the pyramid, it actually represents 38  
6 cases in the general population.

7 Now, this model can be applied to SE to  
8 calculate the approximate numbers of SE that we would  
9 expect to see in the general population. We'll use,  
10 for example, the 1998 PHGIS data. There were 6,035  
11 culture-confirmed cases reported in the United States.

12 If we apply the FoodNet multiplier of 38, we can see  
13 that we estimate in 1998 there were approximately  
14 230,000 cases of SE in the United States. Now, again,  
15 this is based on the 1998 data, and as you saw in  
16 previous slides, the rates have dramatically fallen.  
17 So, obviously if you would have based this on an  
18 earlier year, 1996 or 1997, the numbers would be a lot  
19 higher.

20 Now, we would expect from previous studies  
21 that a proportion of these cases would actually be  
22 associated with consuming raw or undercooked eggs.  
23 However, it's extremely difficult to calculate the  
24 exact number of these people who have eaten eggs  
25 because we don't have information of how individual  
26 people acquired their SE infection. Rather what we do

1 have is information about vehicles in outbreak  
2 settings. And that's the information I would like to  
3 present to you now.

4 Since 1985 CDC has maintained an SE-outbreak  
5 surveillance system which is basically a system where  
6 we keep track of SE outbreaks that are reported around  
7 the United States, and as you can see we reached a high  
8 of approximately 82 outbreaks in 1990. Since then the  
9 numbers have fallen and, in recent years, have leveled  
10 off. And in 1999 there were 44 outbreaks reported from  
11 the entire United States. This slide, again, shows the  
12 outbreaks between '85 and 1999 and, as you can see,  
13 there have been a total of 842 outbreaks representing  
14 approximately 29,000 cases, 2,900 hospitalizations and  
15 79 deaths. And it should be noted that the majority of  
16 these deaths occurred in people that were in hospitals  
17 and nursing homes.

18 This slide shows the SE outbreaks by region  
19 of the United States. It looks like the red line may  
20 be a little difficult to see, but that actually  
21 represents the Northeastern region which has  
22 historically had the greatest number of outbreaks.  
23 Although, in recent years, there has been a dramatic  
24 decline in the number of outbreaks in this region.  
25 Again, the Western region shown in green has  
26 dramatically increased in the early 1990s. And today

1 this region represents half of the SE outbreaks we see  
2 in the entire country.

3 This slide shows the outbreaks of SE  
4 infections by location of food preparation. And,  
5 historically, over 60 percent of the outbreaks have  
6 involved foods that were prepared in a commercial  
7 venue. And by this I mean a restaurant, deli/bakery,  
8 or a catered event. Eleven percent have involved food  
9 prepared in health institutions, 13 percent in private  
10 homes, and 15 percent in other locations; for example,  
11 schools and churches.

12 This slide shows outbreaks by food vehicle.  
13 Now, historically, we've been able to determine a  
14 vehicle in outbreaks in only approximately 45 percent  
15 of outbreaks. And by "determine a vehicle" I mean that  
16 there was either a case control study or a cohort study  
17 done that statistically implicated that vehicle and/or  
18 we were able to isolate SE from a food source.  
19 However, of these outbreaks, 295 or 81 percent of them  
20 have involved foods that were egg associated, that  
21 contained eggs.

22 Now, if you want to translate this into  
23 numbers, we saw from the previous slide 842 outbreaks  
24 represented approximately 29,000 cases; 20,000 of these  
25 cases were in outbreaks where there was a confirmed  
26 vehicle; and 15,000 of these were egg-associated cases.

1           Again, this is just based on outbreak data.

2                       This slide shows the egg-associated vehicles  
3 by category, and I apologize for the slide being  
4 slightly cut off on the side, but you can see the  
5 proportion in green represents traditionally-prepared  
6 egg vehicles such as omelettes and egg-battered foods.  
7           That's been our highest percentage followed by  
8 desserts, sauces and dressings, and then pastas. So,  
9 in conclusion, we can say a couple of things. Based on  
10 our 1998 PHLIS numbers and applying our FoodNet  
11 multiplier, we can estimate that there are  
12 approximately 230,000 cases of SE in the United States  
13 at least for 1998.

14                      Both our PHLIS and our FoodNet Surveillance  
15 have shown that there are nationwide declines in the  
16 number of SE cases. In terms of outbreaks, while there  
17 have been drastic declines in certain regions of the  
18 United States, particularly the Northeastern region,  
19 the number of outbreaks have remained relatively  
20 unchanged in the most recent years, like, '97, '98, and  
21 '99. However, with outbreaks with a known source, we  
22 know that the predominant vehicle remains raw or  
23 undercooked eggs.

24                      So despite the declines in SE we think it is  
25 still a very important health problem that's going to  
26 require cooperation between public health officials and

1 industry at all levels and an entire farm-to-table  
2 approach for prevention. Thank you.

3 MARILYN BALMER: Are there any questions at  
4 this point on the CDC data? Could you please go to a  
5 microphone.

6 KEN KLIPPEN: Good morning. My name is Ken  
7 Klippen and I'm with United Egg Association and United  
8 Egg Producers in Washington, D.C. And, Mary, I just  
9 have a question for you if you could help me with this.

10 In the recent morbidity/mortality weekly report, dated  
11 March 17, 2000, it stated that, and I'll read it, that  
12 SE rates declined, salmonella enteritidis rates  
13 declined, 48 percent from 1996 to 1999 with a 7 percent  
14 decline from 1998 to 1999. Of course, the salmonella  
15 enteritidis is the one that we're most concerned with  
16 because that's the one that's associated with eggs.

17 Why is it declining? What programs have  
18 taken place to substantiate a fall in the SE rates?

19 MARY EVANS: That's a good question. I don't  
20 really have an answer for that. We only collect the  
21 data and monitor the trends. Maybe someone with the  
22 USTIT would have some better ideas about that.

23 JILL SNOWDON: Good morning. Jill Snowdon  
24 with the Egg Nutrition Center. The information that  
25 you put that you're collecting is on all salmonellosis  
26 from SE. So the program that we're looking at is

1 salmonellosis from SE from eggs. So if we're talking  
2 about benchmarks and what we're going to use for the  
3 success of the program and also communicating to the  
4 media, because the media have trouble distinguishing  
5 between all salmonellosis cases, all SE cases aren't  
6 all associated with eggs.

7 Those little details tend to be important.  
8 Likewise, not all cases of salmonellosis, although a  
9 large majority are, are foodborne. So there's also --  
10 the CDC estimates a 5 percent chunk that isn't even  
11 foodborne. So we need to make sure that we are even.  
12 If the program is directed at eggs then we need to be  
13 thinking about measuring the egg involvement with  
14 accurate, stable databases such as the salmonella  
15 surveillance system, such as PHLIS stated, that you put  
16 forward, such as FoodNet. Because it would be  
17 illogical and unsound scientifically and kind of put  
18 everybody in a vulnerable or unfair position if we're  
19 mixing the two. So it's very important to communicate  
20 when the data is representing salmonellosis,  
21 salmonellosis from SE, or SE-based salmonellosis  
22 associated with eggs.

23 The question to what extent outbreaks affect  
24 sporadic cases, particularly since outbreaks are --  
25 What? -- less than 1 percent of all the cases across  
26 the United States in recent years, is another question

1           that we've got to grapple with anybody looking at  
2           epidemiology and how we're going to use it. I mean,  
3           it's a tool. It's a great tool. But, again, I think  
4           we need to be very clear in our communication and very  
5           clear in our goal setting then as to what we're using  
6           as our benchmarks and are they accurate reflections of  
7           what the goal of the plan is.

8           Either that, or we expand the program to  
9           include more than eggs and just take care of all  
10          salmonellosis associated with SE. One or the other.

11          MARILYN BALMER: Okay. Let's progress into  
12          the main portion of the program. Okay. Darren.

13          DARREN MITCHELL: Darren Mitchell with Center  
14          for Science in the Public Interest in Washington, D.C.

15          It sounds like CDC has not yet or won't track down  
16          what the source of the declines are. I'm not saying  
17          that figuratively, I'm just not sure that it's within  
18          your purview. Do the other agencies tend to look at,  
19          sort of, the regional declines and try to see whether,  
20          as the agencies have noted, and other groups have  
21          noted, successful quality assurance programs in places  
22          like Pennsylvania, are the source some of the declines?

23          LOU CARSON: Again, I think, the reason we  
24          are here today and talking about a farm-to-table  
25          approach, both FDA and USDA and CDC do believe that  
26          nationwide consistent standards reflecting the programs

1           that certain states have already enacted, are certainly  
2           indicative of those kinds of preventive controls that  
3           will have a positive effect on reducing SE illnesses.  
4           So the Egg Safety Action Plan is certainly based on the  
5           history of what states in the Northeast and in the  
6           Central region have already taken.

7                     The question you ask though goes to  
8           surveillance and making a direct connection. I think  
9           that is a very complex question. We certainly are  
10          going to attempt to survey and try to link wherever  
11          possible. We may not be able to directly link, but we  
12          will make that effort.

13                    JUDY RIGGINS: I just wanted to add that  
14          research is a very important part of the Safety Action  
15          Plan. And we do intend each year to develop an agenda  
16          for research in cooperation with FDA, and ARS, AMS, and  
17          other agencies. Of course, CDC is central to that  
18          because we use the information from CDC to form the  
19          questions for our further research. So we do intend on  
20          an ongoing basis to determine what research needs we  
21          have each year and to refine the knowledge that we  
22          have.

23                    Understand that we have to start where we  
24          are. We have to start someplace. So it is our intent  
25          to have that ongoing effort.

26                    MARILYN BALMER: Okay. We have a panel today

1 representing various parts of the industry, the public  
2 and the states. On the panel today, we have, starting  
3 on the left, or your right, Tad Gross, who is president  
4 of Hemmelgarn and is also president of the Ohio Poultry  
5 association and the Ohio Egg Processors Association.  
6 Next to him is Meryl Sosa who is with FACT, Food Animal  
7 Concerns Trust. She is manager of their food safety  
8 programs. Next to Meryl is Dave Glauer who is the  
9 state veterinarian for the State of Ohio.

10 These panel members will initiate discussions  
11 after each presentation. The first presentation will  
12 be given by Rebecca Buckner.

13 REBECCA BUCKNER: Good morning. I'm Rebecca  
14 Buckner and I'm with FDA's Office of Plant and Dairy  
15 Foods and Beverages. And this morning I'm going to  
16 give you a brief overview of some of the issues that  
17 FDA is considering for it's proposed rules On-farm SE  
18 Risk Reduction Control.

19 As you heard described earlier, the Egg  
20 Safety Action Plan outlines two strategies for reducing  
21 the risk of SE in eggs. I'm going to discuss a portion  
22 of Strategy I this morning. Strategy I focuses on on-  
23 farm controls, retail, and education for SE Risk  
24 Reduction. Later today there will be a presentation  
25 and discussion on the retail and education efforts.  
26 However, right now, I'm going to focus on the on-farm

1 controls. Under the Egg Safety Action Plan, it is  
2 FDA's responsibility to develop consistent nationwide  
3 standards for on-farm preventive controls. We plan to  
4 implement the inspection and enforcement on the farm  
5 through state contracts.

6 FDA envisions that these consistent  
7 nationwide standards will consist of two parts. The  
8 Plan, or the SE Risk Reduction Plan, and the  
9 verification of that plan. The Plan is composed of the  
10 measures that will actually provide the risk reduction.

11 The verification ensures that these provisions are, in  
12 fact, working effectively and providing risk reduction.

13 Potential components of the Plan include purchasing  
14 chicks from SE-monitored breeders, biosecurity in which  
15 you would maybe limit visitors and not move equipment  
16 between houses and not allow stray poultry into your  
17 houses; also the use of SE-negative feed, cleaning and  
18 disinfection of houses and equipment, a rodent and pest  
19 control program, because we know that rodents and flies  
20 can harbor SE; a flock-health monitoring program and  
21 use of a monitored-water supply. And all of these  
22 provisions are aimed at reducing the production of SE  
23 contaminated eggs. And those would make up the SE Risk  
24 Reduction Plan.

25 The verification of this plan, FDA is  
26 considering perhaps the possibility of environmental

1 testing and perhaps egg testing with diversion if the  
2 egg testing is positive. Verification is necessary to  
3 provide assurance that the components are actually  
4 effectively reducing SE. And that is a basic overview  
5 of these issues. My presentation is very short.  
6 That's the Plan as I have described it and it's  
7 potential that's under construction. We're developing  
8 a proposed rule at this point. So we are very  
9 interested in your input and, therefore, we have the  
10 following three questions for discussion this morning.

11 And they relate to on-farm controls and I guess at  
12 this point I'm going to turn it back over to Marilyn to  
13 begin the discussion.

14 MARILYN BALMER: If we could start the  
15 discussion with those on the panel, the questions are:

16 Are the following appropriate and adequate components  
17 for nationwide SE Reduction Plan. They are  
18 biosecurity, SE-negative feed, chicks from SE-monitored  
19 breeders, flock-health monitoring program, cleaning and  
20 disinfecting of houses, rodent and pest control, and  
21 monitored water supply.

22 Let's start with the first question. Shall  
23 we start with Tad on the end?

24 TAD GROSS: Well, my experience has mostly  
25 been with the program that we have developed in the  
26 State of Ohio here. I feel that all the above

1 mentioned things have been put into place. In the Ohio  
2 program we have come along and started on a small basis  
3 and continued to modify as we went incorporating things  
4 with the help of the ODA to pick and choose what was  
5 brought to our attention.

6 For example, from UEP, they have a 5-Star  
7 Program and we've kind of worked off of that. The  
8 Pennsylvania situation is naturally one of the leaders  
9 in the Egg Quality Assurance Program. Ohio had nothing  
10 when we started. And we've worked to at least focus on  
11 something, got our producers working in the general  
12 directions. We have implicated all of the following  
13 things into this program. And at this point we feel  
14 it's come a long way and naturally improvements can be  
15 made as it goes.

16 MARILYN BALMER: Can we just move along?  
17 Meryl, if you have any comments?

18 MERYL SOSA: Of those elements, we, of  
19 course, feel that all of them are very important, but  
20 I'd like to focus for a minute on the requirements that  
21 there be SE-free chicks placed in the pullet house.  
22 Because even if a small percentage of salmonella-  
23 positive eggs enter the hatching cabinet, the spread of  
24 salmonella from these eggs can be extensive. Chicks  
25 are extremely susceptible to salmonella contamination  
26 because they do not develop immune systems until they

1           are ten days old. In addition, hatchery contamination  
2           can limit the effectiveness of competitive exclusion  
3           products.

4                     A study found that salmonella could be found  
5           inside the beaks of chicks which were still in the egg  
6           but ready to hatch. Here, also, competitive exclusion  
7           products would be ineffective since colonization had  
8           already occurred. Since it is not possible to totally  
9           prevent SE contamination in the chicks, testing of  
10          chick papers is a necessary component of the program.

11                    And the other aspect regarding SE-free chicks  
12          that we would like to talk about for just a second is  
13          the idea of indemnification resulting from the SE-free  
14          chicks. Because if the producer tests the chick papers  
15          on delivery and finds that the chicks are contaminated,  
16          then the breeder should be required to provide a new  
17          batch of uncontaminated chicks. Currently breeders do  
18          not maintain extra stocks of chicks for such  
19          emergencies. Instead, if such an occurrence arises,  
20          the producer must order new chicks; and the flock  
21          houses must remain dormant thereby creating a financial  
22          hardship for the producer. Thus, if the breeder fails  
23          to provide replacement chicks then it should be  
24          required to financially indemnify the producer for any  
25          losses incurred as a result of the inability to  
26          commence the flock in a timely fashion.

1                   And I would like to note that while I am the  
2                   manager of Food Safety Programs, and FACT is an  
3                   advocacy organization, we also have a subsidiary called  
4                   Nest Eggs. And Nest Eggs is a producer of eggs from  
5                   uncaged, drug-free hens. And we have been implementing  
6                   an SE program since 1991 on our farms. And our farms  
7                   have been in existence since 1984. So we do speak from  
8                   sort of both sides.

9                   MARILYN BALMER: Dave.

10                  DAVID GLAUER: Thank you, Marilyn. Just a  
11                  brief diversion from the program just to welcome to all  
12                  of you to the State of Ohio. We are pleased that you  
13                  are here.

14                  From Ohio's standpoint, we did begin work  
15                  back in 1996 relevant to salmonella enteritidis issues  
16                  in eggs, and we have reviewed a variety of different  
17                  state programs and feel that we have put together a  
18                  program that encompasses the individual segments of a  
19                  program that you've seen on the screen before, and that  
20                  are listed here in that program.

21                  We feel that in following those and  
22                  developing those best-management plans on the farm that  
23                  we do have the ability to put in place a program that  
24                  will help reduce SE in the egg.

25                  MARILYN BALMER: Okay. In the audience and  
26                  around the table, I know there are representatives from

1 other states, other producers. The floor is open for  
2 any comment. Can we start with the table first?

3 DARREN MITCHELL: Hi, Darren Mitchell with  
4 CSPI again. I just have a couple of comments on this  
5 portion of the plan. First of all, to CSPI, the most  
6 important element of this entire Egg Safety Plan is a  
7 successful testing and diversion plan for  
8 producers/processors who aren't going to rely on a  
9 "kill step". And there aren't any specific -- I guess  
10 we may get to it in Question No. 6 -- What I assume is  
11 that the agencies, while during rulemaking, hash out  
12 whether the testing should be focused on environmental  
13 only, environmental plus eggs, there's some combination  
14 that makes sense. But we would like to see a lot of  
15 emphasis on that discussion and we would like the  
16 rulemaking to be focused on that in large part. In  
17 terms of what is listed, we also agree that every  
18 single one of those components is critical and we have  
19 a couple of enlargements or additions as well.

20 One is that -- and I'm not sure this is the  
21 appropriate place to put it, but enforcement,  
22 obviously, is critical. And I'm not sure that we're  
23 going to talk about enforcement in the other questions,  
24 but if the state agencies are going to be responsible  
25 for enforcement, we'd like to see very, very strong  
26 federal oversight to the extent that the federal

1 government preapproves or preaudits the state  
2 enforcement program and then conducts regular,  
3 preferably annual, audits of those programs to ensure  
4 that the state agencies are doing a good job. The need  
5 to disinfect and clean, obviously, is critical and we  
6 would like to see SE testing as a means to ensure that  
7 the cleaning and disinfection is actually successful.

8 We haven't addressed the issue of forced  
9 molting. For producers who rely on induced molt --  
10 First of all, we would prefer to see that practice  
11 banned because of it's relationship to SE and the fact  
12 that it increases the colonization of hen intestines  
13 with SE and can also increase shedding. But to the  
14 extent that it's not prohibited, we'd like to see extra  
15 measures in place to make sure that flocks that are  
16 induced, that have induced molting, are tested to  
17 ensure that SE is not being shed.

18 And finally, we think it's important -- we  
19 talked about SE-free chicks -- SE-free pullets prior to  
20 placement in the pullet house, we think, is also a  
21 critical element. So I'll leave it at that. Thank  
22 you.

23 MARILYN BALMER: Anybody else from the table?

24 Meryl.

25 MERYL SOSA: I'd like to elaborate on what  
26 Darren mentioned about forced molting since it's not

1 mentioned as one of the elements there and I don't see  
2 it mentioned under any of the other two questions. As  
3 you are probably all aware, we do not force molt on our  
4 farms. The Risk Assessment stated that 22 percent of  
5 flocks producing eggs on any given day are flocks that  
6 were previously molted. And we feel that this figure  
7 underestimates the extent of the practice. In fact,  
8 according to the recently completed NARMS study, 82.6  
9 percent of all egg farms routinely molt their layers.

10 The West force molts 94.9 percent of it's flocks.

11 Further, 32.1 percent of the last completed flocks in  
12 the West were force molted twice.

13 As more consumers have become aware of this  
14 practice which is both inhumane and hazardous to the  
15 public health, the issue is now being raised at the  
16 state level. In California there is now a bill pending  
17 in the legislature to prohibit this practice. The Plan  
18 calls for, quote, a consistent nationwide program that  
19 addresses each stage of the farm-to-table continuum,  
20 close quote. Thus, if the issue of forced molting is  
21 not addressed in the Plan, then individual states may  
22 start enacting prohibition on the practice which will  
23 defeat the concept of a consistent nationwide program.

24  
25 I just want to mention also that the SE Risk  
26 Assessment demonstrates the need for testing especially

1 on large farms. The Risk Assessment found that by  
2 flock size strata, the largest stratum, flock sizes of  
3 100,000 per flock, contributed almost two-thirds of SE-  
4 positive eggs. And finally, in terms of the test  
5 itself, FACT supports environmental testing over  
6 testing batches of eggs. Environmental tests provide a  
7 more accurate picture of whether or not the flock is  
8 contaminated. Infected hens do not produce  
9 contaminated eggs all the time. Furthermore, not all  
10 hens at a flock house are infected by SE at the same  
11 time. Therefore, testing batches of eggs will not  
12 provide sufficient evidence to determine whether the  
13 flock house is contaminated by SE. On the other hand,  
14 since infected hens will shed SE, environmental samples  
15 provide greater certainty as to whether SE is present  
16 in the hens.

17 So as a final note regarding forced molting,  
18 if the Plan does not include a prohibition from the  
19 practice -- which, of course, we feel it should -- then  
20 at a minimum, mandatory post-molt environmental tests  
21 should be required as part of the Plan.

22 MARILYN BALMER: Anybody else at the table?  
23 Okay. Can we start with the floor?

24 RITCHIE LAYMON: Thank you. My name is  
25 Ritchie Laymon. I'm from Columbus, but I'm  
26 representing United Poultry Concerns which is located

1 the Del Marva area. And I am so glad the two panelists  
2 noticed that glaring omission. That was the first  
3 thing that jumped out at me is there was no mention of  
4 a stoppage of forced molting. When Mary Evans said in  
5 her introductory speech that there was a dramatic  
6 increase in SE in the Pacific region, I immediately  
7 thought of California being number one, at one time, in  
8 the production of eggs and the fact that they used  
9 forced molting on tens of millions of chickens every  
10 year. And I would have thought that CDC would look  
11 immediately at that connection since we know there is a  
12 connection between SE and forced molting. And that  
13 spike in the Pacific I would think would be directly  
14 related to that.

15 And another point, I want to make a vow to  
16 necessity to stopping forced molting because with the  
17 graying of America you have so many elderly people who  
18 eat eggs. It's an easy food to eat for them. I think  
19 you're going to see an increase. I think this trend to  
20 go down will go back up again. And also something as  
21 simple as the Atkin's Diet which asks people to eat  
22 bacon and eggs, you're going to see an increase, I  
23 think, in that area too. Anyway, I would like the CDC  
24 to respond a little bit if there was any research done  
25 on forced molting and SE and the spike in the Pacific  
26 area?

1                   MARY EVANS: I'm not aware of any research  
2 that's currently going on, but that's certainly an  
3 interesting question that we could look at.

4                   MARILYN BALMER: Other comments from the  
5 audience?

6                   ALICE WALTERS: Hi, I'm Alice Walters, the  
7 executive director of the Ohio Poultry Association. My  
8 comment on forced molting would be we have a program  
9 here that will also affect small, medium, and large  
10 producers. Our larger producers may be able to stop  
11 force molting but I seriously doubt that our small and  
12 medium producers would be able at this point in time to  
13 incur the economic losses that would occur if the  
14 federal government does a total ban on forced molting.

15                   I'm sure there's some other producers in the room that  
16 would state that.

17                   So if you are concerned about the smaller  
18 family farmer, you need to take this into consideration  
19 at this point in time. We do have other mechanisms  
20 available to us and we are using them currently in  
21 Ohio. And that is the environmental testing of the  
22 manure. We are not seeing at this point, and maybe  
23 Dave can correct me if I'm wrong, but most of the  
24 flocks force molted that are on our program and have  
25 been on our program since 1996, we're not seeing an  
26 increase in SE in those manure samples that are coming

1 in through the Ohio Department of Agriculture  
2 Laboratory.

3 Also we have available to us the vaccines.  
4 Bioimmune is one, and the Megan Vaccine, that we can  
5 also utilize at this point in time to treat our flocks  
6 here in Ohio. And I think there are some management  
7 tools available to us that can also be built into a  
8 program such as this. One other comment that I would  
9 like to make, and excuse me if I offend anyone, but I  
10 have a problem with this forum being a forum for animal  
11 rights agendas. And I know that Ms. Laymon is also  
12 with an animal rights organization that is very active  
13 against the poultry industry here in Ohio. And I would  
14 just like all of you to also weigh those comments in  
15 that regard. Thank you.

16 MARILYN BALMER: Bob.

17 BOB ECKROADE: Bob Eckroade from the  
18 University of Pennsylvania whose worked with the PEQAP  
19 Program there for many years. My guess is in  
20 Pennsylvania we molt at least 60 percent of the birds.  
21 And our program also requires testing post-molting,  
22 additional testing post-molting. And I can tell you  
23 that in the real world, there is absolutely no evidence  
24 that there's a great increase in the shedding of  
25 salmonella enteritidis in flocks that are monitored  
26 post-molting.

1                   So while there's been some experimental  
2 evidence done by some good people, I think, as always,  
3 when you extrapolate that to the real world, it may not  
4 hold up. And I too think it's important to separate  
5 out the issues of animal rights and the issues of how  
6 best to control the shed of salmonella enteritidis and  
7 still allow our industry to make a profit and to run  
8 its own business.

9                   MARILYN BALMER:       If there are no more  
10 questions, let's move on to the second one that is: Is  
11 environmental testing an appropriate verification step  
12 to ensure that the Risk Reduction Plan is working? If  
13 so, how often and when should testing be performed to  
14 ensure that the Plan is working and that the consumer  
15 is protected from consuming SE-contaminated eggs? At  
16 this time I'd like to reverse the order and start with  
17 Dave on the panel.

18                   DAVID GLAUER:   I think research does indicate  
19 that environmental testing is an appropriate means of  
20 surveillance or at least verification of the  
21 effectiveness of a program from the standpoint of SE.  
22 We are, here in Ohio, doing NAA testing and that allows  
23 us then to effectively react to a house that has a  
24 positive environmental and cleaning and dust infection.  
25       The producers need to review their program, if they do  
26 have a positive, to make sure that all of the best-

1 management practices really are in place and if any of  
2 them need to be improved.

3 MARILYN BALMER: Meryl.

4 MERYL SOSA: We believe at FACT that the  
5 cornerstone of an SE Risk Reduction Program is  
6 mandatory environmental testing. Absence of such  
7 testing, how does the producer know whether the layers  
8 are infected since the infected layers are generally  
9 asymptomatic? Unfortunately, most of the QAPs  
10 including the UEP Program and the Ohio Program, if they  
11 do include any environmental testing, require the test  
12 only two to three weeks prior to depopulation. By this  
13 time, thousands of contaminated eggs could already have  
14 been produced and marketed. The risk assessment  
15 demonstrates the need testing especially on large  
16 farms. It found that by flock size strata, the largest  
17 stratum, flock size is of 100,000 per flock,  
18 contributed almost two-thirds of SE-positive eggs. In  
19 terms of the test itself, FACT supports environmental  
20 testing over testing of batches of eggs as I discussed  
21 earlier.

22 And FACT will be including a copy of the Nest  
23 Eggs SE-testing protocol as part of its written  
24 comments. However, briefly, the protocol requires at a  
25 minimum, environmental tests of chick papers, the empty  
26 layer house, pullets at 10 to 15 weeks, layers at 29 to

1 31 weeks, layers at 44 to 46 weeks. And we feel that  
2 in flocks that are force molted, there should be an  
3 additional test at 5 to 7 weeks following return to  
4 feed. And that a similar protocol is followed by  
5 PEQAP.

6 MARILYN BALMER: Tad.

7 TAD GROSS: The one thing, the thing that  
8 does assure, is that testing does educate us as  
9 producers to verify that we do have problems and, you  
10 know, it has become very essential that the testing be  
11 done at all stages in the Ohio Program. In the initial  
12 offset, we were missing parts of that program and now  
13 have put them into place. And as we go ahead and  
14 continue to put our program together and make it  
15 better, our producers are now becoming more educated to  
16 the fact that you got a problem. You know it. You can  
17 fix it. Without the testing you're lost in the world  
18 and things go on. So the environmental testing is a  
19 very big help for everybody in trying to do the best-  
20 management practices.

21 MARILYN BALMER: Within the Ohio Program, how  
22 often? I need a comparison here.

23 TAD GROSS: We just put the pullet monitoring  
24 in which we had not had prior to about four months ago.  
25 We're doing testing after the molting and we're doing  
26 testing prior to the birds going out. So we basically

1           have an environmental testing in three different  
2           locations in the laying flock now.

3                   MARILYN BALMER: Anybody at the table?

4                   DARREN MITCHELL: Darren Mitchell, CSPI.  
5           Part of the reason I brought up the testing and  
6           diversion under Question 4 and not Question 6 is  
7           because, I guess, the term "verification" is a little  
8           too restrictive from our perspective. We see the  
9           testing program serving both the verification function  
10          to inform producers and the regulators when there is a  
11          problem so appropriate corrective actions can be taken.

12          But also that's part of the egg-diversion component  
13          that's to be used if a "kill step" is not being used at  
14          the processing plant. And I think it may behoove the  
15          group and the national standards work group as well to  
16          tease out those two aspects. There's a verification  
17          component and there's a testing and diversion  
18          component. The same tests could be used for both  
19          purposes but let's tease that out and let's separate  
20          them. Have different categories so it's less confusing  
21          -- maybe I'm totally misinformed -- but, so that it's  
22          less confusing if people are trying to understand the  
23          program.

24                   I noticed in looking over the components that  
25          under 4 there is a verification validation category,  
26          but none of the letters or numbers after it say egg

1 testing and diversion and talk about diversion. So  
2 we'd like to see that change made to both the  
3 components and to the overall Action Plan.

4 MARILYN BALMER: Anybody else from the table?  
5 Okay. Open to the floor.

6 RITCHIE LAYMON: Yes. I'd just like to  
7 respond. I heard the term best-management practices  
8 used seven times and I can't see any justification for  
9 forced molting being called a best-management practice.  
10 And with regard to Ms. Walters' statement that this  
11 shouldn't be turned into a forum for animal rights  
12 activists, I agree with her. It shouldn't be turned  
13 into a forum for AR. But, I think people should know  
14 here that the animal rights activists are very often  
15 advocates for the consumers. It was animal rights  
16 activists that were the first people to alert the State  
17 of Ohio to the best-management practices of the Buckeye  
18 Egg Farm, which is the largest egg producer in the  
19 state, and they are now being pursued by the attorney  
20 general. So I wouldn't dismiss us as not caring about  
21 consumers, just having our own agenda, we do care about  
22 consumers. We are consumers.

23 MARILYN BALMER: I believe there was another  
24 hand.

25 LOU CARSON: You need to identify the  
26 speakers.

1                   MARILYN BALMER: Could you repeat your name?

2                   RITCHIE LAYMON: Yes. Ritchie Laymon. I'm  
3 speaking on behalf of the United Poultry Concerns.

4                   MARILYN BALMER: Okay. If you could go to  
5 the mike.

6                   KEN KLIPPEN: My name is Ken Klippen with  
7 United Egg Producers. And I was much encouraged,  
8 Rebecca, to see that the testing, the environmental egg  
9 testing, would lead to egg testing and then with  
10 positives would lead to diversion of that product. And  
11 that's something that the egg industry is supportive  
12 of. We're not against testing. But we're against  
13 extensive testing when we find there's a negative  
14 environmental test. Why continue testing when it's  
15 negative? So, the product that is actually going to  
16 the consumer is the egg, not the environment, so if the  
17 egg is positive, by all means, those eggs should be  
18 diverted to pasteurization. We are much encouraged to  
19 see that clearly defined. We are supportive of  
20 environmental testing, supportive of when the  
21 environment proves positive to testing the eggs and  
22 then diverting that product.

23                   MARILYN BALMER: Any other comments, any  
24 comments on the number of times? Meryl.

25                   MERYL SOSA: I would just like to pose to Mr.  
26 Klippen the question that the United Egg Producers

1 Program currently -- and this is the program that I  
2 would assume that you are proposing in their comments -  
3 - only requires testing two to three weeks prior to  
4 depopulation. So given the fact that it takes several  
5 days to get the results back, how many eggs would then,  
6 if there was an environmental test, and it proved  
7 positive, then how many eggs would really be then  
8 tested. And really how effective is that going to be  
9 if you're only testing the eggs at the very end of the  
10 cycle and you're not testing throughout the cycle?

11 That's why we really feel, and we've been  
12 doing on our farms, tests throughout the layer cycle so  
13 that we really have a good understanding of whether we  
14 have SE on the farm and we can really do something  
15 about it.

16 KEN KLIPPEN: I think this is the --

17 MARILYN BALMER: Ken, can we just note for  
18 the record that it's Ken Klippen?

19 KEN KLIPPEN: With United Egg Producers,  
20 thank you. I think this is the kind of conversation  
21 that we like to continue, because we have seen some  
22 dramatic changes both in the industry and also some of  
23 the comments we heard this morning. People were trying  
24 to come together on the kind of testing. Now, the  
25 point that we're making is: Why is it necessary to  
26 continue testing when you already have established that

1           you do not have it on the farm? If you test prior to  
2           depopulation and it's negative, well, then you know  
3           that you have not got a problem. Why continue any kind  
4           of testing? So when you replace that flock you do not  
5           have a problem on that farm.

6                     If you do have a problem, well, then you go  
7           into a much more extensive testing program where you  
8           ratchet it up so to speak. You do a cleaning and  
9           inspection. You test extensively at that point. You  
10          test later on in the production cycle, 30 weeks of age,  
11          ect. But the point is: If you haven't -- If it's not  
12          on the farm, why go to the extent that's being  
13          proposed? And that's what we're saying. There's  
14          testing of the chick papers, so you have the initial  
15          tests and it's testing at depopulation. And that is  
16          what we're trying to accomplish. And I think that's  
17          significant and you're seeing some changes in the egg  
18          industry coming over to accepting increased amounts of  
19          testings.

20                    MARILYN BALMER: Dave.

21                    DAVE GLAUER: Dave Glauer, Ohio. Again, I  
22          think as we look at programs and as programs do change,  
23          there are critical areas of intervention that we can  
24          include in these programs. And I believe that the  
25          placement of SE-monitored free chicks, then with a  
26          pullet testing program, that we know what is going on

1 with that pullet, and if they're placed, I agree with  
2 Ken, why continue testing? But if we do have a  
3 positive then this allows the producer again to make  
4 the decisions as to what they are going to do with that  
5 flock. And so the programs do allow for that. And if  
6 a flock is tested throughout its life, then the coming  
7 back with egg testing also makes sense to me from an  
8 economic standpoint. That way we have the ability to  
9 look at what really is going on in that flock and  
10 whether it is a critical food safety issue.

11 MARILYN BALMER: Meryl Sosa.

12 MERYL SOSA: I'd like to respond to the issue  
13 of why would you want to test if the test prior to  
14 depopulation shows no SE. And the response that I  
15 would have is: Based on the research and studies that  
16 have been done, it doesn't take a lot for SE to get  
17 into the house. It can be in the feed. It can be in  
18 the dust. It can come in on rodents which it's  
19 extremely easy for it to come in on. And once it comes  
20 in on the rodents, studies have shown that rodents go  
21 directly to the feed. They leave pellets. And that's  
22 the first thing in the morning that the hens eat. So  
23 without getting too graphic, I just feel that SE can be  
24 introduced into the house at any time. And so it's not  
25 enough to just do it at the beginning and at the end.  
26 But I did want to make one comment which is I had not

1 noticed in the UEP Program prior to this that they do  
2 believe in testing chick papers. So I really  
3 appreciate the fact that they want to add that to their  
4 program.

5 JILL SNOWDON: A general comment that I'm --

6 MARILYN BALMER: Name.

7 JILL SNOWDON: Jill Snowdon, thank you,  
8 Marilyn. Jill Snowdon at the Egg Nutrition Center.  
9 I'm hoping that there's going to be enough flexibility  
10 in whatever is used as verification that as research  
11 reveals new mechanism to verify that a program is  
12 working, or that eggs are free of contamination that we  
13 can roll those in. Because, what is currently could be  
14 considered to be the best means of verifying that a  
15 program is working or that an egg is free of  
16 contamination, could change as research results come  
17 in. So it's a comment suggesting that enough  
18 flexibility to allow the Egg Safety Plan to change to  
19 reflect advances in research and technology. It's a  
20 less than perfect system that we currently have to  
21 predict the probability of a contaminated egg. So  
22 that's certainly an area that we could improve upon.

23 MARILYN BALMER: Phil.

24 PHIL DEBOK: Phil Debok for the Pennsylvania  
25 Department of Agriculture. I think one of the key  
26 statements that Ken made in his comment would be the

1 follow-up action on a flock that was shown to be  
2 environmentally positive at the increased oversight and  
3 the increased testing, that this approach would likely  
4 meet the objectives of the reduction by up to 50  
5 percent by the year 2005 and perhaps win the nation  
6 eradication by 2010. But the other important thing is  
7 it also may be the only affordable way to go. The  
8 amount of testing that's perhaps proposed that's on the  
9 same level as Pennsylvania Egg Quality Assurance or  
10 whatever spread across the country even though the  
11 flocks of Pennsylvania may be barely affordable. This  
12 is somewhat of a compromise but still may meet the goal  
13 that we're after.

14 KEN KLIPPEN: Ken Klippen, United Egg  
15 Producers. I think I'll move my chair right here so I  
16 don't have to say it. I just wanted to make one more  
17 clarification and that is the testing that we are  
18 proposing, the egg testing, is not just a one-shot type  
19 of testing. This is over an extensive period of time.

20 If we find positives and we go to egg testing, we  
21 would test over a four-week period because we recognize  
22 the intermittent shedding of SE. And the second thing  
23 is that if we have a positive house, environmental  
24 sample positive, the recommendation from United Egg  
25 Producers is that they vaccinate. And some of the  
26 recent research we have seen has suggested that that

1 would contribute to furthering the efforts of reducing  
2 the sheds. So that's another step, that the egg  
3 industry has come over to doing what it can to try to  
4 play it's share at reducing the incidence of  
5 salmonella.

6 MARILYN BALMER: Ken, could you clarify that?  
7 You're saying you recommend vaccination when? If you  
8 find a flock positive, the next flock, that flock?

9 KEN KLIPPEN: Correct.

10 MARILYN BALMER: No, I'm asking when are you  
11 saying it? Please clarify.

12 KEN KLIPPEN: Well, if you have a positive  
13 flock, positive house, thank you -- I'm turning to my  
14 expert here --if you have a positive house, well, then  
15 you would start your egg testing. And if you have  
16 positive eggs, you would start to divert those eggs.  
17 You would vaccinate -- the next set of pullets that  
18 would come into the house would be vaccinated. Did  
19 that answer the question?

20 MARILYN BALMER: Yes. Thank you. I just  
21 wanted clarification. Bob.

22 BOB ECKROADE: Bob Eckroade from the  
23 University of Pennsylvania. I'd like to support what  
24 Phil Debok said here about these programs. Certainly  
25 in Pennsylvania we went the hard route of all this  
26 testing and felt that it was necessary to get a handle

1 on the problem. If we use Pennsylvania as a model, and  
2 that may not be absolutely correct, we could predict  
3 that the number of positive houses are probably going  
4 to be down in the 15 percent range, not in the 50 or 60  
5 or 70 percent range. And I think perhaps our program  
6 should be designed to at least identify and then focus  
7 in a very significant way on those positive houses.  
8 And that's not to say that a previously negative house  
9 may not go positive. But I think we need to stand  
10 back. And this is an extraordinary new program; that  
11 is, to think we are going to go on every layer house in  
12 this country and start doing microbiological  
13 assessment.

14 Now, we support the idea that that needs to  
15 be done at some level. I think the question is can we  
16 jump in with a new program and do all this testing when  
17 we could almost predict that only a very small number  
18 of those, relatively small, is going to be positive.  
19 So my own position, having worked in Pennsylvania with  
20 all the testing that we do and still do for a national  
21 program would be to start a little smaller. And it  
22 won't be perfect. And we will miss some of those  
23 flocks, as was said up here by Meryl, that have been  
24 shedding infected eggs for some period of time if you  
25 only test at the end of lay.

26 But I don't think we're going to be able to

1 do the degree of testing on every layer house in this  
2 country in order to achieve that. What I really do  
3 believe is that we start with the chick papers, NPIP  
4 monitored, and the end of lay, and then we really focus  
5 in on the positive houses. And we spend our time and  
6 our money and our efforts directing at that, and  
7 gradually, I believe that the industry itself will  
8 demand even more to control where we have positive  
9 houses, but not to impose a Pennsylvania Program  
10 uniformly on every layer house in this country.

11 DARREN MITCHELL: Darren Mitchell, CSPI. I  
12 would urge UEP and others who are talking about the  
13 prohibitive costs of the kinds of testing that people  
14 like Ms. Sosa are talking about. I would urge them in  
15 their comments to elaborate on what those costs would  
16 be and then let's compare that to the costs to  
17 consumers of the SE problem. Instead of throwing  
18 around statements that things are too cost prohibitive,  
19 let's actually look at some of those numbers, let's  
20 compare them to the CDC numbers and the cost of  
21 foodborne illness and figure out what the cost of  
22 consumers would be if a program like the one proposed  
23 in the Action Plan is not adopted.

24 MARILYN BALMER: Terry.

25 TERRY TROXELL: Terry Troxell, FDA. Bob, if  
26 you're approach would be to identify the positive

1 flocks, then would you be recommending that all flocks  
2 be tested initially at the start of the program so that  
3 one could identify and focus in on those flocks?

4 BOB ECKROADE: That would make sense to me  
5 that you do a national testing and then focus in on the  
6 ones where you have any positive samples. Yes.

7 MARILYN BALMER: With that, could you  
8 clarify? Would you start at any age or at the  
9 beginning at the placement of a new flock?

10 BOB ECKROADE: Well, I would start at the end  
11 because the opportunity for the contamination to build  
12 up in the manure even though we know they can go  
13 negative having been positive would be the more likely  
14 one than to test an empty, just cleaned, layer house.  
15 I don't believe that the testing after cleaning is  
16 absolutely going to correct the problem either. That  
17 is clean, then test and then not allow chickens to go  
18 back in there. That in itself we've seen is not an  
19 indicator of whether that flock will end up being  
20 positive at their end of lay.

21 MARILYN BALMER: There was somebody from the  
22 floor that had their hand up. Can you go to the mike,  
23 please?

24 TOM HERTZFELD: Tom Hertzfeld, Hertzfeld  
25 Poultry Farms. I also am a member of Ohio Poultry  
26 Association and UEP and in regards to the testing of

1 the eggs in Ohio here, which is quite similar to UEP,  
2 if a layer facility environment sample is positive,  
3 sample 480 eggs no later than two weeks from the  
4 initial sample; then in intervals of every two weeks  
5 for a total of four samples. If egg testing results  
6 are positive of SE, eggs from that house will be  
7 immediately diverted to a breaker and in Ohio we will  
8 submit four 1,000-egg samples collected at two-week  
9 intervals. If the four samples are negative, the  
10 production following the last negative sample may enter  
11 the whole-shell egg market.

12 In response to some of the cost associated  
13 with it for the Quality Assurance Program in Ohio, our  
14 biosecurity paperwork and documentation, our research,  
15 indicates that the cost for an Egg Quality Assurance  
16 Program is \$60,000 per year per million chickens which  
17 does not include economic losses or the possible  
18 devaluation for diverted eggs. And then U.S. grading  
19 costs another \$100,000 per million birds. And then  
20 there's also upgraded refrigeration that we're looking  
21 at. Our test kit costs, and then the costs are out  
22 there. And we did poll the producers in Ohio, and  
23 that's where these figures came up from. Thank you.

24 MARILYN BALMER: And you will be submitting  
25 them?

26 TOM HERTZFELD: Correct.

1                   MARILYN BALMER: Thank you. Another one from  
2 the floor and then we'll come back to Meryl.

3                   JILL SNOWDON: Jill Snowdon, Egg Nutrition  
4 Center. To follow-up on cost estimates, the industry  
5 is starting to develop so I just wanted to share an  
6 example with you. I think the point that was made is  
7 very valid that we need to look at specifics on what  
8 things are costing and to flush that out. We're  
9 estimating somewhere for testing costs alone, and I  
10 believe it was only twice during the life of a flock --  
11 Is that right? -- I think we're somewhere near \$20  
12 million. So that just starts to give you some  
13 perspective on it. That would need to be flushed out  
14 more completely depending on what the testing program  
15 is how detailed the analytical process would be, number  
16 of tests and so on and so forth, but you're definitely  
17 talking about millions of dollars, and that's just  
18 testing.

19                  MARILYN BALMER: Meryl, you had your hand up?

20                  MERYL SOSA: Well, first of all, we did bring  
21 our figures on how much it's costing us to test our  
22 flock and, as I said earlier, we have a fairly  
23 extensive flock testing program. So, basically, what  
24 we've found was that it cost us about \$2500 per flock,  
25 and our flocks are about 5,000 hens. So that would be  
26 a cost for a very extensive program. And in addition

1 to that cost, we also vaccinate and that costs us about  
2 \$675 per flock. And then we clean out each flock  
3 house. That cost \$250 per house. And we're performing  
4 water monitoring tests at about \$36 per flock. Finally,  
5 we pelletize our feed at about \$8 per ton. And I think  
6 the total cost came up to be something like \$3900.40  
7 higher package of the plan. Basically, it cost \$16.50  
8 per laboratory sample. So that kind of gives you an  
9 idea.

10 But we also want to mention at this point  
11 that we do feel that there should be some kind of  
12 insurance mechanisms or indemnification programs that  
13 should be out there. Another one we agree with UEP on  
14 is that their proposal that there should be  
15 indemnification to the producer at the dollar value of  
16 differences from the shell-end market value and  
17 breaking-stock egg value when eggs have to be diverted.

18 So I think that some of these mechanisms can  
19 help producers and will encourage compliance by  
20 producers by putting these mechanisms in place. And  
21 they have been used in other areas, in other  
22 food/animal areas.

23 MARILYN BALMER: Tad.

24 TAD GROSS: Tad Gross. The comment that I'd  
25 like to make is: As we developed our Ohio program, and  
26 Dr. Glauer you can correct me if I'm wrong, one of the

1 issues that come up in regards to testing was there was  
2 a lot more testing required and asked for. But it got  
3 to the point with our lab here in the state that we  
4 could bury them in testing work and not get the results  
5 that we needed. So I think some of this has been  
6 sorted down to try to get to a point where it's  
7 effective but also can be worked through our state  
8 laboratory here. In the state was where one of the  
9 problems was that we faced by having so much testing.  
10 So that's the reason we put together what we have.

11 RICH DUTTON: I'm Rich Dutton from Michael  
12 Foods Egg Products Company. I'm going to read in part  
13 and I'll send this in later. Actually, Michael Foods  
14 Egg Products Company accounts for about 12 million hens  
15 and about one and a half million contracts and then,  
16 plus, contract processing also. We've been in a  
17 testing program since 1991. In '92 we had a trace back  
18 and that focused quite acutely at some problems. And  
19 in actuality, those houses had been tested previously  
20 and I'll refer to them later.

21 Our program was basically developed and we  
22 have become very aggressive as a self-administered  
23 program and we also do our own testing. Our many  
24 experiences have given us a wealth of information on  
25 relative value of various SE-intervention strategies.  
26 Over the past three years, well, if we just average up

1 tests in the last three years, we do about 5,000  
2 cultures a year, about 2,300 of those are  
3 environmental, about 500 chick-box samples and about  
4 350 meat and bone samples to give you an idea. What I  
5 have is several comments, and if there are questions  
6 later, I can answer those.

7 Number one is that we confirm that pullet  
8 testing is an important tool for protecting the total  
9 farm environment. Our pullet farms in Nebraska are  
10 washed, disinfected between broods, and the farm or  
11 sister buildings are depopulated at the same time. In  
12 other words, we take the farm, hopefully, and  
13 depopulate the whole farm. In most cases, the farm is  
14 without birds for a short time, hopefully. In the real  
15 world it doesn't always happen. These houses, for your  
16 information, are cement-floored, flat-floored built  
17 houses, primarily.

18 Growths are very few in most cases. We do  
19 and have been checking and culturing chick papers for  
20 some time. In actuality, infrequently, but it does  
21 happen that we do have a positive in a house. In fact,  
22 in one of our circumstances we had, of ten houses, we  
23 had one positive house which was in the center of the  
24 complex. Sister birds that were placed three days  
25 afterwards, the same breed, same strain, same hatchery,  
26 and so forth, never did become positive.

1           Going on to another point, we actually have  
2           been testing chick papers for a long time. In the last  
3           three years we've checked about 1,500 chick papers,  
4           we've had no SE positives. In nine years we've had one  
5           SE positive, and that was early on in the program and  
6           we've not had any since. But, of course, my comments  
7           are relative to our situation. We find rodents are a  
8           major source of SE exchange. The cost of doing a  
9           program would be somewhere between \$15,000 and \$30,000  
10          for a million -- actually, those are figures from a 4-  
11          million-bird complex.

12           Vaccination is the single most effective step  
13          in slowing the contamination of SE in a complex. The  
14          vaccination of one house in the complex does not seem  
15          to be as effective as vaccinating all houses. In our  
16          complexes we have between 18 and 24 houses  
17          predominantly, and one complex of 32 houses. The  
18          vaccination cost for a kill-vaccine program is between  
19          nine and ten cents, generally speaking; for a live-  
20          vaccine program, somewhere in the one and a half to two  
21          cents; for a combination maybe ten to eleven cents; and  
22          in severe cases where you do a double vaccination, a  
23          kill vaccination, that would be somewhere between 18  
24          and 20 cents per bird.

25           Based on effectiveness for dollars spent, the  
26          priority of activities within a Flock Quality Assurance

1 Program should include an effective rodent control  
2 program, a vaccination and sanitation in that order of  
3 importance. The live vaccine has not had the longevity  
4 of use to prove itself in practice although the cost  
5 appear to be attractive and the yearly results look to  
6 be good.

7 And going on to another point, in the last  
8 three years, we tested probably 1,000 samples of meat  
9 and bone. And in our situation, we've had no SE,  
10 although, the salmonella varies from zero in some cases  
11 from some companies to 80 percent.

12 I guess one point I would like to make is  
13 that there is no predictability of when and where you  
14 will have salmonella or SE. Just because we've had a  
15 program in existence does not mean that that house will  
16 remain negative. On the other hand, we have had SE-  
17 positive houses that we've converted to negative.  
18 We've had complexes that we've converted to negative.  
19 We've got complexes with -- the 3.2 million complex has  
20 been negative, and never has had an SE isolation.

21 Our success has come with persistence,  
22 tenacity, and aggressiveness. Rodents are the key  
23 difference between a negative and a positive program.  
24 Actually when we began in 1991, we tested all houses.  
25 We had probably, predominantly, at that time, most of  
26 the contract houses, so we tested approximately 100

1 houses. We had four houses that were positive out of  
2 100.

3 MARILYN BALMER: Rich, could you quickly  
4 summarize because we still have the last question to  
5 bring up.

6 RICH DUTTON: Sure. Egg cultures will cost  
7 between \$500 and \$1000 for a thousand egg sample. And  
8 sanitation costs between \$1000 and \$5000 to sanitize a  
9 house. And actually, we've had a circumstance where we  
10 did a complete sanitation and replaced with negative  
11 birds and did a rodent program and so forth and came  
12 back with a positive house within 12 weeks. And then  
13 going into that, those eggs were diverted then for the  
14 life of the flock. The next flock was vaccinated and  
15 we were then able to, for the next four years, we had  
16 no isolations of SE. I guess in comment to the  
17 environmental testing, our predominant testing program  
18 was testing chick papers at 14 weeks for the pullets at  
19 peak production, at peak-molt production and end of lay  
20 and that gave us the opportunity to control our  
21 situation basically.

22 MARILYN BALMER: The third question is: In  
23 the event that an environmental sample for SE is  
24 positive, what, if any, additional steps should a  
25 producer be required to take with a positive flock  
26 house and with the next flock that will be placed in

1           that house? If we can start, we will start with Meryl.

2                   MERYL SOSA: I'm going to keep my comments  
3 brief since I've already addressed this issue. The  
4 additional steps that should be required with a  
5 positive flock should be that there should be diversion  
6 of eggs. Our program requires that we take some other  
7 measures, you know, increase our biosecurity, you know,  
8 review our plan and then test again to see if we still  
9 have SE and if we do, then we would continue to divert  
10 the eggs. Prior to placing the next flock, of course,  
11 we would clean and disinfect the house and test after  
12 we've cleaned and disinfected because research and  
13 studies have shown that even after you've cleaned and  
14 disinfected, sometimes SE persists in the house and you  
15 need to clean and disinfect again. So, you have to  
16 clean and disinfect until you've made sure it is SE  
17 negative.

18                   MARILYN BALMER: Tad.

19                   TAD GROSS: I think most of it's been covered  
20 here again. You go into environmental samples, you're  
21 going to sample 480 eggs which Tommy Hertzfeld alerted  
22 to. The biggest thing is the continued follow through  
23 of cleaning and disinfecting after the birds are taken  
24 out and following up to make sure it's kept clean. But  
25 I think what we've covered most of what we need to do  
26 here in this particular question.

1                   MARILYN BALMER: Dave.

2                   DAVID GLAUER: A couple of comments, and they  
3 would kind of be encompassing of what we've tried to  
4 approach here, I think, in this first segment. And I  
5 think we've had some figures given on the economic  
6 aspect of the program. Also we need to look at that.

7                   We need to include, then, laboratory  
8 capabilities. We need to focus our testing on those  
9 very critical kinds of areas that can create a control  
10 in the programs that allow us to do the environmental  
11 testing. If it's during a lay, then we have the  
12 ability to continue testing those eggs, divert those  
13 eggs, or whatever the appropriate step may be.

14                   The other aspect that we need to think about  
15 is we put together the critical parts of a national  
16 standard program that allows the use of vaccine.  
17 Vaccine is not the entire program, but it certainly can  
18 be used as a very useful tool.

19                   The best-management practices also are  
20 critical to that. The things again that we had listed  
21 on the screen earlier from those individual  
22 standpoints, I believe, are the individual components  
23 with the addition as we look at environmental testing,  
24 pullets become part of that.

25                   Chick papers, my Pennsylvania colleagues and  
26 I have had many conversations about that. I believe

1 that NAA pullet testing, the environmental, can be  
2 looked at from a scientific standpoint as being a  
3 critical test.

4 MARILYN BALMER: Okay. Those at the table  
5 here. Any comments? Okay. Then we'll start with Tom.

6 TOM HERTZFELD: Tom Hertzfeld, Hertzfeld  
7 Poultry. I'd just like to add that on a house that is  
8 a positive, for us to C & D it here in Ohio, depending  
9 on the size of the house, it is approximately anywhere  
10 from \$4,000 to \$8,000 to wet clean that house. The  
11 concern that people like myself and Tad have is our  
12 contract growers that we've got, this is a substantial  
13 cost for a smaller contract and unless we step in and  
14 help them out with the cost of C & D it's extremely  
15 hard for them to cover that cost so we would ask that  
16 you would consider an indemnity for a situation like  
17 that.

18 MARILYN BALMER: Tom, you gave a range. Is  
19 it style of house or number of birds per house?

20 TOM HERTZFELD: It's basically the number of  
21 birds and the style has a little bit to do with it, but  
22 depending on the size, the \$4,000 range would be right  
23 at a 100,000 bird house -- probably 70,000 to 100,000  
24 bird house and then it would go up from there.

25 MARILYN BALMER: There was another one. Ken.

26 KEN KLIPPEN: Ken Klippen, United Egg

1 Producers. Just a quick comment about environmental  
2 testing and then diversion as Meryl brought up. The  
3 concerns we have about environmental testing and then  
4 the likelihood of a diversion, which has already been  
5 brought out by the panel, are the rodents that we are  
6 trying to control in a farm environment. One rodent  
7 can deposit 100 pellets in the course of one night and  
8 each pellet can contain 25,000 different salmonella  
9 organisms. So you can see how one rodent can really  
10 cause extensive damage to a farm facility if you are  
11 looking at that kind of environmental testing.  
12 Biosecurity is all part of the program, but the  
13 diversion doesn't enter into it until you have sampled  
14 the eggs. That's extensive and we're still working on  
15 the size of the sample. But, sample the eggs and then  
16 when you find those positives, then you divert.

17 RICH DUTTON: Rich Dutton, Michael Foods.  
18 Just on a cost basis, we have a flat floors, stack  
19 decks, belted houses; to wash a house takes at least  
20 two weeks, eight to ten people, and nearly 24 hours a  
21 day washing per day to get it clean. In one case we  
22 had a farm that we washed up, and it took two or three  
23 disinfectings and two or three foggings to get it to a  
24 point where it would be culture negative. The only  
25 thing in all of our changes and problems with houses  
26 and so forth, the only things that we've been able to

1 use has been vaccination and elimination of rodents and  
2 clean up consistently.

3 As to other sources, chicks have not been a  
4 problem. Feed is not a problem. We've not had an  
5 isolation from feed. And water is automatically tested  
6 because of the required AMS Programs and so forth.

7 MARILYN BALMER: Mike.

8 MIKE OPITZ: Mike Opitz, University of Maine.

9 With regard to what should happen if a test house is  
10 positive, I would like to present this philosophy which  
11 we have. We use testing in our area to verify the  
12 management practices which we have implemented on the  
13 farms.

14 We believe that sustainable long-term egg safety  
15 is achieved through the management practices which are  
16 implemented on the farms. Most of them have been  
17 mentioned here. Therefore, as a consequence of a  
18 positive test result, our main emphasis will be on  
19 viewing the management strategies and correcting  
20 management problems that can be refined and improved  
21 and, therefore, test positive results will be a tool to  
22 identify those needed improvements which we may not  
23 even completely understand at this point as we are  
24 sitting here. But we have to keep in mind long-term  
25 sustainable, error-management practices and not look  
26 for short-term bandage solutions.

1                   MARILYN BALMER: If that is it for comments,  
2 we'll take a break and start back again at 10:25.

3                   (A break was taken 10:12 to 10:30)

4                   MARILYN BALMER: Alice Thaler will begin.

5                   ALICE THALER: The information that I'm going  
6 to cover now is information that's directly from the  
7 Federal Register Notice for this meeting and also in  
8 the document that's in your packet which is posted on  
9 the web which is the outline of the information that  
10 the Egg Safety National Standards work group has put  
11 together as a draft.

12                   The question is: What steps will help us  
13 reach our Risk Reduction Goals. And it clearly says in  
14 the notice that we're considering several mandatory  
15 components as part of our Risk Reduction Plan. The  
16 thinking so far is that industry would establish a  
17 HACCP-based system for shell-egg processing and  
18 prerequisite programs to help reduce the risk.

19                   What would it take to implement the proposed  
20 components of a HACCP-based system? Of course, this  
21 morning we had some information provided as to cost for  
22 the producer section and we're interested in costs here  
23 as well. And what are adequate good manufacturing  
24 practices? We need to define those and as a basic  
25 requirement they have to minimize the growth of SE and  
26 prevent cross-contamination during shell-egg

1 processing. We're here to discuss record  
2 keeping; what should be the requirements, things such  
3 as receipt and inventory usage records that would  
4 include returned eggs which perhaps now aren't tracked  
5 as well as they should be. Producer identification,  
6 how important will that be to this effort? Data  
7 production by lot. Records on temperature on  
8 transport. That might help our effort. And monitoring  
9 storage temperatures. Controls and receiving would be  
10 part of the components.

11 For example, methods that a packer or  
12 processor could use to determine how old eggs are when  
13 they are received. Certainly some eggs go very quickly  
14 if you are a producer/packer. Some eggs go directly to  
15 packers, but there are many that seem like they skirt  
16 all around the country before they get there. How  
17 important would getting a handle on that be to our risk  
18 reduction effort? Other controls at receiving,  
19 especially now that we may be identifying and diverting  
20 more positive eggs. That's certainly one of the  
21 issues. What will be the measures to ensure that those  
22 eggs are diverted from the table-egg market, and  
23 measures to make sure that they go and are pasteurized.  
24

25 This was, for example, an issue. If the  
26 status of a flock is not revealed to the packer then

1           they don't have the information on how to deal with  
2           those SE-positive eggs. Where if they knew the status,  
3           they could have something in their plan to address  
4           handling those eggs and making sure that they go to  
5           pasteurization. Packers might require information  
6           about how the eggs were produced. Give them a little  
7           bit more to go on in making their decisions on how to  
8           handle the eggs at packing to know if the producer did  
9           use the components that we heard earlier on-farm plan.

10  
11                    What about the materials that the eggs come  
12           in on? How important is it to control the sanitation  
13           of those materials? Should we go so far as to allow  
14           reusable materials? Should they all be new? All that  
15           is at issue. Under Strategy I, the movement of SE-  
16           positive eggs needs to be controlled. So, again, we're  
17           talking about how do you store them if you're the  
18           packer and they come through your facility because your  
19           a producer/packer?

20                    Refrigeration from the time of gathering to  
21           processing, will that be important to the Risk  
22           Reduction effort? And if so, what would be the  
23           temperature be that would be appropriate is up for  
24           discussion. At the packing plant, refrigeration might  
25           play a role. So what would be the cost of maintaining  
26           refrigeration, for example, let's say 60 degrees

1           fahrenheit, for eggs for grading and packing before  
2           they're packed. They can't get too cold because of the  
3           process they go through for washing and packing as a  
4           shell egg. But in particular, if they're going to be  
5           held for a period of time that would exceed 24 hours  
6           from the time to lay. The prerequisite programs that  
7           FSIS typically use when we're talking about HACCP or  
8           HACCP-based systems would include sanitation, standard  
9           operating procedures, the basics of these require  
10          processors to address basic sanitation of premises and  
11          facilities. And then the plan specifically describes  
12          the food handling practices, the cleaning of the  
13          equipment and the maintenance of the facility itself.  
14          Other prerequisite programs would include the  
15          rodent/pest control, which we just heard, is seen as a  
16          very important thing and on the production side, it is  
17          also important on the packing side, especially if  
18          you're a producer/packer.           Programs to ensure  
19          employee health and hygiene of people handling the  
20          eggs, portable water issues. Prerequisite programs for  
21          controlling the compounds that go into the overall  
22          process. Things used to clean, to stain, sanitize we  
23          have used in, for example, meat and poultry plants.  
24          Letters and guarantees from manufactures is acceptable  
25          if they state that the product is acceptable for the  
26          intended use. Also prerequisite programs can cover

1 things such as guidelines in general and education of  
2 people during the process.

3 We move then from prerequisite programs to  
4 process control, I didn't put HACCP here because we  
5 were talking about HACCP-based at this point with the  
6 shell-egg packers. But that is essentially process  
7 control. Issues such as washing the eggs. How  
8 detailed should we get in the specifics of what's  
9 required for process control programs? We have some  
10 information already in the shell-egg grading program  
11 they address some of those issues and whether or not  
12 what's already available could be used, modified, or  
13 adopted to deal with HACCP-based programs more broadly  
14 for all shell-egg processors. They get down to  
15 specifics such as pH. Should you recommend a specific  
16 level? Should you just make a general statement that  
17 has it has to control microbial hazards? So we're  
18 looking for that level of detail as well. The shell-  
19 egg packers do grading of their own as well as some of  
20 them -- 30 percent being under the USDA grading  
21 program. We have an issue of the tolerances allowed  
22 for the checks and undergrades because of the possible  
23 relationship they might have to increased SE risk. So  
24 it's possible that the tolerance might need to be  
25 changed either now or in the future if that connection  
26 is considered to be important to address, if it exists

1 than it is important to address.

2 And the probably really big one, although  
3 it's only a short line, eliminate reprocessing and  
4 returned eggs for table use, I would imagine, will be a  
5 big issue to discuss. Packaging materials for what  
6 goes out to the consumer, again the question of should  
7 it be limited to new materials, storage and handling  
8 practices for the packaging materials themselves.

9 And then I put down customer specifications  
10 as they relate to the processing of SE-positive eggs  
11 for egg products. We heard some earlier requests for  
12 indemnity. The general question of if the customers  
13 who are going to get the eggs are very concerned about  
14 the SE eggs and where they go, and more eggs are going  
15 through the packer/processor that need to be diverted  
16 to egg products depending on how the eggs flow, what  
17 would be the influence overall to the packer? And  
18 packing shell eggs for the consumer to prevent cross-  
19 contamination.

20 Again, process control, there is to consider  
21 using new packaging materials. But then the question of  
22 what would it take to be able to reuse and have clean  
23 reused materials? Another general broad issue for this  
24 area's labeling, having records that explain what codes  
25 they used, whether or not records should correlate with  
26 the producer and with the company processing records;

1           such as, the actual lot and whether that should be by  
2           case, by carton, how that should be broken down; and  
3           just realizing that there will be some FSIS and FDA  
4           labeling requirements that would be part of what will  
5           affect the shell-egg packer.

6                     Control at storage and transportation,  
7           address the issue of what's best to monitor the  
8           temperature of the refrigerated storage units. Is that  
9           important and should it be an ambient temperature? All  
10          of this is still open for discussion.

11                    Now we'll go through this one quickly and I  
12          was asked to mention, of course, there's another  
13          section farther on that will focus on research and have  
14          the broader question. But, specifically, for the  
15          packer/processor, keep in the back of your mind, what  
16          kind of information don't we have in order to be able  
17          to make statements about some of the earlier issues  
18          that were posed? So just to recap the general areas of  
19          issues, we had the prerequisite programs, we have  
20          labeling, we have Risk Reduction Strategies in general,  
21          controls at receiving, process control, and storage and  
22          transportation and then, of course, research to help  
23          answer some of that. So we'll move to the questions  
24          now. I'll take the first questions now.

25                    MARILYN BALMER: I want to remind everybody  
26          there is at the end of this day an open session where

1           you can give talks in general. Let's try to keep the  
2           comments to the specific questions in this area, the  
3           first one being: What is the cost of maintaining  
4           refrigerated storage, maximum temperature, 60 degrees  
5           fahrenheit for eggs received that are destined for  
6           grading and packing or in-shell pasteurization when  
7           time of processing will exceed 24 hours from the time  
8           of lay? Let's start with Tad first.

9                   TAD GROSS: Tad Gross with Hemmelgarn. As  
10           we're all aware, we now have refrigeration requirements  
11           that we, as processors, are required to live by which  
12           is 45 degrees. In our company's case, we were in  
13           compliance with all that. We stepped up and put  
14           additional refrigeration in to make sure we can  
15           maintain that in the heat of the summer. I guess you  
16           start looking at a cost get towards 80, 90, \$100,000 to  
17           make sure that you've got all your cooling capacity in  
18           place.

19                   We, at our company, have taken extra steps to  
20           make sure that we can do these things. And in our  
21           Quality Assurance Program, we feel that some of the  
22           issues throughout the country have been lax as far as  
23           the temperature thing. There were still people, quite  
24           frankly, a few years ago that didn't even have  
25           refrigeration at all. So as egg processors, we are  
26           starting to get the attention that, yes, we've got to

1 get in focus here and get going. But in answer to the  
2 cost thing, I think we feel it's going to cost about  
3 \$100,000 to make sure that you've got refrigeration in  
4 place.

5 MARILYN BALMER: Meryl.

6 MERYL SOSA: We don't have any comment.

7 MARILYN BALMER: Dave.

8 DAVID GLAUER: I really believe that Tad  
9 covered what I would say. But, again, just in review  
10 of the industry, it does look like in Ohio that  
11 somewhere around \$100,000 is required on a million  
12 birds from a refrigeration standpoint. We do have a  
13 refrigeration law. Here in Ohio our Food Safety  
14 Division from the Department of Agriculture is  
15 responsible for maintaining that. They inspect that on  
16 a regular basis. So that does provide some additional  
17 incentive and makes sure that that part of the program  
18 is followed.

19 MARILYN BALMER: One question to the three,  
20 does there make any difference between offline and  
21 online for refrigeration costs? Any comments on this?

22 TAD GROSS: This is Tad Gross. I guess my  
23 answer to that would be, naturally, on an inline coming  
24 directly into the processing facility they'd have one  
25 facility that they'd have to keep under refrigeration.

26 In our case, with the contract producers in my

1 particular case having 18 or 20 different family farm  
2 operations, each one the facilities have to have  
3 refrigeration at the farm. And then the next step is  
4 the transportation to the processing facilities. That  
5 equipment has to be able to maintain the 45 degree  
6 temperatures that our Egg Quality Assurance program  
7 alludes to as well as in the plant. So in my  
8 particular case, we have three sets of refrigeration in  
9 order to comply with the 45 degree temperatures.

10 MARILYN BALMER: Okay. Anybody at the table?

11 VICTORIA LEVINE: Vicky Levine, FSIS. So  
12 you're saying that for each of those three facilities,  
13 it cost \$100,000 for the equipment? So 300 total?

14 TAD GROSS: Probably at the farm -- I'm  
15 talking from on the farm to the transportation and  
16 you're going to have \$100,000 because we have three  
17 steps in there.

18 MARILYN BALMER: Any other comments from the  
19 table? Okay. Out on the floor? Presently are many  
20 people staying at 45 -- or there's a comment here about  
21 maximum temperature of 60 degrees?

22 TAD GROSS: Tad Gross. Our plant runs two  
23 shifts. We're totally under USDA supervision. Now  
24 when the USDA people come in to do surveillance, they  
25 monitor our air quality, the temperatures in all of our  
26 coolers, to make sure that we are around or close or

1 below that 45 degree temperature. So being a voluntary  
2 program, which USDA is, it puts us, you know, keeps our  
3 act together as far as keeping it. But it also assures  
4 to our consumers that have the USDA product seal on  
5 their cartons that we're maintaining all the things  
6 that we say that we're doing.

7 DARREN MITCHELL: Darren Mitchell, CSPI.  
8 We'd like to see this at 45, actually we've called for  
9 41 degrees, but we'd like to see this at 45 degrees for  
10 the whole process. And, if during rulemaking that 60  
11 degree maximum shows up, we would like to see some  
12 substantiation justification for the 60 degree  
13 fahrenheit number versus the 45 degree number.

14 TAD GROSS: Tad Gross. I think one thing  
15 that you have to remember here, there's two basic  
16 situations in egg processing. You have inline which  
17 comes right out of the chicken house into the egg  
18 grader versus offline, which my particular situation is  
19 different. The problem you've got with your request  
20 is, if you take 45 degree eggs and put them on an egg  
21 grader like I would have to and try to run them through  
22 that washer at 100 degrees, you create checks. And  
23 that's one of the issues that has become very sensitive  
24 between us as egg packers and USDA. Because naturally  
25 that's one of our goals, to eliminate checks. And here  
26 these temperatures are also putting us in a position

1           where we're actually creating checks. So the ultimate  
2           goal is to reduce checks not to increase. If it comes  
3           in there and -- Quite honestly, we see our eggs going  
4           into the egg grader somewhere at 45 to 48 degrees, but  
5           if we get it down to 40 like you suggested, we can  
6           increase checks as high as 3 to 4 percent just because  
7           of the snap of the temperature change. And it's very  
8           crucial and it's very sensitive and, again, the main  
9           goal here is to reduce checks. I mean, obviously, if  
10          you've got a cracked egg, you're susceptible to  
11          bacteria. So let's try to eliminate that thing first  
12          of all.

13                   MARILYN BALMER: Darren.

14                   DARREN MITCHELL: Can I respond to that  
15                   quickly? Darren Mitchell, CSPI. I guess the concern  
16                   is that exceeding 24 hours from time to lay and whether  
17                   that number makes sense, the length of time that the  
18                   eggs are sitting around at the elevated temperature  
19                   makes sense. And there must be some way to do this so  
20                   that the egg sees a higher temperature just when  
21                   necessary for purposes of going in through the washing  
22                   steps, ect.

23                   MERYL SOSA: Meryl Sosa, Food Animal Concerns  
24                   Trust. I'd like to respond to two things that have  
25                   just been said between Mr. Mitchell and Mr. Gross.  
26                   First of all, I can completely understand the idea of

1 preventing checks. We, too, want to do that with our  
2 eggs. But in looking at the General Accounting Offices  
3 Egg Safety Report, they discussed the issue of cooling  
4 and things like that and one of the things that we felt  
5 was really important from that report was that it noted  
6 that rapid cooling at a relatively low cost is  
7 available.

8 And for example, researchers at North  
9 Carolina State University have experimented with  
10 cryogenic gas to rapidly cool eggs. They found that  
11 eggs could be cooled to 38 degrees within 12 minutes  
12 using cryogenic gasses and one company has developed a  
13 prototype cooling method that is soon to be tested in  
14 production or may have already been tested. And  
15 according to that company's estimates, that process  
16 would three cents or less to the cost of a dozen eggs.

17 So we feel that this is possible to have a 45 degree  
18 internal temperature, it would just require an  
19 additional step at the processing.

20 Now, one other thing I would like to take  
21 note of that Mr. Gross said. His main goal is to  
22 decrease or prevent checks. I don't know if I  
23 necessarily agree with that comment because I think our  
24 main goal in breeding is to prevent SE in shell eggs.  
25 I think what we now know is that most of the SE  
26 problems occur on the farm. That's where it gets into

1 the eggs. And the idea that the SE is coming in  
2 through the checks is a possibility. But the primary  
3 location of where SE is getting into the eggs is on the  
4 farm. So we do want to focus on that issue. And the  
5 idea of preventing checks from a grading standpoint is  
6 important, but only one-third of the nations eggs are  
7 graded by USDA. So what we really want to focus on is  
8 all eggs and making sure that all eggs are safer for  
9 consumers.

10 MARILYN BALMER: Terry.

11 TERRY TROXELL: Terry Troxell, FDA. Since  
12 there is a natural protection resistance to outgrowth  
13 of bacteria in the newly laid egg and it depends on  
14 time and temperature, Tad, can you or some other people  
15 comment on the length of time eggs might be stored  
16 prior to processing? You know, the range of times?

17 TAD GROSS: Well, I guess that could vary  
18 from company to company. In our particular case I  
19 would think that eggs are in our plant less than 36  
20 hours. They come in and process and then are shipped  
21 to market. It would be my opinion, again, I'm speaking  
22 for my situation as contract producers who, you know,  
23 have family operations gathering these eggs at the  
24 farm. And in most cases in today's society with the  
25 size of the houses, eggs are most generally picked up  
26 every day. In our case almost every day or every other

1 day. But, I don't really feel that with the way the  
2 chicken houses are designed today and set up that most  
3 eggs lay in the chicken house less than probably 12 or  
4 15 hours before they go in the refrigeration. And that  
5 should not be a basic problem from that end. A comment  
6 to Meryl's suggestion here of refrigeration and quick  
7 chill and whatever, my only comment to that, as a  
8 producer, is how and when and where and why. How can  
9 you justify that expense to do all these things when  
10 you already basically got it down there to 45 degrees?

11 I mean there has to be some give and take here I would  
12 think.

13 MERYL SOSA: I understand the idea of give  
14 and take but I think this overall process that we're  
15 embarking on, we have to recognize that the cost of  
16 eggs is going to increase and the cost of eggs to  
17 consumers is going to increase. And Nest Eggs charges  
18 more to our consumers because we do have an SE Program  
19 and because also because we provide eggs from uncaged  
20 hens. So we do both those parts. But I think that all  
21 producers are going to end up incurring these same  
22 costs. So everybody is going to be charging a little  
23 bit more and consumers are going to have to accept  
24 that. I mean, eggs are much lower cost than meat or  
25 chicken or any other source of protein. So I think  
26 that's really important to keep in mind that while we

1 have low cost now, those costs are going to increase  
2 due to this new program. And so we want to make this  
3 program the best it can be coming out of the box with  
4 some flexibility for whatever research shows. I don't  
5 know the cost for rapid cooling other than the three  
6 cent or less cost of a dozen eggs. I know that Andy  
7 Rhorer from NPIP did a talk at a seminar I was at and  
8 he had studied this issue. So he may be of some help  
9 in providing some figures and costs on this issue.

10 MARILYN BALMER: There was a hand from the  
11 floor.

12 JILL SNOWDON: Jill Snowdon, Egg Nutrition  
13 Center. I just need to reinforce the biology of the  
14 situation and how that affects the cost of food and  
15 relative to the safety of the food. And that is that  
16 the data that we have indicate that SE -- Let me back  
17 up. Refrigeration is only going to control the growth  
18 of the organism. It's not going to control if the  
19 organism is present or not. So we are talking about a  
20 very low incidence to begin with. So if SE happens to  
21 be in there, the egg has a enough natural protective  
22 properties and as long as that egg is below 68 degrees  
23 fahrenheit and that yolk membrane stays intact, that SE  
24 is not going to grow.

25 So what the question is here is talking about  
26 from the time that the egg is laid to the time that you

1 are starting to move it into processing. So the  
2 question as written, I think, is written with the  
3 appropriate science in mind; that is, you're giving  
4 protection make sure that that yolk membrane isn't  
5 deteriorating and the organism has a chance to  
6 multiply. Anything other than that type of thing is  
7 going to increase the cost of food with no commensurate  
8 benefit. And I think that's frivolous because you want  
9 policies then that are going to change the disease  
10 impact and not simply increase the cost of food.

11 So I would say the food cost increases need  
12 to be tied into things that are going to have a benefit  
13 that society is going to value, like, say, for food.  
14 So we need to target what the actions are to the ones  
15 that are going to be reflective of the microbiology of  
16 the situation.

17 MARILYN BALMER: Any other comments from the  
18 table or the floor?

19 KENNETH ANDERSON: Kenneth Anderson, North  
20 Carolina State University. Be careful what you say  
21 because the individual doing the work may be present.  
22 But first of all, a couple of comments. North Carolina  
23 has been on a 45 degree cooling program since the early  
24 '90s. Prior to that we did an egg temperature survey  
25 in the state basically outlining the fact that at that  
26 time producers could not meet that standard.

1           The producers and packers at that time went  
2 in, modified their coolers, and the cost in North  
3 Carolina were a little bit higher. Some of our  
4 processors spent up to \$250,000 to modify their cooling  
5 systems in order to meet the 45 degree ambient  
6 standards and to be able to maintain those temperatures  
7 throughout the processing day. Because as soon as the  
8 doors are opened at 6:00 AM in the morning, when they  
9 start running eggs, temperature fluctuations increase  
10 dramatically.

11           The second comment is on the amount of time  
12 that the eggs can be stored at 60 degrees. It is  
13 fairly extensive. If you look at the work that's been  
14 done in Europe by Humphries in the early 1990s, 1990-  
15 1993 specifically, it basically says that the natural  
16 protection chemical, as well as physical protection  
17 that the egg holds for itself, does extend over more  
18 than seven days so that there is a biological component  
19 that does prevent the growth of salmonella enteritidis  
20 in the egg. In addition, a lot of his work also shows  
21 that the number of organisms in the egg are almost at  
22 the nondetectible level. I mean, you're down in the 1  
23 to 10 organisms, if they are present, which is rare in  
24 itself, are very low. So you have to look at the  
25 combination of things that the natural protective  
26 characteristics of the egg will instill to get a safe

1 product at the processing plant prior to that.

2 A third comment on the egg temperatures. You  
3 really cannot start with a 45 degree temperature coming  
4 out of the production facility. Mainly, because of the  
5 requirements placed upon it by USDA grading regulations  
6 that state that the wash water shall be 90 degrees or  
7 20 degrees warmer than the warmest egg entered into the  
8 processing plant. And like Tad mentioned, you throw a  
9 cold egg into the hot water, you're immediately going  
10 to create thermal checks. In addition, contamination  
11 rates -- contamination does occur in those thermal  
12 checks after the washing process. So you have to be  
13 careful. We're trying to prevent that. And so you  
14 want to keep an intact shell. You need to maintain  
15 that integrity of the product until the consumer gets  
16 it. And anything we do to detract from that actually  
17 defeats the purpose that we're trying to do at this  
18 particular meeting.

19 MARILYN BALMER: Ken, before you leave can  
20 you clarify? You were talking 45. Is that post-  
21 processing?

22 KENNETH ANDERSON: When I talk 45 degrees  
23 ambient, I'm basically talking post-processing. I  
24 think there's some recommendations out right now that  
25 prior to processing the eggs need to be stored at 60  
26 degrees. However, even at that there needs to be a

1           tempering process before the eggs are actually put into  
2           the washing system. And that's basically because when  
3           you exceed a 40 degree temperature differential between  
4           the egg and the wash water, you get thermal checks  
5           creating. And it's a gradual thing, you know, at 40  
6           degrees it may start at 3 to 5 percent, but as soon as  
7           you hit 50 degrees temperature differential, you'll hit  
8           15 to 20 percent of thermal check. So you need to be  
9           very careful about the temperatures. And if you look  
10          at a lot of the wash-water temperatures that are used,  
11          every processing plant that we surveyed, their wash-  
12          water temperature was not 90 degrees, it was 115  
13          degrees which actually changes the initial temperature  
14          that you can actually start the washing process at.  
15          So, I mean, you have to be very careful.

16                   And I think that brings into a fourth comment  
17                   I might as well make while I'm standing here. We've  
18                   talked about something now that we probably should have  
19                   lead off with and that's HACCP. Every processor and  
20                   every producer in this country has different  
21                   circumstances. And if we follow the HACCP principles  
22                   and seven steps and use the testing and whatnot for  
23                   verification that your program is working, if your  
24                   HACCP Program is working, your actual monitoring and  
25                   verification is going to drop. And I think that's what  
26                   a lot of people will show. Bob Eckroade, you know,

1 pointed out that if you test and your levels are low,  
2 you don't need to continue this elevated testing  
3 because your HACCP guarantees that you are doing  
4 everything, best-management practices, everything to  
5 keep that level low.

6 JUDY RIGGINS: Can I ask an additional  
7 question?

8 MARILYN BALMER: Judy Riggins.

9 JUDY RIGGINS: USDA. You said that at the  
10 start when North Carolina first required the 45 degree  
11 ambient temperature, that packers couldn't reach it.  
12 Over what period of time were they able to comply? Do  
13 you have any idea of the percent compliance over the  
14 first year, over the second year? What were your  
15 milestones?

16 KENNETH ANDERSON: First of all, the actual  
17 passage of the law took about a year. But most of the  
18 producers in the state began the modification process  
19 immediately. Most of them saw the writing on the wall  
20 and knew that the 45 degree ambient was going to come  
21 in. So they began modification. So basically within  
22 six months after adoption of 45 degree, the processors  
23 had spent the money and were capable of maintaining 45  
24 degrees in off-run hours. There was still a problem  
25 with the situation during the processing day.

26 It's very difficult when you're moving ten

1 tons of product into a cooler and you're shipping it  
2 out to maintain that ambient temperature. So what a  
3 lot of them have done now is they're not cooling to 45.

4 There coolers are set at 39-41 so that they can  
5 maintain that temperature compliance throughout the  
6 day. And I think by and large I feel that the  
7 producers in North Carolina have done a tremendous job  
8 of meeting these standards of 45 throughout the day.

9 But it has taken time. And it's really difficult to  
10 put a "how many years does it take to do this or that".

11 But, I think basically within six months, we were able  
12 to do the 45 in general; but then it took a little more  
13 refinement of their cooling process to achieve that  
14 consistent compliance throughout the day.

15 JUDY RIGGINS: Can you share with us any  
16 methods, techniques, that individual processors might  
17 have used in achieving their HACCP objectives? One of  
18 the things we've done with meat and poultry is  
19 developed a set of models that are used kind of as  
20 guidance for industry. And you've kind of triggered an  
21 idea in my head. If there is useful, experienced  
22 information that comes from programs that have already  
23 instituted this kind of requirement, that we could  
24 apply nationwide in guidelines, so that when a packer  
25 processor is looking at his or her own situation, can  
26 be used as guidance. Were there things that North

1 Carolina producers did or are doing that help them to  
2 achieve that 45 degree over time throughout the day so  
3 that they know that their systems are actually  
4 effective?

5 KENNETH ANDERSON: Well, I think there were a  
6 number of things employed by the processors to achieve  
7 that goal of throughout-the-day compliance. But I  
8 think by and large, the models that we used -- there's  
9 three. One is the HACCP principles that were actually  
10 outlined by the Pilsbury Association when they  
11 developed their food source for NASA. The second one  
12 is the 5-Star Program from UEP. North Carolina has  
13 adopted that as the basic program for that. And then  
14 the other model is PEQAP. Let's face it. That's  
15 probably one of the premier programs in the country.  
16 And look what they've done as far as that region of the  
17 country as far as SE outbreaks.

18 So I think we've got models out there. And  
19 the Pennsylvania people said a lot of testing -- And  
20 there, again, if you employ the HACCP principles to the  
21 whole development of a farm-to-table program, you will  
22 actually develop a program that works well, that has  
23 adequate testing for verification that the process is  
24 working; and, then, it has procedural steps of  
25 additional testing, like Ken mentioned, that if you  
26 fall out of control, you have additional testing that

1 automatically trips in and comes into play. I think  
2 Rich Dutton mentioned some of those as well from out at  
3 Nebraska. I think the models are there. I think what  
4 we're doing is we're using the HACCP principles in the  
5 industry to develop our programs to make them meet the  
6 needs that the consumer is -- let's face it -- the  
7 consumer is telling the egg people what they want and  
8 we're doing everything we can to comply with that. I  
9 think what we're seeing here is forced introduction of  
10 a component, something of a HACCP Program. And you  
11 don't force a HACCP Program. A HACCP Program grows and  
12 develops over time. And I think that's what we need,  
13 is the time to develop and refine it so you get an  
14 adequate program that works.

15 MARILYN BALMER: Ken, can we delay HACCP  
16 until the end of the day?

17 TERRY TROXELL: Terry Troxell. I have a  
18 follow-up for Ken. Can you comment from the North  
19 Carolina perspective on the range of times from lay  
20 until the shell egg is processed which we were  
21 discussing before? Because, that's relevant to this  
22 question of temperatures.

23 KEN ANDERSON: From the time in offline to  
24 processing plant, is that what you're asking?

25 TERRY TROXELL: The range of times from lay  
26 until processing.

1                   KEN ANDERSON: It will vary from probably an  
2 hour to maybe two days. It depends on the pick-up  
3 schedule at the production unit. I think most of the  
4 offline production units are on daily pick-ups. But  
5 some of them may have a day where they don't pick them  
6 up. But, typically, hours in an inline -- to a day; 48  
7 hours, maximum, for offline.

8                   TERRY TROXELL: Thank you.

9                   MARILYN BALMER: Are there any methods by  
10 which a packer/processor can determine how old eggs are  
11 when they are received? Let's start with Dave.

12                  DAVID GLAUER: I'm not sure I'm the best one  
13 to answer this. I understand that there are some  
14 methods, but I'm sure someone else has a better answer.

15                  MARILYN BALMER: Meryl.

16                  MERYL SOSA: No comment.

17                  MARILYN BALMER: Okay. Tad.

18                  TAD GROSS: Well, obviously, this question  
19 goes back to the old theory of your egg quality and  
20 determining a "AA" from an "A". And in our case, if I  
21 personally don't do it, USDA will walk to the eggs and  
22 take a look and they're going to tell you by the size  
23 of the inner-cell and the interior quality of that egg,  
24 approximately how old it is. And that has been  
25 probably the industry's best indicator. If you buy  
26 eggs from the outside, that's the first thing you're

1 going to look at is under a candling light to see how  
2 big the inner-cell is. It's going to determine whether  
3 it's two days old or whether it's four weeks old.

4 MARILYN BALMER: So you're saying the bottom  
5 line is the internal grading?

6 TAD GROSS: That's how I would approach it,  
7 yes.

8 MARILYN BALMER: Anybody from the table?  
9 Anybody from the floor?

10 JILL SNOWDON: Jill Snowdon, Egg Nutrition  
11 Center. Just a comment that eggs are a pipeline  
12 because chickens are laying them all the time. So all  
13 the market and the dynamics of the process are going to  
14 be for the eggs to be moving promptly.

15 MARILYN BALMER: I know we have a few people  
16 involved in egg grading out in the audience. Is there  
17 any comments as to the age of eggs? Okay. Then we'll  
18 move on. When packing shell eggs for the consumer,  
19 will the use of only new primary packing materials  
20 increase your marketing cost? If yes, what is the  
21 estimated cost? Is there a way to clean plastic  
22 containers to prevent cross-contamination so they can  
23 be reused? Let's start with Meryl.

24 MERYL SOSA: I did talk about this issue with  
25 our farm program manager and he responded that the  
26 packing materials that we use on our farms are not

1 reused unless we know that those eggs are destined for  
2 the breakers. So the other area that we would like to  
3 see more research or testing done are the carts that  
4 the eggs are shipped on. And I know that those are  
5 reused throughout the industry. So that may be a  
6 source of SE. We're not sure.

7 MARILYN BALMER: Tad.

8 TAD GROSS: Well, here again we get back to  
9 the USDA situation. USDA -- again, I'm speaking for my  
10 plant -- but USDA pretty much makes us use new material  
11 for our packaging. In some cases there are people that  
12 use, maybe, something that's used one time. But in our  
13 case, all the stuff that we're packing for consumers is  
14 always in new material. We use a plastic flat for the  
15 eggs coming in from the farm. For an example, they're  
16 on plastic flats so that they can come in and they're  
17 run through a washer and sanitized so that they can be  
18 taken back to the facilities without cross-  
19 contamination. Meryl suggested here that the racks  
20 that we now use today in retail are made so they can be  
21 washed and sanitized also. But in most cases,  
22 especially in USDA plants, they're going to be packing  
23 new material.

24 MARILYN BALMER: When those sanitized plastic  
25 things go back to the farm, do they go back to the  
26 specific farm they came from or could they go to any

1 farm?

2 TAD GROSS: In my case, no. We feel once  
3 we've run them through the flat washer and sanitized  
4 them, that they should be free of any particular  
5 bacteria and they may go in any direction. Now if we  
6 have paper flats -- which we, at this point have a few  
7 left -- those are specifically set aside to go directly  
8 back to that farm. In my case, it's two instances of  
9 two smaller houses. But they're definitely set aside  
10 and designated with names put on them as to where they  
11 go. But 95 percent of our stuff going back and forth  
12 to the farm is washed and disinfected.

13 MARILYN BALMER: Dave.

14 DAVID GLAUER: In our program we speak to the  
15 aspect of the non-reuse of soiled materials and if  
16 there is reuse that they go back to the farm of origin.

17 MARILYN BALMER: Anybody at the table?  
18 Terry.

19 TERRY TROXELL: Terry Troxell. Either Meryl  
20 or Tad, do you have cost figures for -- you say you are  
21 using new materials -- do you have any cost figures?

22 MERYL SOSA: I did ask the farm program  
23 manager for that information. But, he said, in our  
24 program we've always used the new materials and we've  
25 never considered using reused materials. So he didn't  
26 have any kind of figures for comparison. So we've

1 always included that cost  
2 as part of the price of Nest Eggs.

3 MARILYN BALMER: Anybody from the floor?  
4 There are other producers out there. Do you reuse? Do  
5 you use plastics and sanitizers? Any comments? Tom.

6 TOM HERTZFELD: Tom Hertzfeld. I'm also like  
7 Tad. All of our eggs coming in are on plastic and they  
8 are run through a flat washer continually before they  
9 go back out. So we follow the same program.

10 MARILYN BALMER: Rich, you're another  
11 producing area.

12 RICH DUTTON: We also use plastic flats on  
13 eggs coming in. Rich Dutton, excuse me. And we also  
14 sanitize everything going back out.

15 MARILYN BALMER: And they go back to any  
16 house?

17 RICH DUTTON: They go back to any house.  
18 It's pretty difficult if you've got 15 houses or more  
19 that you are doing on any one individual day to  
20 separate out. It takes a lot of storage space and  
21 tracking to keep track of those, especially if the  
22 truck may come in every other day rather than every  
23 day.

24 MARILYN BALMER: Are there any other  
25 producers out there that do not use plastic that still  
26 use the fiber?

1           There are some egg-grading representatives in your  
2           states, do you see fiber or do you see plastic? And  
3           what are the procedures? Would either of you volunteer  
4           comments?

5                   DEANNA BALDWIN: Deanna Baldwin. I'm with  
6           the Maryland Department of Ag. We do see some of the  
7           eggs coming in nest-run and fiber-filler flats and we  
8           have seen reuse of those for graded eggs.

9                   LOU CARSON: Tad.

10                   TAD GROSS: Tad Gross. I see throughout the  
11           State of Ohio that there is some producers that market  
12           strictly nest-run, and sometimes they go throughout the  
13           country. But my experience and exposure to them is I  
14           see the gentlemen using only new because of the  
15           circumstance that we do. And, naturally, if a producer  
16           in the State of Ohio is sending a load to Texas or  
17           wherever, naturally, that becomes a problem to send  
18           them in plastic. So we go back to the issue then of  
19           putting them in new paper and transporting that way.  
20           But the stuff that goes back in and out of the plants  
21           usually stays close and local and usually is in  
22           plastics.

23                   MARILYN BALMER: Any other questions on this?  
24           Judy did you have one?

25                   JUDY RIGGINS: I was going to ask everyone in  
26           the room if there is anyone here who is not under a

1 current AMS Grading Program and what you are doing.  
2 I'm concerned that we're hearing about the more  
3 prescriptive approach that we currently have. But if  
4 we're going to consider the option of moving to a  
5 HACCP-based performance standard approach, how many in  
6 the country, if 70 percent are not under the USDA  
7 Grading Program. What's being done in those programs  
8 is going to be important to us. I was wondering if  
9 anyone had any knowledge of that here.

10 MARILYN BALMER: Are there any comments on  
11 the general area of packer/shell egg processing and  
12 what Alice presented?

13 KEN LOOPER: I'm Ken Looper with Cal-Maine  
14 Foods, Jackson, Mississippi. We have an egg-clearing  
15 house in the United States for trading of eggs and then  
16 UEP has an egg-trading center. Today there's about a 3  
17 to 4 percent of all eggs that are not produced and  
18 packaged on the farm that go from one farm to another  
19 farm. And they go through ECI or UEP. Now there's  
20 another 3 or 4 percent that are handled through private  
21 brokers. So this makes somewhere between 6, 7, 8  
22 percent that are not produced and packed on the farm,  
23 that go to different places. Then there's those  
24 private arrangements where a processor may buy directly  
25 from another producer that doesn't appear on the ECI or  
26 UEP trading block or do not appear with the broker.

1                   Our experience, and ECI has all the actual  
2 data, but all the eggs will either trade on new  
3 material, disposable new material, or on pallets and  
4 racks. UEP does the same thing. It will be all-new  
5 material, like graded- loose will be new material,  
6 nest-run would be on racks with plastic or on  
7 disposables, which would be new disposables. And then,  
8 beyond that, all other material in our processing plant  
9 for some time, to my knowledge -- and I know at the  
10 USDA plants -- will go out in new material or plastic  
11 baskets or on dollies. But all those materials would  
12 be new. But most material today is new. It would be  
13 interesting to hear from those plants that are not  
14 USDA. I think you'd find probably the same thing. I  
15 know from the eggs they would buy off of ECI or UEP.  
16 Thank you.

17                   MARILYN BALMER: Was there a question from  
18 the table here? Terry? If there are no more comments  
19 on this section, we'll break a little early for lunch.

20                   If you're in the hotel, check-out time is up until  
21 noon. Be back here at 12:35 promptly so to start the  
22 next section, please.

23                   (Recess for Lunch 11:25 -12:35)

24                   VICTORIA LEVINE: All right. This afternoon  
25 we are starting off with an egg products processing  
26 discussion by Roger Glasshoff of FSIS. Now, before we

1 get started, I'd just like to remind you, if you're  
2 going to make a general comment at the end of today's  
3 session, please, go outside and register to do so.  
4 Thank you.

5 ROGER GLASSHOFF: Now that your stomach is  
6 full, you can doze off and you won't miss anything.  
7 This morning we spoke about the Action Plan and  
8 Strategy I which is the methods of reduction and the  
9 risk associated with SE and shell eggs marketed to the  
10 table market for consumer use. This afternoon we're  
11 going to address Strategy II which essentially is  
12 marketing eggs for further processing which will be  
13 subjected to lethal treatment which will essentially  
14 destroy salmonella.

15 I'm going to begin with egg products and then  
16 come back and talk a little bit about in-shell  
17 pasteurization. Currently the department is working to  
18 develop proposed regulatory changes, to incorporate  
19 HACCP as a basis for the Egg Products Inspection  
20 Program.

21 The approach on this program is to change  
22 from a prescriptive requirement that currently exists  
23 in our regulations to various instructions and policies  
24 which have existed over the last 30 years for egg  
25 products for the Egg Products Inspection Program.

26 Under HACCP, the focus will be directed upon

1           verifying the effectiveness of processes and process  
2           controls to ensure food safety. With the incorporation  
3           of HACCP in the Egg Products Inspection Program, the  
4           agency will have then correlated its meat, poultry and  
5           egg products inspection programs to use HACCP as a  
6           basis for determining food safety.

7           Each company under HACCP will be required to  
8           complete its own written HACCP Plan. These plans will  
9           be individually tailored to the company processing  
10          procedures and the products produced. HACCP will  
11          provide a great deal of flexibility and innovation that  
12          allows a company to achieve a performance standard to  
13          produce safe food in a manner which will assure  
14          consumers that they will not be faced with problems of  
15          the food products for which FSIS has jurisdiction.

16          The HACCP Plan will identify the process and  
17          establish the critical control points. This is  
18          accomplished through hazard analysis. Critical limits  
19          could be established. Essential to the program is  
20          monitoring. Through monitoring, you would also  
21          identify any critical corrective actions necessary and,  
22          of course, record keeping and verification.

23          The key point here is record keeping.  
24          Documentation will be essential. USDA will move from  
25          monitoring individual aspects of processing to a  
26          verification and oversight procedure. The company will

1 be responsible for monitoring in-process aspects and  
2 documenting their verification of compliance or  
3 conformance. The Plan will also describe who,  
4 within the company, is responsible for oversight of the  
5 Plan. The agency is interested in implementation of  
6 HACCP including documentation to demonstrate compliance  
7 with the sanitation, standard operating procedures, and  
8 establish performance standards. For the development  
9 of Performance Standard for Pasteurization of Egg  
10 Products, FSIS is seeking information on the  
11 enumeration of salmonella in liquid eggs prior to  
12 pasteurization. Currently we have some scientific  
13 information that could be as old as 30 to 40 years.  
14 Research that was conducted to develop the current  
15 relationship of time and temperature for the  
16 pasteurization of egg products.

17 We also have a risk assessment that was  
18 completed in 1988 which will be used as predictive  
19 modeling for the development of a performance standard.

20 We mentioned the sanitation standard operating  
21 procedures. This is part of a prerequisite program.  
22 This morning, those that addressed you referred to your  
23 prerequisite components to a HACCP-based Program to  
24 reduce the risk of salmonella enteritidis in shell eggs  
25 destined for the consumer.

26 We would anticipate that in a true HACCP

1 program, the processor would also maintain  
2 documentation from the producer as to what strategy  
3 they are participating in to reduce the risk of  
4 salmonella enteritidis. That would be part of the  
5 documentation that would be verified by our field  
6 operations staff.

7 We began speaking about producer-implementing  
8 components of the prerequisite programs, and one of the  
9 questions that still is at issue is whether or not  
10 environmental testing would be a valid component of  
11 Strategy II. Other issues are refrigeration as an  
12 intervention to microbial growth when eggs are not  
13 processed within 24 hours from the time of lay.

14 We heard previously about the aspects of the  
15 shell egg having inherent characteristics to inhibit  
16 the growth of salmonella. These issues would be  
17 addressed through the hazard analysis that is conducted  
18 by each processing establishment. We also heard this  
19 morning about the impact of eliminating the reuse of  
20 fiber and pulp packaging materials. In the egg  
21 products industry, quite frequently, materials are  
22 reused. We are seeing a trend, a movement towards, the  
23 use of plastic which can be cleaned and sanitized, but  
24 there's still quite a bit of the pulp-filler flats  
25 being used.

26 One of the principle record-keeping aspects

1 of a HACCP Program is the identification of production  
2 lots. We have in the situation of diversion of eggs  
3 from SE-infected flocks, the requirement to assure that  
4 those eggs are pasteurized or treated in a manner to  
5 destroy salmonella.

6 In a processing plant where FSIS has  
7 jurisdiction, the company would be responsible for  
8 documentation of receipt of these eggs and the  
9 inspector would verify that they are, in fact, broken  
10 or treated in a manner to destroy salmonella.

11 We've also heard from a number of industry  
12 members that some of their customers are beginning to  
13 develop specification that restricts or prohibits the  
14 use of eggs that have been diverted from SE-infected  
15 flocks. We would like to collect more information with  
16 regard to that comment also. It definitely would have  
17 some influence on the price of eggs being marketed.

18 The basic time line for establishing HACCP as  
19 part of the inspection program is as follows: A  
20 proposed rule will be developed within the fiscal year.

21 Hopefully, we'll achieve the clearances for  
22 publication in the Federal Register. Upon receipt of  
23 the comments to that proposed rule, we would determine  
24 when the final rule would be published. But again, we  
25 project fiscal year 2001. That final rule, of course,  
26 will address the implementation dates.

1                   We have been urging everyone in the industry  
2 to utilize publications that are available from FSIS.  
3 Many of these, such as the Sanitation Performance  
4 Standard, are available through the Internet address  
5 which is posted here. As we develop the HACCP-based  
6 Inspection Program, many of the current instructions or  
7 prerequisite regulatory aspects of the program will  
8 either be changed or they will be converted to  
9 guidelines. These guidelines can be utilized in the  
10 development of the HACCP Plan if it is applicable to  
11 the process at a particular plant.

12                   We would also envision the development of  
13 generic HACCP model which would assist the industry in  
14 development of their HACCP Plan.

15                   Let's move on to in-shell pasteurization. At  
16 this time, this is the only process that we are aware  
17 of for the destruction of salmonella for shell eggs  
18 that are being marketed for table use. This process  
19 usually involves some type of water immersion for the  
20 destruction of salmonella. Again, we would envision a  
21 HACCP-based Program where the processor would again  
22 request the information from the producer of the shell  
23 eggs or the source of those shell eggs that are  
24 proposed for treatment as to what strategy they are  
25 participating. Will it be Strategy I or Strategy II?

26                   That documentation would be maintained for

1 verification and audit purposes. At this time it will  
2 appear that we will continue the performance standard  
3 as it currently exists for the destruction of  
4 salmonella in shell eggs that was established several  
5 years ago. Currently, it is referenced as a five log  
6 reduction of salmonella and it's derivatives. However,  
7 there may be a number of processing procedures that can  
8 accomplish that type of a performance standard. As you  
9 recall, under HACCP it allows plenty of freedom for  
10 innovation and flexibility. So the door remains open  
11 to development of various processes in the future.

12 One of the concerns of pasteurization of  
13 shell eggs is to ensure the integrity of the product as  
14 it is distributed to the market. Under such  
15 conditions, it will either be packaged to maintain the  
16 integrity or the individual eggs would be identified to  
17 ensure that the customer is comfortable that those eggs  
18 that are in the container have been properly treated.  
19 Packaging material, of course, would meet the labeling  
20 criteria established for shell eggs with the exception  
21 that the warning, or as it has been referred to "the  
22 warning statement", would probably not be included in  
23 the format of the label. Although the eggs have been  
24 pasteurized, the pasteurization process occasionally  
25 may only injure cells of salmonella.

26 So at this point we're still considering

1           whether or not these types of products should be  
2           shipped under refrigeration to the retail level. Under  
3           the proper controls, that is a written description of  
4           the identity of a lot or the quantity that was  
5           processed, the containers would be identified for  
6           purposes of trace back. Under a HACCP-based Program,  
7           the company would be responsible for all documentation  
8           and verification of their process. The documents would  
9           demonstrate conformance on a continuing basis. It  
10          would identify oversight of the HACCP-based system  
11          maintained by each firm, and a USDA representative or  
12          designee would verify the pasteurization criteria of  
13          being met before the validated process as it is  
14          described.

15                         And with that, I think we'll move on to the  
16          questions that we're seeking information to complete  
17          rulemaking.

18                         VICTORIA LEVINE: We'll run this afternoon's  
19          session exactly like we did this morning. Let me  
20          remind you when you are commenting, please, give your  
21          name and your affiliation. Before we go on with the  
22          question, let's start with any general comments. Front  
23          table? Anybody in the audience? Yes.

24                         JILL SNOWDON: Jill Snowdon, Egg Nutrition  
25          Center. I just want to make sure I'm understanding.  
26          You used the phrase "HACCP-based" with in-shell

1 pasteurization, do you mean that it's a HACCP Program?

2 And the reason I'm asking that is when working with a  
3 production system, we use the phrase "HACCP-based" to  
4 indicate that we don't have the guaranteed control that  
5 you did with food for astronauts where HACCP was  
6 originally applied. The principles are all there. We  
7 just recognize it's not a guaranteed control. Where as  
8 I would think with in-shell pasteurization, you would  
9 be much closer to real HACCP and could actually call  
10 that a HACCP Program. So are you saying that for in-  
11 shell pasteurization it's a HACCP Program and you just  
12 happened to use the phrase "HACCP-based" to indicate  
13 it's nature, or are you using it the way I do which  
14 means that it's not exactly guaranteed?

15 ROGER GLASSHOFF: Jill, I was referring the  
16 HACCP-based Program as it contains the aspects of HACCP  
17 including the lethal destruction of salmonella for in-  
18 shell pasteurization.

19 JUDY RIGGINS: Let me add my comments on  
20 that. We have not yet done the rulemaking. So we are  
21 not prejudging or predicting where we may come out in  
22 the rulemaking. What we do think is important is to  
23 have a system that embraces the principles of HACCP.  
24 We recognize in the packer area that we are forging new  
25 ground. We are sure of our path with respect to  
26 breaking and liquid pasteurization and we are going to

1 propose a HACCP system for liquid pasteurization,  
2 pasteurization of liquid eggs, in processing plants.  
3 But with respect to packers, we are still exploring  
4 that.

5 We have shared with you our thinking about  
6 the use of performance standards at the packer level  
7 because understanding that this is not a monolithic  
8 industry and that there are a number of ways that a  
9 public health performance standard could be met, we  
10 want to give maximum flexibility in order to achieve  
11 that. So we are considering what options we might  
12 propose that would be HACCP-based in principle, but not  
13 necessarily as formalized at the HACCP system that we  
14 currently have for meat and poultry which we are  
15 extending to pasteurization plants. We don't want to  
16 prejudge where we are at this point.

17 KEN LOOPER: My name is Ken Looper, Cal-Maine  
18 Foods. Will the in-shell pasteurization have the same  
19 oversight? I know you just went through a description  
20 there that you haven't done that yet, but as I  
21 understand it, there is in-shell pasteurization going  
22 on today. Do they have an oversight plan or program?

23 JUDY RIGGINS: Roger, you need to speak up to  
24 this. But we are aware of two currently running  
25 operations right now. AMS is currently in each of  
26 those facilities because they are co-located at

1 facilities where there is also grading. How we use  
2 inspection resources will depend greatly on where  
3 facilities are located. If a processor decides to co-  
4 locate a grading and an in-shell pasteurization  
5 facility in the same building, or in connecting  
6 buildings and AMS is currently there doing grading,  
7 then for us it would mean a better use of resources to  
8 have AMS conduct whatever inspection of in-shell  
9 pasteurization of eggs.

10 KEN LOOPER: An oversight will be the cost of  
11 the in-shell pasteurization company like in egg  
12 products that the federal funded?

13 JUDY RIGGINS: No. No. Let me explain.  
14 Under the Egg Safety Action Plan, the decision was made  
15 to redelegate, that the secretary of agriculture would  
16 redelagate to FSIS, responsibility for shell-egg  
17 inspection. It will not be a fee for service. It will  
18 be conducted as we currently conduct inspection in  
19 meat, poultry, and egg plants. So unless the  
20 administration proposes fees, user fees, and that  
21 passes in Congress, things will remain as they are. So  
22 it will not be a fee for service as far as we know now.

23 LOU CARSON: Let me also add a clarification.  
24 Currently, a processor considering in-shell  
25 pasteurization will submit documentation of that  
26 process to FDA to review from a technical standpoint.

1 We then share our review of that process with AMS if  
2 that processor wishes to have AMS in the shield, then  
3 we work together with AMS on that process. Just as  
4 Judy has mentioned, in the future when the standards  
5 that we are proposing become final, then FSIS would  
6 oversee that entire process either in consultation with  
7 FDA or on their own.

8 VICTORIA LEVINE: All right. The first  
9 question we're going to address is Number 9 in the  
10 Federal Registered Notice. In the event eggs from an  
11 SE-positive layer flock are diverted from the table-egg  
12 market, what measures should be implemented to ensure  
13 those eggs are pasteurized? We'll start up front with  
14 Dave.

15 DAVID GLAUER: Currently, I believe the  
16 system is in place that when we have positive  
17 identification of an egg, it would fit into our law  
18 from an adulteration standpoint. Therefore, parts of  
19 ODA would be brought into that process that would  
20 track, with producer records, the effect of those eggs  
21 being diverted to a breaker pasteurizer.

22 MERYL SOSA: Meryl Sosa, from FACT. FACT is  
23 not aware of the proper steps necessary to ensure  
24 pasteurization of egg products. However, from an on-  
25 farm perspective, we believe records must be created  
26 and maintained on the farm to demonstrate compliance by

1 the farm with diversion requirements. By maintaining  
2 such records for the period of one year, the farm can  
3 prove, in the event of an outbreak that it properly  
4 shipped the contaminated eggs to a breaker plant. By  
5 doing this, the farm insures that it will not be liable  
6 in the event of an outbreak and that the breaker will  
7 be responsible for any deficiencies in it's own  
8 pasteurization process. However, it should be  
9 recognized that pasteurization is not a substitute for  
10 a strong on-farm SE Risk Reduction Program.

11 And we'd also like to mention at this time  
12 that we believe that this area of the continuum  
13 represents the safest area of the farm-to-table  
14 continuum. And while there have been a few outbreaks  
15 resulting from improper pasteurization, this is a safe  
16 assessment because it includes a "kill step". Despite  
17 the fact that this area includes a "kill step", the  
18 USDA has chosen to employ 120 inspectors to inspect  
19 these facilities. But this proportionate quantity of  
20 inspectors is highlighted by the fact that FDA has only  
21 one person assigned to oversee on-farm issues related  
22 to eggs. And this example provides a clear  
23 illustration of the problem of having multiple agencies  
24 overseeing the issue of shell-egg safety.

25 TAD GROSS: Well, I think Dave and Meryl have  
26 covered most of it, but, again, I think the most

1 important factor here is the paper trail that we need  
2 to create. You know, if we have eggs to be diverted  
3 that we can show to anyone that wants to see it that we  
4 are following the guidelines with verification of  
5 invoices back and forth. Sometimes it even comes down  
6 to sealing the trailers. USDA can become involved in  
7 that, but verification and a paper trail is the most  
8 important thing here.

9 VICTORIA LEVINE: Anyone else at the table?

10 DARREN MITCHELL: Darren Mitchell, Center for  
11 Science in the Public Interest. I'd like to reiterate  
12 in support with what Ms. Sosa said about the problem of  
13 resource allocation and too much resources going to the  
14 pasteurization process and too few to other areas which  
15 pose greater risk. And we would expect that if we  
16 don't have consolidation into a single agency for egg  
17 safety, that the resource allocation issue would be a  
18 primary thing that you look at in proposing the Egg  
19 Safety Action Plan.

20 VICTORIA LEVINE: The audience? Going once.  
21 Going twice. Okay. We will now go to Question No.  
22 11. Do customer specifications exist that prohibit the  
23 processing of SE-positive eggs for egg products?  
24 Considering your production volume and available market  
25 for egg products, will this influence the price for SE-  
26 positive eggs? Tad.

1                   TAD GROSS: This is a very important question  
2 from a producer's standpoint. Naturally we would be  
3 the first to admit if we have an SE problem that we  
4 need to do everything in our power to correct the  
5 situation. One thing that continually comes up or that  
6 I've been exposed to is diversion to a breaker. We  
7 also have breakers now that say that their customer  
8 base will not allow them to even process or put SE-  
9 positive eggs into their product. So as a producer, we  
10 get a little paranoid because we potentially are going  
11 to take in the past anywhere from four to six cents  
12 less for these eggs because of the potential SE  
13 problem.

14                   Now if we lose that right or the potential to  
15 go to a breaker, that situation could even -- instead  
16 of four to six it could be double that. From our  
17 standpoint, we get very cautious about that and it has  
18 always been my feeling that pasteurization is exactly  
19 what the word means. It's to remove any bacteria.  
20 Hopefully, we can get everybody to agree that, yes, we  
21 can divert these eggs and work with them from there.

22                   VICTORIA LEVINE: Meryl.

23                   MERYL SOSA: Meryl Sosa for FACT. We have  
24 not had that experience regarding the SE-positive eggs,  
25 but from the breakers that we use for other reasons,  
26 for cracked eggs or what have you, they have not

1 indicated to us that they would not accept those to  
2 kill their eggs. So we haven't had that experience  
3 yet, but possibly it's because we don't have as  
4 enormous a volume as other producers have. So that's  
5 one possibility. And, secondly, I guess, in speaking  
6 to it, the price differential would be, I think, about  
7 35 cents at least for our eggs by going to the  
8 breakers. So obviously it would be a very difficult  
9 situation for us to address. And that's why we  
10 recommend that sometimes indemnification according to  
11 the guidelines that UEP has proposed.

12 VICTORIA LEVINE: Do you have any comments  
13 Dave?

14 DAVID GLAUER: No, I really don't. I think  
15 Tad has covered it.

16 VICTORIA LEVINE: Front table?

17 BOB ECKROADE: Based on my recollection of  
18 the Pennsylvania Pallet Program -- Is it on? Oh,  
19 thanks. Bob Eckroade, University of Pennsylvania and  
20 PEQAP. Based on my recollection of the pallet program,  
21 when diverted eggs went under a USDA red tag to the  
22 pasteurization plants, they took a bath. There was no  
23 doubt that the pressure will be on to pay far less for  
24 those eggs than normally would be paid for eggs going  
25 to pasteurization.

26 And while I think we have to do whatever is

1 necessary to guarantee that the diverted eggs end up in  
2 pasteurization, I also agree that we have to do what we  
3 can to avoid a disaster for the fellow who happens to  
4 get caught up in having SE-positive eggs.

5 VICTORIA LEVINE: The audience?

6 LEONARD BALLAD: I'm Leonard from Ballad Egg  
7 Products. We're an egg-products company. We are not  
8 breaking SE eggs because there were three national  
9 concerns that have given us specifications for bidding  
10 on the breaking of SE eggs. We have or we know of  
11 other firms that will break them because there are no  
12 restrictions by their customers. On the other hand,  
13 there is no doubt that there will be a great economic  
14 disaster for anybody that has to send those eggs to an  
15 egg-products plant because of the fact that there are  
16 limited customers that take them.

17 DARREN MITCHELL: Darren Mitchell, CSPI.  
18 We're still investigating the indemnification issue and  
19 trying to decide where we come out on it. But I can  
20 tell you a little bit about our thinking process in  
21 hopes that it will you a little bit and that is: We  
22 like incentive-based regulations, and we think that the  
23 potential loss of profit is an incentive for improved  
24 management practices and everything else in the SE  
25 Reduction Program. Having said that, the question is:  
26 How much incentive do you need and does it really need

1 to be full loss and shouldn't there be some partial  
2 indemnification?

3 So that's what we're grappling with right  
4 now.

5 JAY SCHUMAN: Good afternoon. I'm Jay  
6 Schuman with the Michael Foods Egg Products Company and  
7 we represent the Papetti's and M.G. Waldbaum brand  
8 name. Actually, we're going to be addressing this  
9 question. We're going to have a session with several  
10 of our different operations. We'll be addressing this  
11 in the written comments.

12 I was a little slow to the trigger to get up  
13 after the last question, Question 9, but I did want to,  
14 for the record, comment on Ms. Sosa's comment earlier.

15 I just want to clarify one point. We do agree with  
16 Ms. Sosa that an aggressive SE Risk Reduction Program  
17 on the farm is very valuable and I think we've proven  
18 that. As Dr. Dutton has described, our program has  
19 been around for nearly a decade. And that is part of  
20 our entire integrated approach to pasteurized egg  
21 products. We do a full range, liquid, frozen, dried,  
22 precooked, as well as we are the innovators in in-shell  
23 pasteurization.

24 But the statement was made in passing. I  
25 don't want to let that go without challenge that egg  
26 products, pasteurized egg products, have been involved

1 in cases or outbreaks of salmonellosis in humans. And  
2 to my knowledge, of all the literature, that has never  
3 been documented. And that's a very proud record of our  
4 industry ever since passage of the Egg Products  
5 Inspection Act of 1970. When we talk about egg  
6 products, we're talking about USDA-inspected  
7 pasteurized products under strict standards and  
8 specifications. I think sometimes we lose clarity when  
9 we use the words "egg product" when what we really mean  
10 to say is an egg-containing food or a complex food made  
11 using shell-eggs. So for the record I would like to  
12 challenge that. Thank you.

13 VICTORIA LEVINE: Anyone else? All right.  
14 The final question we'll address in this portion of the  
15 program is Number 17. Are the proposed components of  
16 the national standards for packing and processing of  
17 shell eggs and egg products appropriate and adequate to  
18 reduce the risk associated with SE?

19 DAVID GLAUER: The national standards that  
20 are proposed, I think, have many of the component parts  
21 to them that will reduce SE in shell eggs. Some of the  
22 comments that were made in the past relevant to the  
23 economic aspect really are also important in this  
24 aspect. But I believe that a set of records that  
25 assure the final destination of these eggs is  
26 important.

1 VICTORIA LEVINE: Meryl.

2 MERYL SOSA: We don't have a response.

3 VICTORIA LEVINE: No response? Fine. Tad.

4 TAD GROSS: I would like to speak for what  
5 I've seen that has happened here in our state here, in  
6 the State of Ohio. The awareness that we've taken back  
7 to the farm is getting these people involved with  
8 understanding what SE is, number one, and what they can  
9 do to help straighten this out, I mean, 5-Star  
10 Programs, what we document in our state and got  
11 everybody working on, I think the program that's in  
12 place has merit. I agree there's a lot of unanswered  
13 questions, but I think that everything is going in the  
14 right direction.

15 The farmer is kind of a different breed. You  
16 don't see them walking up and down the chicken coops  
17 with a laptop computer in their hip pocket, you know.  
18 So probably their worst thing to do is document stuff,  
19 and in our case, is to get them to understand that one  
20 of the most important things of any of these programs  
21 is to make record keeping a first priority. And I  
22 think as we continue to develop this education from the  
23 farm all the way to the store, and everybody pulls  
24 together, that what is being proposed by the 5-Star  
25 Program, the Pennsylvania Program, as well as Ohio's  
26 and anybody else's, they're all in the right direction

1 and have a lot of merit and they continue to work for  
2 them. I think we can get this thing in order.

3 VICTORIA LEVINE: Anyone else at the table?  
4 All right. The audience?

5 KEN KLIPPEN: Ken Klippen with United Egg  
6 Producers. In answer to Question No. 17, the answer  
7 is, no. It's not comprehensive enough. There is more  
8 that can be done. And that's what the egg industry is  
9 trying to tell USDA and FDA right now. We need a  
10 uniform nationwide quality assurance program that  
11 assures consumers that our product is safe. The egg  
12 producers are trying to develop their own programs and  
13 trying to come forward with something that demonstrates  
14 uniformity.

15 The administration's plan doesn't go far  
16 enough as it relates to repackaging. I mean, it talks  
17 about conducting research on repackaging of eggs which  
18 is a practice that is not occurring universally, but it  
19 has happened in the past. We shouldn't study this  
20 practice, we should ban this practice. Repackaging  
21 eggs should not occur. And in the United Egg Producers  
22 Program, we actually are proposing that. And you'll  
23 hear that a little bit later when Ken Looper presents  
24 his comments. We should have stronger incentives  
25 to implement promising vaccination programs where rapid  
26 progress is taking place. We've talked about this over

1 and over again about the plans putting so much emphasis  
2 on testing rather than putting emphasis on good quality  
3 assurance. The first question I asked today when I  
4 stood up here is: Why are we seeing reductions in  
5 salmonella enteritidis over the last four years?  
6 Nobody answered that question. I'll answer the  
7 question now. It's because we have quality assurance  
8 programs out there. And more and more people are  
9 participating. So the answer to Question No. 17 is,  
10 no, we need to go further, and we have some plans of  
11 actions that we're going to introduce today to suggest  
12 that. Thank you.

13 VICTORIA LEVINE: Meryl.

14 MERYL SOSA: Meryl Sosa for FACT. I'd like  
15 to take this opportunity to agree with Mr. Klippen on  
16 two of the points that he made. First of all, we  
17 believe that the plan does appear to include  
18 repackaging as a component. And while USDA/AMS  
19 temporarily prohibited the practice of repackaging and  
20 redating eggs, that prohibition at least currently  
21 would apply only to the one-third of the nations eggs  
22 graded and packed under the AMS voluntary grading  
23 program. FDA has not taken any measures to address  
24 this issue. And there are two key risk factors that  
25 can affect the growth of SE in eggs, age and  
26 temperature. And experts agree that an egg's natural

1 defense to SE can break down as the egg ages or is  
2 exposed to high or fluctuating temperatures. Eggs that  
3 are repackaged must be transported to the processing  
4 plant and, therefore, may be subject to temperature  
5 fluctuations as well as additional heating during  
6 rewashing; therefore, ensuring that eggs are fresh and  
7 are maintained under a consistent, appropriate  
8 temperature from packing to the table. These are  
9 critical SE Risk Reduction measures. We would agree  
10 with you on the last point that you made.

11 DARREN MITCHELL: Darren Mitchell, CSPI.  
12 While we're adding to the plan, another lacking element  
13 is a required expiration date based on the date of lay.  
14 That's something that we strongly believe should be  
15 included in this plan and I would also like to agree  
16 with both UEP and FACT on the point of repackaging.  
17 It's something that we've argued long and perseveringly  
18 for. Thank you.

19 DANNY HUGHES: Danny Hughes with Arkansas  
20 Livestock and Poultry Commission. I have a question as  
21 far as egg products as it pertains to the shell-egg  
22 handlers. At the present time, they're not registered  
23 under the Egg Products Inspection Act as it relates to  
24 the eggs that are picked up at hatcheries, shell-egg  
25 plants. Will there be any restrictions on them where  
26 they're picking all these eggs up and then their

1           destined for an egg-products plant for egg  
2           pasteurization? Will they come under temperature  
3           requirements, any age requirements or anything of that  
4           nature?

5                     ROGER GLASSHOFF: Roger Glasshoff. Currently  
6           the Egg Products Inspection Act requires that all the  
7           eggs be of current production. Those records are to be  
8           available to the egg-products inspector as part of the  
9           documents maintained by the processor. As far as  
10          refrigeration, there's no refrigeration requirements on  
11          the movement of eggs currently from the producer level  
12          to egg-products processing plants. We haven't  
13          completed our rulemaking with regard to that aspect and  
14          it will probably be taken under consideration.

15                    DANNY HUGHES: One more comment on the gaps  
16          in the food safety program as far as areas like food  
17          banks that are scattered all over the United States  
18          where they're receiving eggs from distributors that  
19          have been damaged for one reason or another; and then  
20          they are donated to food banks. I don't know if that's  
21          going to come under FDA or FSIS as far as the  
22          monitoring of these type operations or not. I know in  
23          Arkansas we've had some bad experiences with food  
24          banks. And I was just wondering if that was going to  
25          be a part of it.

26                    LOU CARSON: That is a part of it and that

1 would be covered by FDA.

2 DANNY HUGHES: One more and I'll sit down.  
3 The repackaging was brought up. What about the  
4 repackaging at the store level? Was that under  
5 consideration at this point?

6 LOU CARSON: We'll take that under  
7 advisement. I don't think we've talked about  
8 repackaging in the Plan per se so we need to look at it  
9 at all levels. There is a segment of the plan on  
10 retail. And so we'll have to look at repackaging at  
11 retail.

12 DANNY HUGHES: Thank you.

13 TERRY TROXELL: Terry Troxell, FDA. Darren,  
14 you said that CSPI believes that expiration dating is  
15 useful. If eggs are maintained at 45 or less, where  
16 outgrowth doesn't occur, could you elaborate on what  
17 public health benefit the expiration dating will  
18 provide?

19 DARREN MITCHELL: We see it as an extra  
20 measure of safety. The system that the Action Plan is  
21 proposing governed by several agencies. There's some  
22 gaps. We can not be sure that the eggs can be  
23 maintained at 45 degrees. We've heard comments about  
24 the post-production preprocessing time period where we  
25 could get some outgrowth. Things like that, we think,  
26 argue for an expiration date.

1 MERYL SOSA: Meryl Sosa, FACT. I'd like to  
2 respond to Mr. Troxell's question because at FACT we  
3 put out Nest Eggs. We also get the calls from Nest  
4 Eggs. And that is one of the most common questions  
5 that we get at our offices. And I'm not sure about AEB  
6 or UEP. But, how long can I keep the eggs; what is the  
7 expiration date; what does the expiration date mean?  
8 And they may not even ask us about our eggs. They may  
9 ask about other eggs. But we don't really know what  
10 other people are basing their expiration dates on. So  
11 there's this whole continuum of what the expiration  
12 date means that's on the box, because some people date  
13 it from the date of lay, some people date it from date  
14 of processing. Some people have 30 days. Some people  
15 have 60 days. It's just a whole mixed bag. And so I  
16 think it would be a great element for consumers to give  
17 them some confidence in the eggs because they would  
18 know the expiration date means from date of lay and I  
19 can keep the eggs for this many days in my  
20 refrigerator. And that's the way it is and I don't  
21 have to worry about whether the egg is from Nest Eggs  
22 or whether from Dominix or wherever they come from.  
23 They will all be the same.

24 VICTORIA LEVINE: Do you have a comment?

25 RICH DUTTON: Rich Dutton, Michael Foods.  
26 From a practical point of view, I'd just like to

1 comment. I'm not sure if you're getting 30 or 40 lots  
2 or whatever. They may be eggs from a farm that just  
3 came in. Preferably it would be eggs by date where the  
4 next eggs are done. But there could be some lots that  
5 were two days old versus one day old. That would make  
6 a horrendous problem with trying to change the date on  
7 the carton.

8 I do have one other question. I am reluctant  
9 to bring this up. There are about 30 percent of flocks  
10 that are currently broken and designated breaker  
11 flocks. The question is whether those flocks are  
12 handled the same as shell-egg flocks? And the reason  
13 for asking that is we've identified rodents for being a  
14 source of SE potentially. Then breaker flocks,  
15 unmanaged, would likewise become a source. On the  
16 other hand, I realize that diversion allows the  
17 breaking of those eggs from those flocks anyway.

18 ROGER GLASSHOFF: One comment as a response.

19 This is Roger Glasshoff with FSIS. As part of the  
20 HACCP System that would be implied for the processing  
21 plants with regard to pasteurization for egg products,  
22 we would anticipate that that HACCP Plan would include  
23 components of the prerequisite program which we are  
24 addressing for the producer. In other words, rodent  
25 control, in the case in which they were washing the  
26 eggs prior to shipping them to the breaking plant, they

1 would be utilizing a proper source of water, things of  
2 that nature. But not necessarily environmental  
3 testing. Does that answer your question better?

4 RITCHIE LAYMON: Ritchie Laymon, United  
5 Poultry Concerns. Getting back to the repackaging.  
6 When Dateline NBC did their expose at Buckeye Egg on  
7 repackaging of eggs where the eggs were repackaged  
8 several times. Discovery of this situation wasn't made  
9 through federal inspections or state inspections, it  
10 was made because of a whistleblower. And I was  
11 wondering if there is a whistleblower contingent in the  
12 Plan here or if just the general federal whistleblower  
13 protection pertains here?

14 JUDY RIGGINS: Well, with respect to USDA or  
15 FSIS programs, yes, there is a general whistleblower  
16 provision that would apply to all employees and  
17 companies that are under inspection by FSIS which, of  
18 course, we do respect and take seriously. So, yes, the  
19 answer is when we extend our inspection authority to  
20 packer facilities, the whistleblower provision would  
21 also apply to them as they do currently to egg  
22 processing and meat and poultry slaughtering  
23 processing.

24 VICTORIA LEVINE: That was Judy Riggins.

25 LOU CARSON: This is Lou Carson for FDA.  
26 Obviously, as we would receive any information

1 concerning the safety of a product, we would follow up  
2 on it whether it's whistleblower or other means. So it  
3 would be the general procedure that we would follow.  
4 Any information we would be responsible in following up  
5 on.

6 VICTORIA LEVINE: Any other comments? Moving  
7 right along. We will now hear from Nancy Bufano who is  
8 going to give us an overview of retail food service and  
9 consumer issues.

10 NANCY BUFANO: The last segment in the farm-  
11 to-table continuum is the retail food service and  
12 consumer segment. Or I should say, the last, but  
13 certainly not the least segment in the farm-to-table  
14 continuum. I'll start with the discussion of the  
15 retail and food service segment. FDA is considering  
16 codifying certain egg-related provisions of the 1999  
17 Food Code. One of the first provisions that the Food  
18 Code talks about is temperature and condition of shell  
19 eggs upon receipt at retail.

20 If these provisions were codified, they would  
21 require that shell eggs received at retail would be at  
22 45 degrees fahrenheit or below, be clean and sound, and  
23 not contain more restricted eggs than allowed in U.S.  
24 Consumer Grade B. The temperature for holding shell  
25 eggs at retail will be addressed by FDA's final rule on  
26 labeling and refrigeration of shell eggs at retail.

1 This final rule will be published later this year and  
2 I'm sure most of you know that the proposed rule which  
3 was published in July specifies this temperature as a  
4 45 degree fahrenheit ambient temperature.

5 All liquid, frozen, dry eggs, and egg  
6 products received at retail would be required to be  
7 received pasteurized. Four retail establishments that  
8 specifically serve at risk consumers -- here we're  
9 talking about your hospitals, nursing homes, and day  
10 care centers -- these establishments would be required  
11 to substitute pasteurized eggs or egg products for raw  
12 eggs in menu items that either traditionally contained  
13 raw egg ingredients and are not subsequently thoroughly  
14 cooked, or are prepared by combining or pooling and  
15 then holding eggs prior to service or are prepared by  
16 holding eggs following cooking prior to service. And  
17 then, additionally, soft-cooked eggs and meringue made  
18 from raw shell eggs would not be allowed to be served  
19 for retail establishments that do not specifically  
20 serve at-risk consumers. And, just for clarification,  
21 this would include family restaurants and bakeries,  
22 ect. Raw eggs would have to be served fully cooked or  
23 the establishment would be required to substitute  
24 pasteurized eggs or egg products or raw shell eggs in  
25 the preparation of foods that traditionally contain  
26 raw-egg ingredients and then are not subsequently fully

1 cooked. Or if the establishment is going to serve or  
2 offer undercooked eggs or food containing undercooked  
3 eggs, they would be required to inform consumers of the  
4 increased risk that consuming those types of foods pose  
5 to at-risk consumers.

6 So FDA will be crafting consumer advisory  
7 language for those retail establishments -- and those  
8 are the ones that do not specifically serve at-risk  
9 consumers -- language for them to use to inform the  
10 consumers of the increased risk that consuming raw or  
11 undercooked eggs poses to at-risk consumers.

12 The very last segment of the farm-to-table  
13 continuum is obviously the consumer. FDA is not going  
14 to regulate the consumer, but we want to make you aware  
15 of the current food safety education efforts that have  
16 been underway, that are underway, and that will  
17 continue and will be strengthened. FDA has published  
18 two fact sheets, one for the consumer, one for food  
19 service relating to eggs. I believe they're both in  
20 your packet. They're also on the display in the back,  
21 the Fight BAC! display. These fact sheets explain that  
22 salmonellosis is associated with fresh eggs and they  
23 explain who is at high risk. They outline safe buying,  
24 handling, preparation and storage of eggs and egg  
25 dishes, and they explore the hidden risk in foods  
26 containing raw or undercooked eggs, and how to avoid

1           them. These fact sheets have been widely distributed  
2           to the media; 82,000 day care centers; 22,000 school  
3           district food service directors; 13,000 nursing home  
4           directors. They are posted on FDA's web site which is  
5           FDA.gov. They are available from FDA's food safety  
6           hotline, 1-888-SAFEFOOD. And the consumer fact sheet  
7           was included in the 1999 National Food Safety Education  
8           Month Consumer Education Planning Guide.

9                     FDA has also developed a video news release  
10           which alerts consumers to the potential risks of  
11           undercooked eggs and egg foods and the simple steps  
12           they can take to avoid these risks. This was produced  
13           and distributed last July at the same time FDA's egg-  
14           labeling-and-refrigeration regulations were proposed;  
15           and this video news release has been carried by 18  
16           stations with a viewership of 2.5 million.

17                    We've also developed two feature articles on  
18           egg safety, one in English, one in Spanish which have  
19           been distributed to print media nationwide, and these  
20           have appeared in -- Howard Seltzer who is sitting at  
21           the table who is with our food safety initiative  
22           education staff, he just updated me that it is now over  
23           1200 publications and a readership would be more than  
24           74 million.

25                    The Fight BAC! brochure which is also  
26           included in your packet and is also available at the

1 Fight BAC! display in the back of the room also  
2 includes safe egg-cooking information that has been  
3 widely reproduced and distributed both in English and  
4 in Spanish as part of the Fight BAC! campaign and it is  
5 also available on the Fight BAC! web site the  
6 foodsafety.gov web site and FDA's food safety hotline.

7 And lastly, FDA has developed in conjunction  
8 with USDA has developed a patient handout for  
9 physicians which is currently under review. It  
10 includes both safe cooking information and the  
11 identification of persons at risk of foodborne illness  
12 from raw or undercooked eggs. It is developed for the  
13 American Medical Association, FDA, USDA, CDC, physician  
14 food-safety initiative. And with that, I will turn it  
15 back over to Vicky, and I'll leave you with the retail  
16 food service consumer discussion questions.

17 VICTORIA LEVINE: Again, before we hop right  
18 into the questions, are there any general comments?

19 KEVIN KEENER: Kevin Keener, North Carolina  
20 State University. My question is in regard to a lot of  
21 the educational materials and things that you've  
22 developed, have those been distributed some of the  
23 cooperative extension type services?

24 HOWARD SELTZER: Howard Seltzer, FDA. Yes.  
25 The Fight BAC! materials particularly have been widely  
26 used by cooperative extension. I don't know if they

1 have at North Carolina State, but I know they've been  
2 distributed literally by the tens of thousands through  
3 extension. The egg fact sheets I don't have that much  
4 data on. We send the National Food Safety Education  
5 Month Planning Guide to extension agents all over the  
6 country, to our own public affairs specialist, and last  
7 year to school-food service directors and to a lot of  
8 other people, the idea being that they would then use  
9 these guides to develop activities at the local level.

10  
11 So, I would say, to a large extent, yes, they  
12 have been distributed through extension.

13 KEVIN KEENER: Okay. Thank you.

14 VICTORIA LEVINE: We are going to start with  
15 Question No. 18 in the Federal Register Notice. Do the  
16 provisions in the 1999 Food Code which apply to shell  
17 eggs adequately protect at-risk consumers in retail  
18 establishments? If not, what other provisions are  
19 necessary for their protection? Let's start with Tad.

20 TAD GROSS: I guess my comment on this  
21 question would be there's a very big need for education  
22 at the retail and institutional level. I mean, as an  
23 egg producer, and as someone who sometimes has to be  
24 forced to make deliveries, you pull into a restaurant  
25 or institutional place of business and put your eggs in  
26 the proper part of the refrigerated cooler and decide

1 to have lunch and go in and come back out find your  
2 eggs sitting outside and the chickens went in. Again,  
3 as an egg producer, frustrations come out of my  
4 fingers. I'm saying, "What did I do here?"

5 But it's not only a situation that the Food  
6 Code may have enough in it. It's for everybody to  
7 understand that the necessities to follow that Food  
8 Code to ensure and to help ensure the producers that  
9 we're doing our part and we need to go up to that end  
10 of it. So education to me is one of the biggest things  
11 here that needs to go through the system. And,  
12 obviously, they're doing this with the Fight BAC! But  
13 to me, it's very important.

14 VICTORIA LEVINE: Meryl.

15 MERYL SOSA: My name is Meryl Sosa, I'm  
16 manager of Food Safety Programs for FACT. We do not  
17 believe that the Food Code is an adequate solution for  
18 providing protection to at-risk consumers in retail  
19 establishments. And during Ms. Bufano's discussion she  
20 mentioned that the USDA and FDA are considering  
21 codifying the Food Code.

22 And by that I assume that means that they are  
23 going to put it into a set of regulations. We would  
24 definitely encourage that thought. The Food Code is  
25 only operable in states that have adopted its  
26 provisions. States currently are free to adopt any or

1 all of the provisions of the Food Code. The GAO, in  
2 preparing its Egg Safety Report, found that 24 of the  
3 50 states did not require food service operators to  
4 serve highly susceptible populations pasteurized eggs  
5 or any food items that usually contains raw eggs such  
6 as Caesar salad dressing.

7 Further, the Food Code is not a federal  
8 regulation. It only has the force of law when it has  
9 been adopted by a state or local governmental entity  
10 and when sufficient penalties are imposed under the  
11 adopted provisions and the state adequately enforces  
12 such provisions. Thus, the reliance by the FDA on the  
13 Food Code as a method of protecting the safety of food  
14 is completely inadequate. Regulations should be  
15 included as part of the Egg Safety Action Plan that  
16 provide adequate protection for at-risk consumers in  
17 retail establishments rather on relying on the hit-or-  
18 miss approach offered by the Food Code. It cannot be  
19 emphasized enough that the Plan is an opportunity to  
20 provide a comprehensive regulatory approach to the  
21 issue of egg safety, providing regulations that truly  
22 govern all aspects of the farm-to-table continuum.

23 DAVID GLAUER: Dave Glauer, Ohio. Again, I  
24 think producers, for a period of time, have been held  
25 to refrigeration standards. And I believe that by  
26 codifying at least the principles that are here within

1 the Food Code do bring the next level of the whole  
2 farm-to-table continuum that will help reduce foodborne  
3 contamination.

4 VICTORIA LEVINE: Comments from the front  
5 table?

6 DARREN MITCHELL: Darren Mitchell, CSPI. I  
7 also encourage the adoption of the Food Code  
8 provisions, its regulations. It's something that we've  
9 been pushing for across the board throughout the Food  
10 Code. And, actually, Mr. Gross' comment on the  
11 training, that sort of arises there again. At this  
12 year's Conference for Food Protection, there will be a  
13 certification program, a training program for managers  
14 at the retail level. If that's not part of what's  
15 codified for egg safety, it's not going to happen in  
16 many, many jurisdictions.

17 So as much of that as you can get into this  
18 plan as well, would be extremely helpful, I think.

19 VICTORIA LEVINE: Any other comments? Anyone  
20 in the audience?

21 KEN KLIPPEN: Ken Klippen with United Egg  
22 Producers. Is this how we address problems is with  
23 more regulations? More regulations trying to command  
24 and control people who just by implementing common  
25 sense -- I'm going to pull some figures that were given  
26 earlier. In food preparation areas between 1985 and

1 1999, 87 percent where there was an outbreak  
2 occurrence, it was in restaurants, health care  
3 facilities, schools or churches 87 percent of the time.  
4

5 In those occurrences where they were able to  
6 identify the vehicle, 45 percent of the time they  
7 identified eggs. Now let me just share with you an  
8 FSIS document that says salmonella serotypes isolated  
9 from raw meats and poultry -- January 26, 1998 to  
10 January 25, 1999. And this is where the agency  
11 identified 1,174 positive isolates from large plants  
12 subject to pathogen reduction testing requirements.  
13 And then, of those, 903 they actually serotyped. And  
14 it's interesting to reflect on this identification.

15 In the boiler plants, the salmonella isolates  
16 of serotypes, they had upwards of 31 percent  
17 salmonella, Kentucky; 17 percent salmonella,  
18 Heidleburg; you go down the list. You get down to  
19 salmonella enteritidis, 2.4 percent in the ground beef  
20 or the beef plants. You had upwards of 19 percent  
21 salmonella isolates. You get into the pork.

22 VICTORIA LEVINE: Mr. Klippen, could you make  
23 the connection for me?

24 KEN KLIPPEN: The point is, that the  
25 incidence of salmonella enteritidis in eggs is .005  
26 percent. That is the risk. And the reason why we

1 don't see this happening is because people are using  
2 common sense. They are cooking their food. And that's  
3 what we are saying is cook your food. If we can just  
4 educate people, that is the most important element in  
5 all of this is to educate people to handle this food  
6 properly. And once they cook that food properly, then  
7 we're not going to have a problem. We're not going to  
8 need the warning labels that are being proposed. We  
9 don't need to alarm consumers. We need to educate  
10 consumers. And that was the point.

11 VICTORIA LEVINE: Thank you.

12 JILL SNOWDON: Jill Snowdon, Egg Nutrition  
13 Center. I would give a yes and a no answer to that  
14 question. And there is so much complexity on the  
15 subject of food handling, food preparation, and  
16 specifically egg preparation that I'd urge the agencies  
17 to consider the retail end of things and the food  
18 handling in a more amplified light whether it be a  
19 meeting, another public meeting, or a separate Task  
20 Force. But this is classically where food protection  
21 has the biggest problem. And I'm going to give a  
22 couple of examples of that.

23 But I cannot cover, in the few minutes that I  
24 know you want me to limit my comments to, all of the  
25 aspects of this that I could. I'll try to do that in  
26 written comments. I'll speak more to it in Sacramento

1 also. But that's my first point is there is so many  
2 nuances and subtleties on this that I'm asking for more  
3 emphasis and thought on the food service end of things.  
4

5 To give some examples to that effect then,  
6 let me state that the United Egg Producers was very  
7 supportive of the use of pasteurized product with at-  
8 risk consumers. So there's no objection to these  
9 concepts that are coming through Food Code from the  
10 viewpoint of needing to protect individuals and work in  
11 collaboration with this end of the chain. So we're  
12 supportive of that. I am finding that there are lots  
13 of instances where it's inadequate and does not cover  
14 the specifics of the situation. And I'll work with the  
15 Conference for Food Protection in Milwaukee to that  
16 effect and any other mechanisms that we can.

17 A couple of examples. The food handling  
18 practices in nursing homes presumably have changed  
19 because we don't have near the number of outbreaks or  
20 the numbers of illnesses associated with that  
21 demographic group that we used to when we first  
22 discovered this issue. So there's been a change. But  
23 the outbreaks that we now have in this instance, they  
24 are usually egregious food handling practices, the  
25 gloved hands, cutting up raw animal product and then  
26 tossing the green salad with the same gloves on those

1 hands.

2 So this cross-contamination issue and the  
3 food preparation practices, those types of things are  
4 not going to be addressed by this type of thing whether  
5 it came originally from an egg or a non-egg source.  
6 The egregious practices is what's coming through in  
7 that particular at-risk population. Another example is  
8 the at-risk population of the young. Salmonellosis  
9 typically hits those below age one in large numbers.  
10 With SE, it's about 25 percent of those under age 10.

11 And so I think we have a greater need in  
12 working in food protection to tie in the specifics of  
13 that epidemiological information than with our  
14 education and action plans both at retail and  
15 consumers. We're not necessarily addressing either  
16 anybody in a restaurant or anybody in a consumer  
17 situation of spreading a product, contaminating a  
18 counter, and then putting the baby's nipple or baby's  
19 bottle on that counter top without a disinfection of  
20 that counter top in between.

21 So these are the types of specific things  
22 that these broad recommendations that are coming  
23 through Food Code aren't going to address. And I'm  
24 assuming that you mean the receipt of eggs at 45  
25 degrees ambient in coming in as the recommendation.  
26 And, again, going back to the speed at which eggs are

1 delivered from the producer to the retail  
2 establishment, the natural protective properties of the  
3 intact shell egg -- so that's pretty well covered, very  
4 well covered with 45 ambient. But we're not covering  
5 the temperature of that egg in that restaurant once  
6 it's broken out and pooled.

7 Is it kept on the line, in a pitcher,  
8 unrefrigerated before it's turned into a scrambled egg  
9 or a french toast or an omelette or what not? Is it  
10 handled in a fashion such that that pitcher or that  
11 container that's making the french toast is cleaned  
12 periodically or simply the next batch comes in? So you  
13 can see I could go on and on with the examples, and,  
14 given the chance, as I work with you individually, I  
15 will. So I will try to list some of the specific  
16 examples. But my key point is that this is a very  
17 broad subject and I think, certainly, it's a good start  
18 with Food Code and consumer education, both, on the  
19 things we need to do.

20 I'm going to do one more example. If we  
21 really want to come up with blocking disease  
22 transmission, we've got to look at the epidemiological  
23 information and pie it into our messages. Nowhere do I  
24 hear being addressed frozen casserole that is taken out  
25 and put in the oven without the oven being preheated  
26 first. Or a thermometer inserted in the middle of the

1 deep dish casserole so that we see that we actually get  
2 the temperature there. The hollandaise sauce that was  
3 made without a thermometer making people sick. But, in  
4 the same restaurant upstairs, same machine, same eggs,  
5 the only difference is the chefs upstairs used a  
6 thermometer because they were chefs and not short order  
7 cooks. Those people didn't get sick, the others did.  
8 So we've got a lot of things that we could be doing and  
9 it involves a little more detail and specificity than  
10 we've got a start on here.

11 TERRY TROXELL: Terry Troxell, FDA. Follow  
12 up so that I understand correctly. Then the position  
13 of the UEP is that -- I mean, you said about supportive  
14 of the concepts of the Food Code, but are you  
15 supportive of the need for the Food Code egg provisions  
16 being codified so that we can get greater adherence to  
17 that, the refrigeration and the cooking, or as Ken  
18 said, this is a necessary command and control? Or was  
19 that just with respect to the warning label? Would you  
20 please clarify?

21 JILL SNOWDON: I have to let UEP respond to  
22 that directly as I'm providing technical and scientific  
23 information for them. So I'll let them respond to the  
24 specifics of that. I simply wanted to make a point  
25 that we are supportive of the concept of protecting at-  
26 risk populations and using techniques to do that.

1                   KEN KLIPPEN:       Ken Klippen, United Egg  
2                   Producers.       We're supportive of enforcing whatever  
3                   regulations are that are adopted.   If we do go along  
4                   the lines of codifying the model Food Code, then it  
5                   must be enforced uniformly.   That's why we're asking  
6                   for uniformity within the egg industry as well, a  
7                   uniform enforcement.   That's all.

8                   It's just that it's frustrating to us to see  
9                   the predominant area where there is abuse and not to be  
10                  directing the attention to that immediately.   I think  
11                  Tad said it well.   He's frustrated.   We're frustrated  
12                  when we see this area not being addressed as rapidly as  
13                  we are focusing on the farm.   And that is such an  
14                  important element when you look at the tremendous  
15                  contributing factors being the abuse at the restaurants  
16                  and food service establishments.

17                  VICTORIA LEVINE:   Any other comments?   Our  
18                  next presentation is by Robert Scharff.   And he is  
19                  going to talk about the role of economics in the  
20                  rulemaking.

21                  ROBERT SCHARFF:   Well, we've heard a lot  
22                  about costs today.   We know a lot of people have been  
23                  talking about that and we know a lot of people don't  
24                  like hearing that, but as an economist, I have to say  
25                  that I love hearing about that.   So you can keep  
26                  talking about it as far as I'm concerned.   Anyway, as I

1           said, I'm an economist. I work at FDA in the Center  
2           for Food Safety. And I'd like to talk a little bit  
3           about how we analyze regulation from an economic point  
4           of view.

5                        We basically are required to analyze  
6           regulations based on two requirements. One is the E.O.  
7           12866. That's a standing order by the President. And  
8           that's what requires us to do cross-benefit analysis,  
9           regulatory impact analysis, things like that. The  
10          other is the Regulatory Flexibility Act of 1980 as it's  
11          amended by the Small Business Regulatory Enforcement  
12          and Fairness Act of 1996. And what that requires us to  
13          do is to look at the impact of any rule on small  
14          businesses.

15                      Going a little deeper into E.O. 12866, the  
16          Executive Order says, and these are quotes, each agency  
17          shall assess but the cost and benefits of the intended  
18          regulation. And I know there was some concern earlier  
19          today about, you know, that we were just talking about  
20          cost and that we were not going to include the cost to  
21          the consumer of SE. And that is something that we are  
22          going to look at and we are going to include in our  
23          analysis.

24                      Furthermore, each agency shall base it's  
25          decisions on the best reasonable attainable scientific,  
26          technical economic and other information. Now, we have

1           pretty good resources with regards to trying to get  
2           this kind of information. We don't know everything.  
3           You are really the experts in a lot of cases. So  
4           anything you can tell us is very useful. We're also  
5           required to identify and assess alternative forms of  
6           regulation and tailor our regulations to impose the  
7           least burden on society. The regulatory impact  
8           analysis, which I talked a little bit about before is  
9           what comes out of this. This is the report that the  
10          economists write. This is true at both at FDA and  
11          FSIS. As I said, that's required by the E. O. 12866,  
12          and in that we assess the positive and negative impacts  
13          of the rule.

14                 So we will look at what SE reduction will  
15          occur from the rule, but we will also look at what it  
16          will cost the industry. And this is written by  
17          economists with input from agencies, scientists and  
18          policy makers.

19                 Now, for the Egg Safety Action Plan, the  
20          benefit that will be discussed in the RIA will be the  
21          reduction of illness due to SE in eggs. Pretty  
22          straightforward. The costs of the Plan are going to be  
23          the increased expenditures due to the implementation of  
24          the Plan's components. I listed a few of these.

25                 Now, it's important that you look at that  
26          word "increased". I italicized it and underlined it

1           because it's important.    If people are already doing  
2           things, that's not considered a cost by the agency.    So  
3           if you want to report what the increased cost will be  
4           to you from this Plan, not what the total cost is going  
5           to be.

6                         Now, the Regulatory Flexibility Act of 1980  
7           requires that agencies assess the impact of proposed  
8           regulation on small businesses in something called the  
9           Regulatory Flexibility Analysis.    That's also a report  
10          that we put out.    That's actually written at the same  
11          time as RIA.    And it provides for the participation of  
12          small businesses in rulemaking through notes in the  
13          Federal Register, public hearings and review in  
14          response to comments.    That's part of what this meeting  
15          is all about.    We're talking to large businesses, but  
16          we're also hoping that there are some small businesses  
17          that are represented here as well.

18                        Now, this next flag, I labeled it -- How  
19          should small businesses comment?    Now, this is true for  
20          everybody, small or large businesses who are going to  
21          comment.    You should submit detailed information that  
22          will assist us in assessing the value of the proposed  
23          rule.    And you should also submit detailed information  
24          about your company.    Recognizing that we've become  
25          publicly available, everything that you give us goes  
26          into our docket.    So anything that's proprietary that

1           you do not want getting out to the public, you don't  
2           want to give us. But if there's anything that you can  
3           give us that's detailed information about what your  
4           operation is like and what the cost to you would be,  
5           that's great, we want to hear it.

6                        Comment's that provide little detailed  
7           information are not useful to the agency. This rule  
8           will put us out of business. People often write  
9           comments like that. That's not as useful as telling us  
10          about cost structure of your farm and how it's going to  
11          be affected and why it's going to go out of business or  
12          it is going to go out of business. At the FDA, we have  
13          several resources to help you make comments which came  
14          in the packet you were provided with this guide. It's  
15          a guidance for small business. As I said, it's also  
16          relevant for large businesses and submission of  
17          comments for CFSAN rulemaking. And it basically goes  
18          through detailed instructions on how to make comments  
19          and what comments will be useful to us.

20                       We also have a web site where the same  
21          brochure is located and the address is there if you  
22          would like to write it down. Also, one other thing  
23          about this, I have a number of these guides, so if you  
24          are a representative in a state and you'd like to  
25          distribute some of these, I can give you a few. I  
26          don't have a whole lot, but I have a few of them.

1 Another thing we have is a small business hotline. The  
2 phone number is located on the back of the guide. This  
3 is meant for small business, it's not for large  
4 businesses. And the purpose of this hotline, is to aid  
5 small businesses in making comments that are going to  
6 make sense. Because, often, small businesses do not  
7 have the expertise in regulatory work to know what  
8 exactly would be useful. So, what we will do if  
9 somebody calls is say, if you give us this information,  
10 this information will be recorded and it will be useful  
11 to us.

12 The one thing I want to stress is we cannot  
13 use this hotline to record comments. So if you call up  
14 this hotline and say, well, we have this cost structure  
15 and this is happening, it's not going to be recorded.  
16 It's not a good way to make comments. The hotline is  
17 there purely to assist you in making your comments.  
18 And, I guess, that's it.

19 Excuse me. One other thing. Since we were  
20 talking about comments, in the Federal Register Notice  
21 for the meeting, where to send your comments and how to  
22 technically make the comments is listed under Part 5.

23 VICTORIA LEVINE: All right. It is now time  
24 for a short break. I have 2:05 on my watch, so we'll  
25 reconvene at 2:15.

26 (Break from 2:05 to 2:15.)

1                   VICTORIA LEVINE: Apparently there were a few  
2 questions for Bob. So we will recall him to the  
3 podium. Ms. Laymon.

4                   RITCHIE LAYMON: Ritchie Laymon, United  
5 Poultry Concerns. I had a question for Dr. Scharff  
6 about other costs involved in the economics of this.  
7 If the National Centers for Infectious Diseases can be  
8 believed, the actual cases of salmonella enteritidis  
9 are 38 times the reported cases. So that's a lot of  
10 people running off to the emergency room in the middle  
11 of the night and missing work for several days. Who  
12 does the economics of the costs beyond the producer to  
13 the consumer and to the tax payer?

14                  ROBERT SCHARRF: We also do that. If you  
15 want to get an idea of how we do it -- I'm not sure if  
16 it has been released yet, but I know when the final  
17 rule comes out for the refrigeration rule for eggs, we  
18 did an economic analysis where we did both sides of  
19 the costs and the benefits. We looked at salmonella  
20 and we measured the value of illness and  
21 hospitalization and death that results from salmonella.

22                  So we do include it. Any other questions?

23                  JILL SNOWDON: Jill Snowdon, Egg Nutrition  
24 Center. Is that posted or available? That analysis?

25                  ROBERT SCHARRF: I'm not sure. Does anybody  
26 here know?

1                   TERRY TROXELL:    Terry Troxell.    Certainly,  
2                   the proposal on the egg labeling and refrigeration was  
3                   out last July and their Egg Impact Analysis for that  
4                   was out thereabouts.

5                   JILL SNOWDON:    I'll check that again.    And  
6                   that included the specifics on the cost of illness too?  
7                   It did, didn't it?    Thanks Terry.

8                   MERYL SOSA:       Meryl Sosa for FACT.    You  
9                   mentioned that as part of your analysis you just wanted  
10                  the increased costs that people would incur.    Now, in  
11                  getting the information that you need, will that be  
12                  somewhat difficult by the fact that some people are  
13                  already in these quality assurance programs?    They're  
14                  different?    Each program is different.    I'm just trying  
15                  to figure out how that's going to play into it.

16                  ROBERT SCHARRF:    That's a very good point.    I  
17                  guess I should be a little bit clearer on that.    There  
18                  are some places where some people are doing something  
19                  and other people are not doing it.    In those cases the  
20                  people who are not doing it would probably be the ones  
21                  who want to complain about the costs or write about the  
22                  costs.    And they would just say, okay, well, it's going  
23                  to cost me "X" amount.    The other people who are doing  
24                  it, they may want to say that they're already doing it.

25                  We will try to determine through other means how many  
26                  people are in compliance or not in compliance with

1 different provisions.

2 But there are other components where there  
3 may be an increase in something. So for example, if  
4 you have an SE-positive flock, one of the things that  
5 has been talked about is increased rodent control. And  
6 there are some things you can do for rodent control  
7 that you were not doing beforehand. We're not looking  
8 at the total cost of your rodent control problem.  
9 We're just looking at the cost that would occur due to  
10 this rule from the increased rodent control. So,  
11 you're right. It depends on what we're talking about  
12 whether you want the total cost or whether you want  
13 just the incremental cost.

14 But, when we measure it, we're going to  
15 measure everything as incremental costs and some of  
16 them will be weighted averages. So it will be the cost  
17 say -- Let's say you already have a testing program  
18 that's the same as what we end up doing. For you the  
19 cost will be zero. For somebody else, the cost will be  
20 the full cost -- somebody who's not doing anything.  
21 The weighted average is the incremental cost in that  
22 case. So it's a little bit confusing but it's the same  
23 principle.

24 BOB ECKROADE: Bob Eckroade, University of  
25 Pennsylvania. As someone who has worked for years with  
26 producers convincing them that certain practices carry

1 with it great benefits for more than the single disease  
2 than they're working at, I've always said that the  
3 investment in education that we just spoke about of the  
4 consumers and the cooks and what have you, would not  
5 just eliminate salmonella enteritidis; it would reduce  
6 all the others. And so we get way beyond what that  
7 investment would bring us back for the E.coli and the  
8 shegellas and all of the others by simply educating  
9 them to handle food properly.

10 And I don't know whether you can put a value  
11 on that. But I would like to re-emphasize that I think  
12 the dollars spent there is going to pay back tremendous  
13 benefits in food safety in general that we may not get  
14 into. But it's going to have that effect.

15 ROBERT SCHARRF: That's a good point. There  
16 are going to be some external benefits. When we try to  
17 reduce salmonella, we reduce other pathogens as well.  
18 Because the purpose of this program, however, is  
19 salmonella reduction and because of the complexity of  
20 trying to answer the question of what else is reduced,  
21 we're probably not going to do an explicit analysis of  
22 that; however, if anybody wants to send in comments  
23 about how other pathogens could be reduced through this  
24 program, we'd be happy to at least qualitate that we  
25 mentioned that as a positive side effect.

26 JILL SNOWDON: Jill Snowdon, Egg Nutrition

1 Center. I don't get it. I don't get that the producer  
2 that has been an industry leader, gotten ahead of this,  
3 done a quality assurance. His costs are not included  
4 because he's already doing what the federal government  
5 plans to do for everybody else. And the person who  
6 said, I don't know what's expected of me and I don't  
7 want to proceed until I know what's expected of me, his  
8 costs count?

9 ROBERT SCHARRF: I understand that does sound  
10 unfair. But, in fact, what we are doing is we are  
11 trying to analyze what the effect of the rule is going  
12 to be. Basically, it cuts both ways. The benefits  
13 from the guy who is already doing the right thing,  
14 those benefits have already been realized. We've seen  
15 a tremendous decrease in SE in the last few years and  
16 it's because of the guys who have been responsible and  
17 who have pulled their act together. Those benefits are  
18 not going to be included in the analysis. It's only  
19 going to be the increased benefits that will accrue due  
20 to the rule and the increased costs that will accrue  
21 due to the rule that are going to be in the Regulatory  
22 Impact Analysis.

23 JILL SNOWDON: So we've had the 50 percent  
24 reduction already without federal regulation and that  
25 part is not going to count?

26 ROBERT SCHARRF: Not for this rule. Because

1 that's happened in the absence of this rule. We're  
2 only going to look at what this rule --

3 JILL SNOWDON: But this rule was necessary?

4 ROBERT SCHARRF: Yes.

5 JILL SNOWDON: I'm getting a needle here  
6 because this is not motivating to an industry to say  
7 all that investment that you've put in just doesn't  
8 factor into the economic analysis.

9 ROBERT SCHARRF: It does, in fact, because it  
10 gives us some information about how well the steps they  
11 have taken -- what the effects of those steps have  
12 been. And we have seen this tremendous decrease in SE.  
13 And from that we can project, what the additional  
14 decrease in SE will be from requiring everybody to do  
15 it. So in a sense, they've laid the groundwork for  
16 this rule.

17 TERRY TROXELL: Terry Troxell here. Jill,  
18 you may recall CDC's presentation that there's over  
19 200,000 illnesses. So there is need for further  
20 controls and I think everybody has been arguing for  
21 some national uniform consistent approaches so that  
22 those people who have taken the steps to use best  
23 practices will not be paying a penalty so to speak  
24 because of those people who have not.

25 So we're trying to get everybody up to the  
26 same level. And the baseline we're at right now is

1           what today is and the impact of the rule will be,  
2           whatever the effect it will have, once it's  
3           implemented. That's the way costs are done, otherwise  
4           we go back a few years ago where we had 600,000 cases  
5           estimated and the health impact of that. So that's the  
6           way the economics are done for all rules.

7                   JILL SNOWDON: Perhaps my suggestion is more  
8           of an academic one, Terry, I think somewhere along the  
9           line, we need to model the sense of the economic burden  
10          on food production relative to the ultimate public  
11          health benefit and not as "is it worth it". Because,  
12          certainly, even one illness is too much. So, yes, it's  
13          always worth it, but in terms of are we directing our  
14          resources at production at the most efficient  
15          mechanisms to give the public health benefit from it.  
16          So I'm being a little bit of an agitator here because  
17          in terms of the economic burden that gets passed on to  
18          the consumer, that's not being realized in this type of  
19          analysis.

20                   And I think what you're telling me is it's  
21          not appropriate to this type of analysis because you're  
22          only talking about what's changed. So my suggestion  
23          may be more of an academic research one than pertains  
24          to regulation making.

25                   PHIL DEBOK: Well, I just wanted to interject  
26          a cautionary comment here, at least, from the

1 production side of the house. Currently many of the  
2 major egg producing states already have upwards of  
3 maybe 85 or percent or more of their production already  
4 enrolled in quality assurance programs that are similar  
5 to what we are talking about mandating here. And I'm  
6 not sure that enrolling the other 15 percent is going  
7 to make a significant reduction over what we've already  
8 seen. So you need to take that into fact. Because  
9 doubling the effort here is not necessarily going to  
10 cut your cases in half as a result.

11 VICTORIA LEVINE: That was Phil Debok.

12 ALICE WALTERS: Alice Walters, Ohio Poultry  
13 Association. I guess I'm like Jill here, it's a matter  
14 of academic research, but in your own safety plan, it  
15 states you're going to use the data compared in 1998  
16 baseline values, not currently. So I would call upon  
17 you to compare those 1998 baseline values and also put  
18 into that analysis what people are paying currently  
19 that are in the program. Because as Phil states, we do  
20 have a large majority of the largest egg producing  
21 states on a program like this.

22 So if you're going to an economic analysis  
23 you need to include those figures in this analysis.

24 VICTORIA LEVINE: Anyone else? Good.  
25 Speaking of research, that is our next topic. Robert  
26 Brackett.

1                   ROBERT BRACKETT:       One of the important  
2 provisions of the Egg Safety Action Plan has been from  
3 the inset that the recommendations and the policy that  
4 come out of it are to be based on sound science and  
5 sufficient scientific data. And during the creation of  
6 the plans, a number of different data gaps were  
7 identified that would need to be addressed in order to  
8 do this.

9                   The overall research questions addressed in  
10 the Plan that were suggested were based on these gaps.

11                  And just as sort of a review of what the Plan entails,  
12 as has been stated all the way through the data,  
13 through the two strategies: Strategy I, which deals  
14 primarily with controlling SE at the production level  
15 versus Strategy II, which is to focus on the lethal  
16 treatments to eliminate SE in eggs.

17                  And this is important for a research point of  
18 view too, because the way in which you address the  
19 research will be fundamentally different depending on  
20 which of these two strategies that you are addressing.

21                  And it's also important to the research to remember  
22 the overarching goals to the whole plan which is to  
23 eliminate all egg-associated SE illnesses by 2010 and  
24 to also meet the interim goal of reducing by 50 percent  
25 egg-associated SE illnesses by 2005. And this will  
26 also impact the research that's chosen to be done.

1           The mechanism that has been selected for  
2           reaching both of these goals are addressed in eight  
3           objectives and they are listed in the plan that you  
4           have. The one that I'm going to focus on, obviously,  
5           is Objective 7, and that is to ensure adequate current  
6           information is available to make decisions about SE,  
7           preventative controls, the surveillance and the  
8           education; and that, again, is based on sound science.

9  
10           From this, four sub-objectives were  
11           identified. And when you look through the Plan, it  
12           sort of looks like these are just a list, but, in fact,  
13           there are some organizational reasons for this. The  
14           first research sub-objective which I call 7.1 here is  
15           to develop and evaluate on-farm intervention strategies  
16           as far as technology. And this primarily addresses  
17           Strategy I, that is, on-farm control. And it would  
18           include such things as forced molting and other stress  
19           factors, vaccines and immunomodulators, SE- competitive  
20           exclusion and such technologies as ion air scrubbers in  
21           hatcheries. Now with this objective and those that  
22           come after it, these were the initial identified tasks  
23           or gaps in the data that were needed to enact the Plan.

24  
25           These are not the only things, and as good  
26           research usually does, as more is learned from this

1 research, they may be changed, they may be addressed  
2 and new ideas may come from them, and that's the way  
3 research should work. The sub-objective 7.2, the  
4 second one, was to address and to provide additional  
5 information about the commercial processing  
6 technologies and practices for reducing SE in eggs.

7 Obviously, this addresses primarily Strategy  
8 II and it would include research on such topics as in-  
9 shell pasteurization of eggs, rapid cooling before and  
10 after processing, the issue of continuous re-washing  
11 and re-packaging, pasteurization of egg products and  
12 additives. And the first thing that you might notice  
13 is that even though we're into the year of 2000 here,  
14 that several of these have already been addressed. In  
15 fact, there have been publications on this and these  
16 are moving more towards commercial and practical  
17 applications; that is, in-shell pasteurization of eggs  
18 and pasteurization of egg products and additives. So  
19 as these are addressed, of course, we may have new  
20 questions and new ways of doing this.

21 The third sub-objective involves improving  
22 testing methodologies for salmonella enteritidis on  
23 farms and in eggs including identification of virulence  
24 factors and development of rapid tests, screening  
25 tests, sampling protocols for sub-typing SE isolates.  
26 Now, this particular sub-objective really provides

1 tools that could be used both in Strategy I and/or  
2 Strategy II.

3 And finally, the fourth sub-objective that  
4 was identified are those that again would address both  
5 Strategies I & II, but were more of a fundamental or  
6 long-term nature. And this will be shown by the time  
7 line. And this is to understand the ecology and the  
8 epidemiology of SE in the hen and farm environment and  
9 includes such research topics as the sources of SE in  
10 the environment; the actual mechanisms of colonizing;  
11 how these organisms colonize the layer house; factors  
12 affecting the infection of the hens and the  
13 contamination of eggs mechanisms; pasteurization again,  
14 characteristics of salmonella enteritidis that promote  
15 infection of hens; and then more of the fundamental  
16 topics like biochemical characteristics; immunological  
17 and other factors that affect humans in their  
18 infection; and risk factors associated in humans that  
19 affect infectivity as well.

20 One of the research issues that all of these  
21 have to address and these are the issues that are taken  
22 into account by both government as well as academic and  
23 industry researchers first of all is the immediate  
24 versus long-term results. This goes back to  
25 remembering the interim goal of reducing by 50 percent  
26 SE by 2005. Some research is geared long term such as

1 the fourth sub-objective; some is much more applied and  
2 can be used right now. And that's where most of the  
3 research has been addressed so far.

4 There's also the issue of practicality and  
5 economics of the solution which was addressed by Bob  
6 previously. And then one also has to ask the question  
7 of who is best to conduct the research? Some types of  
8 research are best done by government, some by academia  
9 and some by industry. And it's when the three  
10 different groups together work and share the research  
11 results that the research questions become answered.

12 And so the whole idea of the research  
13 component of the Food Safety Action Plan must consider  
14 these three particular issues as well as some others,  
15 and be understood to be sort of a moving target or a  
16 progressive type of situation where research in the  
17 future will be built upon the research that's done now.

18 And that is all I have to say.

19 VICTORIA LEVINE: All right. Shall we start  
20 with any general comments?

21 KEN ANDERSON: Ken Anderson, North Carolina  
22 State University. Simple question, who's going to pay  
23 for this research? It's extremely expensive to do  
24 long-term studies dealing with issues such as molting  
25 and what effect it can have on the microbiological  
26 characteristic. Who is going to pay for it?

1                   BOB BRACKETT: This is Bob Brackett, FDA. It  
2 turns out that as was shown in the last one, it's going  
3 to end up being that everybody pays for it. Some of  
4 the programs are going to be addressed in the form of  
5 government-competitive grants, as has been done. Much  
6 of the research that already has been done has been  
7 paid for by industry, quite often, through  
8 universities; and others have been done within  
9 different state programs that have paid for salmonella  
10 enteritidis research for research as well.

11                   JUDY RIGGINS: Judy Riggins, USDA. As a part  
12 of the Food Safety Initiative, one of the areas that  
13 the administration or the sister regulatory agencies  
14 are collaborating on is research. And the intent is  
15 that for each budget year, each fiscal year, when we do  
16 our budget formulation, there will be collaboration  
17 among the agencies first of all to decide on the  
18 priorities. Obviously, SE is one that has been  
19 identified as a priority. The agencies will come  
20 together and agree on an agenda for not only government  
21 research, but also for grants and other mechanisms that  
22 would engage the private sector. So it is something  
23 that is an ongoing operating agreement among the  
24 regulatory agencies with respect to research for food  
25 safety. So it's being included in that umbrella.

26                   JILL SNOWDON: Jill Snowdon, Egg Nutrition

1 Center. Certainly if the plants identified are in  
2 keeping with what industry scientists and academicians  
3 have been speaking about -- and we are, certainly,  
4 particularly at the Egg Nutrition Center since we do  
5 research and education. We're delighted to have  
6 continued emphasis in the research area as well as all  
7 that the federal government and others have provided in  
8 the decades -- not quite decades yet -- but the years  
9 have already gone by. And so I thought I'd just make a  
10 couple of comments and emphasize a few things and  
11 identify a couple of gaps. Again, it's a such a large  
12 area that I'm hoping there will be another meeting to  
13 deal with some of the scientists and researchers and  
14 whatnot to flush it out a little bit more.

15 But in a quick response, and simply to  
16 emphasize the need for understanding transmission,  
17 there are still things at the farm level that need to  
18 be addressed and certainly support for the concept of  
19 improving testing methods so that we could better  
20 identify a farm that's at risk of producing the  
21 contaminated eggs. We've got some information on that,  
22 but it always can be improved upon. If the new  
23 technology can be developed due to direct detection of  
24 the contaminated egg, that would be pie in the sky but  
25 certainly ideal.

26 And the thing that I think I would like to

1 touch on most though is the social science research.  
2 When we deal with food-safety questions, particularly  
3 ones that are microbiological in nature, we don't tend  
4 to think about research other than microbiological  
5 research and where it ties in. But that's one of the  
6 gaps that I'm seeing is some sense of understanding  
7 about -- How should the messages be phrased? So that  
8 we have a risk communication based on consumer research  
9 and not simply somebody's opinion on what somebody  
10 ought to hear. But rather let the public health  
11 professionals identify what does the consumer as an  
12 example or the food service worker, as another example,  
13 need to know. And then get the social scientist to  
14 help us craft -- How do you get that message across?  
15 Along with completing the feed-back loop of where were  
16 we when we started, and what have we accomplished then  
17 by our educational programs?

18 This whole area of the social sciences as  
19 applied to food safety is not one that I've heard very  
20 much about and so there are a wealth of opportunities  
21 here so that we can see if we are being effective and  
22 accomplishing what it is that we're setting out to do.

23 Likewise, consumer attitudes, knowledge, and  
24 practices, yes, I know that the agencies do some work  
25 to that effect, but I think that the results end up  
26 coming back that you either fry an egg completely or

1 don't fry an egg completely. And again the specifics  
2 of what are the cultural practices and attitudes on it?

3  
4 Who's cracking the raw egg into a glass of  
5 Coca-Cola for breakfast or orange juice? It's a  
6 cultural practice that's been described to us. Using  
7 that type of product as a health remedy is also a  
8 practice that we've gotten from market research. So  
9 this type of thing, I think, is a gap in our knowledge  
10 and understanding on this. Because how the consumer is  
11 preparing the food and, in more specific detail, are  
12 the eggs runny or not is, again, something that we're  
13 not knowledgeable about or understanding.

14 And, likewise, with food service attitudes,  
15 knowledge and practices, to what extent are the  
16 handling practices that are going on at the commercial  
17 level appropriate to the situation? And also their  
18 limitations, a better understanding of what their  
19 constraints are, relative to the things that could be  
20 recommended. I think there is always more room for  
21 detail in epidemiological study. Both the case  
22 controls and both the study of outbreak and sporadic  
23 disease are opportunities to plum for more details than  
24 we currently have on that. As I eluded to earlier on  
25 the educational ideas, if we have some more specifics,  
26 if we're using either the data that we have or

1           developing a little bit more, it will give us more  
2           information on which to base the programs that are  
3           coming out.

4                       And ultimately, the research information is  
5           not as effective if it's not communicated. If the data  
6           that's developed at either the private sector or the  
7           public sector isn't communicated to the rest of the  
8           world, a single presentation and an abstract at some  
9           obscure scientific conference somewhere doesn't count,  
10          the availability and the ability to access the research  
11          data that has been developed is part of all this.

12                      And then the technology transfer that comes  
13          with it so that when we develop solutions on things get  
14          ideas, get information out, how to get it out into the  
15          field, and into practice no matter what it is that we  
16          call the field.       So compliments, certainly, to  
17          everything that's been accomplished and those are just  
18          some thoughts in terms of additional things that we can  
19          go forward on.

20                      VICTORIA LEVINE:   Dr. Opitz, did you want to  
21          comment?

22                      MIKE OPITZ:   No.

23                      VICTORIA LEVINE:   Any other comments? If you  
24          look at Question 20 which I know is out of order, you  
25          can see that that's where we sort of are at the moment.  
26          So why don't we finish addressing that one.   The

1 question is: What research on SE in eggs is already  
2 under way and what additional research is needed to  
3 assist producers, packer/processors, and retailers in  
4 proper practices? We'll start with Dave.

5 DAVID GLAUER: Certainly we've seen a lot of  
6 different research projects or -- from Dr. Brackett --  
7 what needs to be done. As I would look at it from the  
8 producers standpoint, certainly the areas of  
9 transmission, how do we get a colonized in a house, the  
10 use of vaccines? Where do they fall into a  
11 preventative program or into an overall flock-health  
12 management? Also I think there's a lot of data that is  
13 being generated in academic as well as departments of  
14 Agriculture's laboratories. And there is a risk  
15 assessment module out there in which a lot of this data  
16 can be put in. I think we ought to make some  
17 utilization of that risk assessment module and maybe we  
18 can help address the issues of what test samples where  
19 they should best be taken. So I think there are a lot  
20 of opportunities there.

21 MERYL SOSA: Meryl Sosa for FACT. First,  
22 there are four areas of research that FACT would like  
23 to recommend: Research to develop or to make more  
24 available and effective live vaccine for SE; research  
25 that compares SE contamination rates between deep-  
26 litter floor systems and cage systems; research on the

1 issue of which breeds of layers are more susceptible to  
2 SE so that the strains that are less susceptible to SE  
3 could be used; research that determines the  
4 relationship if any between hen density in cages and  
5 the shedding of SE.

6 Finally, under that particular list, we heard  
7 from the CDC that they have some information from  
8 FoodNet and PHLIS and those would be sporadic cases as  
9 I understand it. And then they have other information  
10 that's based on outbreaks. And as far as the  
11 information on outbreaks, they have some knowledge of  
12 the causes of those outbreaks whereas, with the  
13 sporadic cases, they don't have any information on what  
14 those particular cases are. And so we'd like to see  
15 that type of research come out so we can learn more  
16 from that.

17 Second, FACT recommends the creation of a  
18 central information database. Researchers would be  
19 aided by the creation of such a database. The Plan  
20 should include a requirement that results from farms  
21 operating under Strategy I and should be forwarded to a  
22 central authority such as FDA or CDC in a format that  
23 includes as identifying information only the state in  
24 which the farm is located, but not any other  
25 identifying information.

26 Collection of this information would be

1 useful in determining the actual incidence of SE in  
2 shell eggs. The only other method of surveillance  
3 relies on determining the incidence of SE in shell eggs  
4 by inference from information derived from SE  
5 outbreaks. This may not provide an accurate picture of  
6 the actual incidence of SE. Finally, this  
7 centralization of information will provide a measure of  
8 the success of the Plan by analyzing the results of the  
9 sampling protocol combined with data obtained from any  
10 trace backs that have been conducted and FoodNet.

11 TAD GROSS: Tad Gross, OPA. As producers, I  
12 think we're all open to suggestions and practices that  
13 are developed by the universities and FDA and whoever,  
14 but I think, more importantly, from my standpoint as a  
15 producer being in Ohio Egg Quality Assurance Program  
16 now for three years, the data that we have collected  
17 ourselves here in this state has been very beneficial  
18 to all the participating members.

19 We as the egg processors are sharing what's  
20 working, what's not working, and we've grown in  
21 knowledge bouncing off ideas amongst ourselves and  
22 learn to understand these things better as producers  
23 and the more we continue to educate ourselves and keep  
24 our ears open to what the University of Ohio State in  
25 our case advise us to do, has been very beneficial.

26 VICTORIA LEVINE: Any comments from the

1 table?

2 MARY EVANS: I just wanted to say that there  
3 haven't been no -- I'm sorry. Mary Evans from CDC.  
4 It's not that there have been no case-control studies  
5 of sporadic illness done. There have been and I'm not  
6 aware of all of them offhand. One in particular was a  
7 sporadic case-control study done in the FoodNet sites,  
8 1996 and 1997, that specifically looked at SE. And I'm  
9 not sure if this information has actually come out yet,  
10 but there were increased risks from consuming runny  
11 eggs outside of the home. There is also increased risk  
12 from consuming chicken outside the home.

13 So there have been studies that have been  
14 done. It's just that we haven't actually taken those  
15 studies and quantified them into a risk that we're able  
16 to apply to the total number of SE illnesses. So,  
17 that's certainly something that we're working on.  
18 Research is ongoing and it's just something we need to  
19 actually pin down.

20 VICTORIA LEVINE: Any other comments? Okay.  
21 The audience.

22 BEVERLY BYRUM: I'm Beverly Byrum. I'm from  
23 the Ohio Department of Agriculture Animal Disease  
24 Diagnostic Lab. And the topics we're talking about  
25 now, remind me a little bit of what we discussed this  
26 morning in terms of what's the correct environmental

1 sample that we should be taking? The question that  
2 we've been facing is what's the correct number of eggs  
3 that should be collected when you're looking at an  
4 environmentally-positive house? And I would suggest  
5 that there's data that is currently available applied  
6 to research, you might say, that could be utilized to  
7 answer some of these questions.

8 In 1996, I think it was the FDA and the USDA  
9 got together and started to create a model in which  
10 they've collected data, a large part of it which was  
11 coming from the Pennsylvania SE pilot program with some  
12 other information as well. And they came up with a  
13 conclusion and a report called the Risk Assessment of  
14 Salmonella Enteritidis in Shell Eggs and Eggs Products.  
15 And they made some suggestions using that data.

16 But I think that that data and some  
17 additional data that's being generated by other states  
18 including Pennsylvania and Ohio can be applied to  
19 answer some of the questions like: Which samples  
20 should be collected? I don't think those questions  
21 have been asked utilizing that data. I would suggest  
22 that that's readily available and that we take that a  
23 step further and apply the existing information that we  
24 already have and answer some of these questions. Thank  
25 you.

26 VICTORIA LEVINE: Anyone else?

1                   MIKE OPITZ: I'm coming back to management  
2 strategies that were solved in the reduction of the  
3 risk. In those suggested strategies, terms like  
4 cleaning and sanitation and rodent control -- which we  
5 know are very important -- have been mentioned. I  
6 would suggest that priority in the research should be  
7 placed on refining and defining and improving those  
8 management strategies which are on the top of the  
9 priority list.

10                   It means measures like vaccination,  
11 sanitation, and disinfection. There are new procedures  
12 and new technologies out there which involve, also,  
13 cultural engineering and so on which need to be taken  
14 into consideration. And I think there if we get more  
15 research done in those areas which is usually involved  
16 and very expensive. But see how we could make the  
17 quickest progress, the fastest progress in improving  
18 our methods to reduce the risk.

19                   I would urge not to spend too much time on  
20 looking for sources, for new sources, where the  
21 infection might come from and how flocks can get  
22 infected. We know an awful lot about this. The last  
23 twelve years have not passed by without research. A  
24 lot of research has been created. A lot of information  
25 is available at this time. We also have to  
26 realize that many of the strategies which we are asking

1 for here are done under extreme constrains by  
2 environmental protection, by OSHA, and, therefore, we  
3 have to look for measures that can be implemented under  
4 those restrictions under which the industry is allowed  
5 to operate.

6 VICTORIA LEVINE: That was Mike Opitz.  
7 Anyone else? Then we'll move to the final question  
8 which is number 19 in the Federal Register Notice.  
9 Rewashing of shell eggs is a widespread industry  
10 practice. Are there data or research to support it?  
11 And if it is disallowed, what economic effect will it  
12 have on the shell-egg industry? Tad.

13 TAD GROSS: Tad Gross, OPA. I'm not exactly  
14 sure that there's much of a problem in this particular  
15 question as what some people may think. If there is,  
16 the economic outcome would probably be somewhere at 30  
17 cents a dozen less for your product if you can't rewash  
18 it. A dirty that would go through a second time would  
19 be cleaned up. So you're making a Grade A down to a  
20 Grade C under USDA specifications. So that's somewhere  
21 near 30 to 40 cents depending on market spread there in  
22 that area.

23 MERYL SOSA: Meryl Sosa for FACT. We don't  
24 engage in this practice on our farms or at the  
25 processing plant that we use, so we really don't have  
26 any information that we can help with.

1 VICTORIA LEVINE: Dave.

2 DAVID GLAUER: No additional comment.

3 VICTORIA LEVINE: Front table? Audience?  
4 Okay. We will now turn the mike over to Lou Carson.

5 LOU CARSON: We're going to now go to the  
6 section where people have asked to make a general  
7 statement at the end of this meeting. We have allotted  
8 a certain amount of time. We have 16 people currently  
9 who would like to make a statement. So based on that  
10 and the amount of time, we would ask you to try to keep  
11 to three to four minutes rather than five minutes if  
12 you could. So then we can allow each person to make  
13 their statement. First on the list is Ken Looper from  
14 Cal-Maine Foods.

15 KEN LOOPER: My name is Ken Looper. I am  
16 vice chairman of Cal-Maine Foods which is an integrated  
17 egg operation consisting of production, processing,  
18 packing and distribution. We're located in 15 states  
19 and have about 300 hen houses and 22 egg-processing  
20 plants that are USDA inspected and have been for some  
21 time.

22 I'm the immediate past chairman of United Egg  
23 Producers, I'm the current chairman of the Egg Quality  
24 and Food Safety committee that is working with the food  
25 safety. And I'm very interested in the Egg Safety  
26 Action Plan and any other efforts that are designed to

1 decrease the incidence of SE in our eggs. Enclosed  
2 with this document that I am presenting to put on the  
3 record, is twelve of the ways to improve egg quality  
4 and safety that's found in UEP's Streamlined Grading  
5 Inspection Program that I would like to have included  
6 in the record. As most of you know, UEP is a  
7 national cooperative representing approximately 80  
8 percent of all the egg producers in the U.S. These 12  
9 items represent our recommendation to the Food Safety  
10 Action Plan: No. 1, Quality Assurance Program based on  
11 HACCP provisions at the farm and shell-egg packing  
12 plants and enforced by USDA, AMS, or USDA/APHIS. 2.  
13 Uniformity among all egg producers and packers in  
14 addressing food safety. No. 3, A streamlined  
15 monitoring program for grading inspection and  
16 surveillance of shell-egg plants administered by  
17 USDA/AMS. No. 4, Change from continuous inspection to  
18 a continuous monitoring of performance standards  
19 program for all shell-egg plants. 5. Requirements for  
20 shell-egg refrigeration and storage and transportation.  
21 6. Requirements regarding repackaging of shell eggs.  
22 7. Requirements regarding the dating of shell eggs. 8.  
23 A validation testing component and incentive for using  
24 SE vaccine. 9. Uniform trace-back procedures of shell  
25 eggs. 10. Documentation, verification, and third-party  
26 validation procedures. 11. Tax-payer funding

1 consistent with meat and poultry inspection programs  
2 that are now in existence. 12. Indemnification to  
3 producers who divert eggs from the table-egg market to  
4 pasteurization as a result of the flock being SE  
5 positive.

6 Those are the 12 items included in our 12  
7 point program. I think it will be very difficult to  
8 have an effective food-safety program without an  
9 effective food-handling program. An effective food-  
10 handling program in the egg business starts with an  
11 egg-processing plant. An effective food-handling  
12 program for eggs must contain mandatory inspection of  
13 all egg-processing plants funded by the federal  
14 government, the same as all other poultry and livestock  
15 plants. The President's Food Action Plan, as I  
16 understand it, does not include contain these  
17 provisions. The President's Food Action Plan  
18 overemphasizes environmental testing at the farm and  
19 does not recognize at this time the benefits of  
20 vaccination of hens to prevent SE. The United Egg  
21 Producers Plan as has been recommended to the  
22 President's Food Safety council addresses these two  
23 important issues. The producers of eggs in the U.S.  
24 strongly recommend that our plan be adopted and we will  
25 have an effective Food Safety Program that will reach  
26 our objectives. Again, Thank you for having the

1 opportunity to comment.

2 LOU CARSON: Thank you. Mr. Jay Schuman from  
3 Michael Foods.

4 JAY SCHUMAN: Yes. Thank you. I would just  
5 like to use my couple of minutes to revisit the issue  
6 of retail food service, food safety. I didn't weigh on  
7 that topic earlier. I just wanted to state that in the  
8 food service setting, as several people have already  
9 said, food handling plays a key part in any food safety  
10 or risk management system that we could look at. It's  
11 a very visible portion of the total SE foodborne-  
12 disease illness burden that is currently in the United  
13 States.

14 I would like to mention that I did hear Dr.  
15 Bob Tokes from CDC at a meeting about a month ago in  
16 Atlanta, the Watt Poultry Summit, and I was surprised  
17 to learn that I guess upwards of 90 percent of the  
18 cases are believed to be sporadic or individual cases  
19 that are not picked up in major outbreaks. I believe  
20 food service settings are where most of the outbreaks  
21 can be traced. At the food service setting, I believe  
22 the model code Michael Foods has long supported a more  
23 widespread implementation of the egg-relevant portions  
24 of the Model Food Code.

25 The Food Code is a very rational science-  
26 based document, and it's involving a transparent

1 process with the Conference on Food Protection that  
2 happens every two years and is about to happen again  
3 this April. And we would just support any effort to  
4 make these provisions mandatory. And part of that, as  
5 was mentioned by one of the panelists, the Certified  
6 Food Manager Program, I think, will effectively address  
7 the overall context in which food safety issues are  
8 dealt with in a food service setting that were  
9 mentioned by one of the other speakers. So we  
10 do support codification or mandatory requirement of the  
11 egg-relevant sections of the FDA Model Food Code. That  
12 wraps it up. Thank you.

13 LOU CARSON: Thank you. David Farmer from  
14 Praxair Incorporated.

15 DAVID FARMER: Good afternoon. My name is  
16 David Farmer. I'm the marketing director at Praxair  
17 Incorporated. Praxair is global leader in industrial  
18 air products and application of those products that  
19 benefit our customers and help add value to their  
20 businesses around the world.

21 In response to your questions on the adequacy  
22 of the imposed components of the Risk Reduction Plan,  
23 Praxair believes that given the time-temperature  
24 sensitivity of eggs related to the growth of  
25 salmonella, the proposed plan should be more emphatic  
26 on reducing the egg as quickly as possible to

1 inquellebrate an internal egg temperature of 45 degrees  
2 or less followed by storage and transportation and  
3 ambient air temperature of 45 degrees or less.

4 It is a well-accepted fact that the growth of  
5 salmonella is slow in cooler temperatures. Research  
6 documents that packaged eggs in the center of a pallet  
7 requires as long as six days to reach the ambient  
8 temperature in refrigerated storage. Rapidly reducing  
9 the internal egg temperature and maintaining it through  
10 distribution reduces the possibility for increases in  
11 salmonella population.

12 Praxair and North Carolina State University  
13 Scientists have jointly developed the technology to  
14 cool shell eggs with cryogenic carbon dioxide to  
15 inquellebrate an internal temperature of 40 to 45  
16 degrees and a processing time of approximately 80  
17 seconds. This process of rapidly cooling shell eggs  
18 before packaging is expected to cost less than seven  
19 cents per dozen. Rapid-cooling technology may be seen  
20 as an economic alternative to pasteurization processes  
21 and it may also be complimentary to pasteurization  
22 processes which may need to quickly reduce egg  
23 temperatures after high-temperature treatment.

24 The rapid-cooling process with carbon dioxide  
25 provides several benefits to the egg industry. These  
26 benefits include enhanced food safety, extension of the

1 shelf life of shell eggs, and enhanced quality of shell  
2 eggs. In the food safety area, research was completed  
3 in a laboratory environment evaluating the growth of  
4 salmonella in inoculated eggs after being rapidly  
5 cooled by carbon dioxide. Inoculated eggs cooled  
6 cryogenically, actually showed reduction in the number  
7 of salmonella organisms over a 14-week storage period  
8 thereby enhancing the safety egg. Eggs that had been  
9 rapidly cooled with carbon dioxide were found to have  
10 stronger vitellin membranes which protect the eggs and  
11 prevent migration of salmonella by separating the  
12 contents of the yolk and the albumen. Strengthening  
13 the vitellin membrane could relate to a longer shelf  
14 life over time. Preliminary testing shows that shelf  
15 life could be extended from current industry practice  
16 of 30 days to 60 days. Rapidly cooled eggs also have a  
17 statistically higher haulage value than the eggs that  
18 were not cooled with carbon dioxide.

19 Praxair is currently in the process of  
20 commercializing the technology to rapidly cool shell  
21 eggs with carbon dioxide. A prototype egg cooler is  
22 currently being tested in a production facility for  
23 shell eggs. It is expected that the units will be  
24 available to the egg industry in the second half of  
25 this year. Thank you for your time.

26 LOU CARSON: Thank you. Alice Walters from

1 Ohio Poultry Association.

2 ALICE WALTERS: Well, hello again. As you  
3 heard earlier, we've had a program in place in Ohio  
4 since 1996. Currently, 98 percent of our egg producers  
5 are part of the Plan. But it wasn't the Ohio Poultry  
6 association alone that developed that Plan. We had a  
7 great deal of help and hard work from partners in the  
8 plan, and that's our egg producers, the State  
9 Department of Agriculture, our State Department of  
10 Health, our Food and Drug Administration regional  
11 office, the Ohio Grocers Association, the Ohio  
12 Restaurant Association were also part of that.

13 And credit needs to go to Dave Glauer who  
14 sits on your panel because he has also been very  
15 proactive in a lot of the implementation of the areas  
16 that we have started here in Ohio. It's important  
17 during the process that we're undergoing today, that  
18 the federal agencies that are developing these  
19 standards and guidelines that are going to be  
20 implemented amongst the states and across the nation  
21 that we have a program in place that can pass to  
22 implement those and also takes into account what's  
23 happening in the state associations and with the state  
24 systems already in place. And, also, the producer  
25 could choose to be part of the state association or  
26 national program.

1           An effective guideline which we haven't  
2 talked about very much today is the National Poultry  
3 Improvement Plan Program which is in place and  
4 operating similar to this which could be used as a  
5 model for the National Egg Safety Program. In the  
6 interest of time, I brought with me and I gave to Linda  
7 out in the hall disks of the copy of our program so you  
8 could have those of the complete program here in Ohio.

9           Since the implementation of our shell-egg  
10 program, the Ohio Department of Health, which is one of  
11 the partners in our program, has reported that the  
12 cases of SE has dropped from 332 cases to 157 cases in  
13 Ohio, of course not all these cases are egg related.  
14 That's based upon the data that's available to us, but  
15 the 1998 FoodNet surveillance reported a 44 percent  
16 decrease in the United States from SE in eggs as you  
17 heard earlier.           During 1999, this is some data  
18 I know some of you were looking for, Ohio had 1,204  
19 manure-picked environmental samples from 223 flocks  
20 tested by the Animal Disease Diagnostic laboratory at  
21 the Ohio Department of Agriculture, they're the third-  
22 party tester in this program. The lab is an AAVLD  
23 accredited lab, one of only 36 in the nation. In 1999,  
24 2.9 percent of our environmental samples which were  
25 from 21 flocks in Ohio were positive. And this was an  
26 environmental program, but 98 percent of the producers,

1           once again, were part of it.

2                       We do require a mandatory training of those  
3 individuals charged with implementing the program at  
4 the farm levels. The training includes biosecurity,  
5 management records, insect and rodent control, and  
6 manure testing. The program also requires manure --  
7 and even egg -- testing if the manure sample is  
8 positive. The keeping of management records is  
9 required to be part of a program. And this year, we've  
10 started third-party auditing by the Ohio Department of  
11 Agriculture. They'll be going to all the farms and  
12 doing those record checks.

13                      We meet regularly, all of us involved as  
14 partners in this program to discuss what works and what  
15 does not work. I would encourage you to have  
16 flexibility of some sort built into the program because  
17 we have found we have to be flexible. As technologies  
18 change, and as other areas change within the industry,  
19 we have to sometimes also change and add new parts to  
20 the program or delete some parts that aren't working.  
21 So I encourage some type of flexibility.

22                      Once again, this whole set of comments will  
23 be put into the record. But for the interest of time,  
24 I'm skipping over a lot of it. You also heard this  
25 year that pullet testing will also be included in the  
26 program. Environmental samples will be taken in the

1 pits of the pullet houses at 8 to 12 weeks of age prior  
2 to placement in the layer house. Probably the greatest  
3 cost to producers could occur if a pullet house does  
4 turn up positive. We haven't had that yet occur in  
5 Ohio and it could be costly to the producer. There are  
6 a couple of mechanisms in place as I mentioned earlier  
7 such as an SE vaccine and then further egg testing.  
8 But, once again, it could be costly especially to  
9 contract growers.

10 You've heard about our egg-processing plant  
11 participation and the oversight of that program lies  
12 with the Food Safety Division in the Ohio Department of  
13 Agriculture. That is required by law. It is in the  
14 Egg Quality Program, but 45 degree ambient temperature  
15 and twice a year inspections by Food Safety are  
16 required in the egg-processing plants under Ohio law.  
17 Thank you very much for allowing to present testimony  
18 today.

19 LOU CARSON: Thank you. Dr. Jill Snowdon,  
20 the Egg Nutrition Center.

21 JILL SNOWDON: Thank you. I'm going to  
22 confine my comments to two topic areas. And to no  
23 great surprise they will reflect and repeat some of the  
24 things I've already said earlier in the day. The first  
25 subject is that of training, the need to make sure we  
26 are taking the information that we have and getting it

1 out where it needs to be so that when we think about  
2 training. I've got four categories. We think about  
3 industry training, technology transfer on control  
4 techniques.

5 This is an opportunity that we have to take  
6 the information that we know from the years of research  
7 and get it implemented. Some of that is needed to help  
8 and support individuals that may want more knowledge  
9 about things, rodent control, the effectiveness of  
10 vaccines, whatever the technologies or processing  
11 technologies that might help. Another category of  
12 training is certainly the consumer area, the concept  
13 of a consumer using a fresh, intact, cool egg that they  
14 cook completely. Training in terms of cooking for  
15 large groups.

16 What does it mean as a volunteer food service  
17 operator when you're working either for a large family  
18 gathering or with an organization that you're working  
19 for and then preparing food for large masses? We get  
20 outbreaks associated with that kind of thing on a  
21 regular basis.

22 The importance of cleaning or choices, in the  
23 dietary choices, what recipes might be a little more  
24 risky than others, what are the options and  
25 alternatives on that kind of thing? And food service,  
26 certainly training comes into play there time and time

1           again. The concept of pooling. And even if we start  
2           with pasteurized product for pool product, then you're  
3           taking another product and combining it with that which  
4           is perhaps contaminated. So starting with pasteurized  
5           product may not be adequate. But all of these details,  
6           the cross-contamination, the inadequate cooking --

7                        The fourth category under training is  
8           training of those who tend to serve the vulnerable  
9           population. We might want to be thinking of that as a  
10          completely separate category whether we're talking  
11          about the aged, the ill, or the young.

12                       And the second category on comments is what  
13          I'm calling low technology control options that in some  
14          instances I think that we can use simple solutions to  
15          complex problems or at least not overlook them. And  
16          I'll give a couple of examples of what I'm talking  
17          about on that, and this is to amplify and support all  
18          the other alternatives that we have, other options for  
19          control techniques including the technologies that are  
20          available or the new technologies that might be  
21          developed.

22                       But one example is the use of pasteurized  
23          liquid product. We already have pasteurized liquid  
24          product that's available and the food service industry  
25          is using it. And so there is an option that we have  
26          that doesn't take time or money to access, but maybe

1           it's a change in attitude, advertizing, marketing,  
2           education, or some such thing like that. If we knew  
3           maybe more about consumer preferences or if we knew  
4           what would stimulate the use of that type of thing --

5                     Again, it's a low cost, low technology option  
6           here that's going to amplify alternatives in this  
7           situation. Another low technology technique is the  
8           communications and technology transfer and the social  
9           science studies that I've been talking about earlier.  
10          They may be kind of obscure to us, and they may be  
11          sophisticated in terms of social science, but they're  
12          not extraordinarily expensive or hard to implement.  
13          The studies, getting the actual results out there,  
14          might be a little more difficult. Vector control is  
15          another example, but that again is a technique that is  
16          not terribly sophisticated but can be a gap that can  
17          continue to be addressed on this.

18                    Another example would be the small and  
19          backyard producer that the program, as it's currently  
20          designed, is only addressing the large commercial  
21          operations. And so if the role of the program is to  
22          eliminate disease associated with eggs, then there is a  
23          gap here and that is with the small and backyard  
24          producer. We're talking about millions of eggs.  
25          You've got thousands of backyard producers across the  
26          nation. A handful, again, more of those who may be

1 producing with small flocks for the localized areas,  
2 for niche markets, specialized markets, that may be on  
3 the increase in some instances.

4 This is going to represent millions of eggs.

5 Any one hen -- let's say if somebody has a flock of  
6 ten birds, you know, that's going to be thousands of  
7 eggs coming out in the course of the year just from  
8 that flock alone. So we're talking about thousands of  
9 illnesses here, but we're also talking about millions  
10 of eggs that aren't included in this kind of program.

11 And so from a public viewpoint, I have to  
12 wonder is it just the large commercial production we're  
13 concerned about or is this a gap that we want to  
14 address on that.

15 And then forced-air cooling is another  
16 example of a low technology technique that in some  
17 instances punching holes in the sides of boxes and  
18 putting fans and cooling units and things of that  
19 nature. California is the one that did the study on  
20 that. But that's an example of a low technological  
21 approach that would amplify the chilling of the  
22 product. It's based on the chilling that's done with  
23 fresh fruits and vegetables, that forced-air cooling  
24 type of thing.

25 So I'm simply encouraging us to think of the  
26 basics as well as the sophisticated as we move forward

1 on all of the plans that we have going on. Thank you  
2 very much.

3 LOU CARSON: Thank you. Ms. Ritchie Laymon,  
4 United Poultry Concerns.

5 RITCHIE LAYMON: Yes. I'd like to thank FSIS  
6 for making this a public forum. I think it's very  
7 important that everyone in the community get a chance  
8 to speak. I was very pleased to see that in the  
9 research portion that you do have forced molting on the  
10 list of things to be studied. Starving livestock to  
11 increase production is not only barbaric, but I think  
12 it's unsafe and I hope it will be outlawed at some  
13 point. And I have two fact sheets I'd like to enter  
14 into the record. Thank you.

15 LOU CARSON: Thank you. Tom Hertzfeld,  
16 Hertzfeld Poultry Farms Incorporated.

17 TOM HERTZFELD: Tom Hertzfeld, Jr., vice  
18 president of Hertzfeld Poultry Farms near Toledo, Ohio.

19 Our farm has over 1,400 acres and 900 layers. These  
20 have been operated by our family since the 1930s and  
21 employs 100 employees with 18 of those being family  
22 members. We market our eggs in Ohio, Michigan, and the  
23 East Coast from our USDA-graded egg-processing plant.

24 We have two contract growers and the rest of our  
25 layers are company-owned birds. There also is a  
26 separate grain mill. We have been a participant in the

1 Egg Quality Assurance Program since it started in 1996.

2 The Ohio Egg Quality Assurance Program has  
3 helped us to look at the management of our operation in  
4 such areas as egg quality and HACCP issues. Rodent  
5 control has much more emphasis than it did before being  
6 on the program and our participation has made us more  
7 knowledgeable in the area of food safety and  
8 biosecurity.

9 I want to commend the Egg Safety Action Plan  
10 for bringing this meeting to Ohio and my  
11 recommendations will be based upon what we as egg  
12 producers know already works because of Ohio's Egg  
13 Quality Plan. You have heard Alice Walters the  
14 Executive Director of the Ohio Poultry Association  
15 comment on Ohio's plan, and I would like to follow-up  
16 on some other areas that should be emphasized on the  
17 federal level.

18 All of the egg-processing plants in Ohio are  
19 part of the Ohio Egg Quality Assurance Program and  
20 Inspected by Ohio Food Safety laws. Our laws in Ohio  
21 also require that all eggs be refrigerated at 45  
22 degrees ambient temperature from farm-to-table this law  
23 has been in place since the early '70s and it is  
24 enforced by the Ohio Department of Agriculture Division  
25 of Food Safety. Most of our processors also have USDA  
26 egg-grading services. So effective HACCP programs are

1 required.

2           However, under food safety laws in Ohio, all  
3 Ohio egg-processing plants are inspected twice a year,  
4 and the critical control points and HACCP plans that  
5 have been established are monitored. There is also a  
6 policy letter issued by the ODA to all our egg  
7 processors that prohibit repackaging by retail food  
8 markets and excludes the retailer from returning eggs  
9 to the processor for repackaging. The only time that  
10 the eggs are allowed to be reprocessed and repackaged  
11 is if the USDA grader finds dirt in the lot at the egg-  
12 processing plant. Therefore, it is important that  
13 there is an indemnification plan built into the  
14 program.

15           Most of our egg-processing plants also have  
16 flat washers for plastic flats. Processors are  
17 encouraged to wash pallets and flats to return to the  
18 grower to reduce the possibility of contamination.

19           Since a level playing field is necessary to  
20 prevent unfair marketplace competition, the federal  
21 government should oversee the program in those cases  
22 where state departments of agriculture have the  
23 capability and willingness to participate. The day-to-  
24 day implementation of a program should be left to the  
25 state as is true with the National Poultry Improvement  
26 Plan Program.

1           Ohio's program is effective only because we  
2           have worked jointly with the Ohio Poultry Association  
3           and various state agencies like the Ohio Department of  
4           Agriculture, Health Department, and the FDA regional  
5           office, in its development.

6           As for additional labeling of egg cartons,  
7           unless it is a seal for this program similar to the egg  
8           pasteurization seal, it is impractical because wording,  
9           for one, will not fit on the cartons.

10          I would call upon the FDA to spearhead  
11          initiative to help egg producers on this program to be  
12          able to establish a price floor for their table eggs.  
13          This would allow them to cover the increased costs of  
14          being on an egg safety program. Otherwise, only larger  
15          egg producers can compete because of the greater  
16          flexibility to spread costs in a larger operation. Egg  
17          prices have not increased dramatically in the last 20  
18          years while inputs to egg producers involved in HACCP  
19          implementation have risen in cost.

20          In Ohio, all of the water used in our  
21          processing plant is required to be monitored by our  
22          local health department and EPA twice a year. The test  
23          results are submitted to USDA. The layer houses are  
24          also tested twice a year for iron, choliform, ect. Our  
25          state also encourages farmers and rural residents to  
26          have their water wells to have tests conducted. So I

1 do not believe additional federal oversight is needed  
2 in this area.

3 Additional research is needed as a cost-  
4 effective strategy for producers to produce SE. The  
5 mechanism whereby SE is transmitted also needs to be  
6 defined. Reliable rapid detection kits would also be  
7 extremely helpful. We know that a trace back of SE to  
8 a farm has severe economic consequences for that  
9 producer. In fact, oftentimes, it seems as if the  
10 producer stands alone burdened with all the risk even  
11 if the product was mishandled and contaminated by  
12 humans with SE at another level of preparation.  
13 Safeguards against food mishandling or contamination  
14 must be incorporated for the producer. When the  
15 producer already incurs the cost associated with an  
16 effective egg HACCP Program, it is unfair if  
17 mishandling it at another level causes blame not to  
18 mention all the negative media coverage to be laid on  
19 his or her farm doorstep.

20 I've mentioned that a C&D of a positive  
21 barn can be anywhere from \$4,000 to \$8,000. In  
22 surveying our producers in preparation for this public  
23 meeting, we have been able to determine costs  
24 associated with implementing an egg safety standard.  
25 Many of our farms in Ohio have personnel totally  
26 dedicated to implementing our egg quality assurance

1 program.

2 There are employees for rodent and pest  
3 control, quality control, biosecurity, paperwork and  
4 documentation. Our research indicates that the cost  
5 for an egg quality assurance program is \$60,000 per  
6 year per million birds annually, which does not include  
7 the economic losses for the possible devaluation for  
8 diverted eggs. USDA grading costs another \$100,000 per  
9 million birds annually. To upgrade refrigeration could  
10 be a one-time expenditure of \$100,000. This is why it  
11 is important that whenever a new program is developed,  
12 we check the cost consequences for small, medium, and  
13 large producers.

14 In fact, we have contract growers in Ohio  
15 concerned about the consequences for them if the  
16 pullets they are growing come up positive or if the  
17 contract layer house come up positive. To date,  
18 contract holders have been willing to help contract  
19 holders absorb C&D costs. But this may not be true in  
20 other states. That is all the more reason for the  
21 establishment of either a fund to indemnify or an egg  
22 price floor for participants. If you wish to protect  
23 the family farmer, then this area must be seriously  
24 considered.

25 Thank you for allowing me to present  
26 testimony today. I hope that the comments from those

1 of us who are already participating in a program in  
2 Ohio will be helpful in planning a federal program.

3 LOU CARSON: Thank you. Phil Debok, the  
4 Pennsylvania Department of Agriculture.

5 PHIL DEBOK: I'm making this statement on  
6 behalf of the Department of Agriculture and the  
7 Pennsylvania Egg Industry. Unfortunately, it was  
8 written based on the plan as we reviewed it, and we  
9 didn't have the benefit of some of the information  
10 that's been put out at the meeting today. Pennsylvania  
11 received this draft notice very early in the SE war.  
12 Our egg industry answered this call to arms willingly  
13 and at great expense.

14 Based on this considerable experience, we do  
15 feel that shell-egg safety could best be managed  
16 through voluntary cooperative federal, state, and  
17 industry programs as evidenced by the success of the  
18 National Poultry Improvement Program, our own Egg  
19 Quality Assurance Program, other states quality  
20 assurance programs, and corporate programs as described  
21 by the representatives from Michael Foods and Nest  
22 Eggs.

23 Voluntary programs have the disadvantage of  
24 perhaps taking a little bit longer, but that's probably  
25 offset by industry buy-in and ultimate savings to the  
26 taxpayer. That said, however, we will support the

1 National Egg Safety Plan and it's mandated approach to  
2 egg safety. We do this with full realization to the  
3 significant expense that will be borne by all parties,  
4 federal, state, industry, and the taxpaying consumer.

5 However, there are several portions of the  
6 Plan with which we have concerns. Number one,  
7 priorities for research. Objective 7 of the Action  
8 Plan focuses on adequate current information that is  
9 available to make decisions about SE preventive  
10 controls, surveillance and education based on sound  
11 science. With that purpose stated, the timeline for  
12 research then proceeds to have pasteurization listed as  
13 an action to be completed ahead of intervention  
14 strategies, on-farm testing, and even ecology and  
15 epidemiology of the SE organism. Now, that may be a  
16 misinterpretation on our part, but in our opinion, the  
17 research on ecology and epidemiology of SE in the  
18 chicken and on the farm, should be the top priority for  
19 the research guidelines.

20 Specifically, we need to determine why, even  
21 with applications of known best-management practices,  
22 are we unable to eliminate infection in some houses or  
23 complexes and what can be done to more effectively  
24 decontaminate a premises. We also need cheaper, more  
25 sensitive, and rapid tests with which to validate the  
26 effectiveness of our program.

1                   Warning labels, you maybe didn't want this  
2                   discussed at this venue, but this is something that the  
3                   industry in our state feels strongly about. In the  
4                   scope section of the Action Plan, it mentions a  
5                   proposed rule that would require a safe-handling  
6                   statement on the package. Objective 8 of the Action  
7                   Plan, Section 8.3.3 adds warning labels as a part of  
8                   the statements required on those packages. This is an  
9                   area of concern to us. We support safe-handling  
10                  instructions and refrigeration labeling for all eggs  
11                  produced and marketed in the United States. Our  
12                  concern is with the specific wording of the warning  
13                  label that is mentioned in 8.3.3, the July 1st, 1999  
14                  press statement from USDA which states the proposed  
15                  handling instructions will include the following  
16                  statement: Safe- handling instructions, eggs may  
17                  contain harmful bacteria known to cause serious  
18                  illness, especially in children, the elderly and  
19                  persons with weakened immune systems. For your  
20                  protection, keep eggs refrigerated, cook eggs until  
21                  yolks are firm and cook foods containing eggs  
22                  thoroughly.

23                   The first part of this label is not a safe-  
24                   handling statement. It is an overly aggressive warning  
25                   that alarms consumers who may very well interpret it as  
26                   these eggs may kill my child or grandparent and I

1 better not even open the carton or someone may get  
2 sick.

3 To require an industry to undergo intense  
4 monitoring, implement certain production management  
5 practices, and then at the same time tell their  
6 customers that the product may be unsafe seems counter  
7 productive to us. Our recommendation is to include a  
8 true safe handling instruction statement on all cartons  
9 of eggs that says, keep refrigerated at all times, cook  
10 eggs until yolks are firm, and cook foods containing  
11 eggs thoroughly. This is a simple statement that  
12 consumers will understand and that will accomplish our  
13 objectives. Funding for implementation at the  
14 state level. Testing, monitoring and education  
15 programs are very expensive and many states may be  
16 unable to adequately fund an effective program. Since  
17 this is being proposed as a nationally mandated food  
18 safety plan, we would encourage the federal government  
19 to provide funding proportional to the size of the egg  
20 industry in each state for states to implement the  
21 Action Plan.

22 Also, when developing standards, please  
23 remember that at least on the state level this program  
24 will be in competition with a number of other quality  
25 assurance programs such as a Units Disease Program,  
26 Dairy Quality Assurance Program and others that are all

1 rely very heavily on microbiological testing.

2 We need to tailor the Egg Safety testing  
3 program to get the maximum effect with the minimum  
4 testing. In other words, if we can address 80 or 90  
5 percent of the problem with "X" number of dollars,  
6 let's think long and hard before we commit to spending  
7 three or four "X" dollars to attack the other five or  
8 ten percent of the problem.

9 That concludes my comments. Thank you.

10 LOU CARSON: Thank you. Beverly Byrum,  
11 Animal Disease Diagnostic lab. Darren Mitchell, Center  
12 for the Science in the Public Interest.

13 DARREN MITCHELL: I thank you. I will keep  
14 my remarks pretty brief. I thank you for the  
15 opportunity to sit at the table and comment on other  
16 aspects of the Plan. CSPI believes that the Egg Safety  
17 Action Plan is a giant step forward compared to what we  
18 have today. And we commend and applaud those of you  
19 who have worked very hard on it. As we said before,  
20 it's a long time coming, but we are very pleased that  
21 the overall strategy, the two-pronged strategy we think  
22 will really improve egg safety.

23 However, our concern is that what looks good  
24 on paper may not bear fruit in practice based on the  
25 fact that the Plan doesn't, in our view, adequately  
26 address the highly fragmented federal program. And we

1 think that a single independent safety agency dedicated  
2 to egg safety is necessary and what we need really is  
3 consolidation, not more attempts at cooperation and  
4 coordination.

5 Just one more brief point. I wasn't going to  
6 mention labeling, but since the last speaker did, I'd  
7 like to say our position on the labeling issue is that  
8 the language -- we don't completely agree with the  
9 current language. We think it may be a little lengthy.

10 We believe strongly that there needs to be a tie-in on  
11 the instructions to handle eggs safely due to the  
12 hazard. I think FDA research has shown that that's  
13 necessary and that's something that we believe in very  
14 strongly.

15 We do, however, for those states and programs  
16 that are currently using quality assurance programs  
17 that have seemed to work, think there's room for sort  
18 of a two-tier system until there's a mandatory uniform  
19 national standard where perhaps people with PEQAP-type  
20 programs that have those kinds of standards could use a  
21 label that is less harsh. And ultimately, as the  
22 program is used on a national level, and data shows  
23 that it's being effective, we can revisit the labeling  
24 issue and see if different language makes sense.  
25 That's it. Thank you again.

26 LOU CARSON: Danny Hughes, Arkansas Livestock

1 and Poultry Commission.

2 DANNY HUGHES: I am employed with Arkansas  
3 Livestock and Poultry Commission, however, my  
4 statements this afternoon represent the National Egg  
5 Regulatory Officials. We're a group of member states  
6 which now consists of the majority of the states across  
7 the nation made up primarily of program managers and  
8 program directors. We got together back in '92 to try  
9 to get the states more uniform with their state egg-  
10 marketing laws. We have made some headway towards  
11 that. Our meeting and annual work that we do is  
12 getting better each year.

13 Due to the food safety issues, we've become  
14 more involved with the federal agencies, both the FDA,  
15 FSIS, AMS, and when all of our states working as hard  
16 as we have, many of us for 30 years involved in our egg  
17 state laws because of the absence of federal  
18 regulations, the states have developed their own  
19 programs for the egg safety based on the regional risk,  
20 industry practices, funding, and our legislative  
21 support. Because of this, this has created a lot of  
22 variations in our programs and in enforcement across  
23 the country.

24 A mandatory program with funding provided at  
25 the federal level will eliminate these variations.  
26 USDA and FDA have successfully used contracts and

1 cooperative agreements with states for many federal  
2 programs; example, the sea food and animal disease  
3 monitoring for APHIS, poultry and egg volunteer grading  
4 programs, and the surveillance for the Egg Products  
5 Inspection Act.

6 Many of our states have been involved in both  
7 the grading and Egg Products Inspection Act for 25-30  
8 years. The majority of the inspections under the  
9 surveillance program with AMS is conducted by state  
10 employees. These employees are licensed by USDA and  
11 follow inspection guidelines issued by USDA. This  
12 program has been very successful. The state employees  
13 are highly qualified and their use is very cost  
14 effective. The program has been uniformly enforced  
15 throughout the country.

16 For these reasons, we believe the use of  
17 contracts with states would be extremely effective.  
18 Because of the experience of the state people and the  
19 majority of them who are involved in both grading and  
20 surveillance, we have probably got more years of hands-  
21 on experience in shell-egg processing plants and the  
22 surveillance program than all the federal agencies put  
23 together. And for those reasons, our integrity has  
24 been proven and I think that would be backed up by the  
25 federal agencies which we've had partnerships with.  
26 There again, we would very much like for not only FDA

1 but FSIS to consider the state departments of  
2 agriculture when it comes to the enforcement of  
3 distribution at the retail level and in the plant. I  
4 appreciate you for your time.

5 LOU CARSON: Thank you very much. Meryl Sosa  
6 from FACT.

7 MERYL SOSA: Before I get into my final  
8 additional comments, I did want to ask one question to  
9 FSIS, FDA which is a bookkeeping requirement -- when  
10 are the written comments due?

11 LOU CARSON: The written comments are due by  
12 April 20th to either docket.

13 MERYL SOSA: Again, we'd like to thank the  
14 USDA and the FDA for asking us to participate in the  
15 meeting. It is our hope that the USDA and the FDA will  
16 use the Egg Safety Action Plan to develop a  
17 comprehensive, mandatory federal program with uniform  
18 standards designed to eliminate the threat of SE in  
19 shell eggs.

20 Earlier, we discussed the issue of the 120  
21 inspectors currently used to inspect a processing  
22 facility. We believe that in a single egg agency, the  
23 head of the agency would recognize that using 120  
24 inspectors to inspect the safest area of the shell-egg  
25 continuum is a tremendous waste of resources. It would  
26 redeploy such funds and employees to other areas of the

1 continuum such as on-farm where they would be better  
2 utilized. Under the current version of the Plan, FSIS  
3 will continue in it's role and the Plan does not  
4 provide for a position with responsibility for  
5 oversight of the entire continuum.

6 Thus, it may be assumed that this type  
7 of anomaly will continue. By continuing the division  
8 of responsibility between three departments of two  
9 agencies, many of the same deficiencies existing in the  
10 current system will continue. First, confusion on the  
11 part of producers and consumers will continue. For  
12 example, the Plan merely states that "FDA" will develop  
13 standards for egg producers that the states and the FDA  
14 will enforce.

15 However, the Plan does not disclose which  
16 department or departments within FDA will perform these  
17 functions. Second, nothing within the Plan addresses  
18 the issue of conflicting mandates within the same  
19 agency. For example, part of the USDA's purpose is to  
20 both promote egg sales and to regulate portions of the  
21 egg industry. When the USDA permits producers to affix  
22 the USDA Grade A stamp on egg cartons, which mandate is  
23 being fulfilled?

24 The consumers may believe that the stamp  
25 certifies that they are purchasing a safe product. In  
26 fact, the stamp is a promotional tool signifying that

1 the egg meets certain quality standards, not food  
2 safety criteria. The USDA regulation regarding stamp  
3 does not include any provision for the prevention of  
4 SE. In the final analysis, the juxtaposition of these  
5 two purposes within one agency conceivably places the  
6 interests of the food industry over and against the  
7 food safety needs of consumers. Nothing in the plan  
8 addresses this source of confusion to producers and  
9 consumers as well as the possible conflicting mandates.

10 Fourth, FACT disagrees with the use of AMS as  
11 the agency for enforcement of performance standards for  
12 packers and egg-products processors. AMS is an  
13 inappropriate choice. AMS's only role with regard to  
14 eggs to date has been to assist in the marketing of  
15 eggs by ensuring that eggs from those producers  
16 participating in the USDA grading program meet USDA's  
17 quality standards. Of course, it should be noted that  
18 only one-third of egg producers participate in the  
19 voluntary AMS egg-grading program. Thus, AMS does not  
20 have the expertise to support an egg-safety department.

21 Fifth, the Plan leaves enforcement of on-farm  
22 regulations to the FDA and the state. This is not a  
23 viable option as it allows for variation among the states  
24 since states have different priorities and fiscal  
25 abilities. For example, some states may not place a  
26 high priority on egg safety and, therefore, will not

1 allocate sufficient funds towards enforcement of egg-  
2 safety regulations. This may lead, as it has with hog-  
3 concentrated, animal-feeding, operations to egg  
4 producers making their citing decisions based on the  
5 strength of a state's egg-safety enforcement program.  
6 This should not be permitted.

7 In conclusion, FACT believes there should be  
8 a single egg-safety agency with responsibility for the  
9 entire farm-to-table continuum. Absent a single agency  
10 at a minimum, there must be put in place a method for  
11 effective coordination among the agencies in order to  
12 avoid duplication of efforts, allow for clear roles and  
13 responsibilities, and to ensure the efficient and  
14 effective enforcement of regulations regarding egg  
15 safety. Thank you.

16 LOU CARSON: Thank you. David Stein, Indiana  
17 State Egg Board.

18 DAVID STEIN: Thank you. I have no  
19 statement.

20 LOU CARSON: Richard Dutton, Michael Foods.

21 RICHARD DUTTON: I'd just like to reaffirm  
22 some of the comments that have been made. Actually, we  
23 would reaffirm that the pullet-testing program as  
24 stated is essential. Reaffirm also that NPI Programs  
25 have been effective and support their continued use.  
26 Also that vaccination is an essential part of a

1 program, that without it there will not be success.  
2 Also that sanitation is short term in effectiveness  
3 although temporarily effective. Multiple testing of  
4 houses is essential. One test will not be effective in  
5 reducing the problem. We would encourage the use of  
6 certified laboratories and for testing of samples.  
7 Also, support the third-party verification programs  
8 preferably with one coordinator at least. Also that  
9 uniform requirements across all producers and all  
10 states are essential, and then bring up a couple of  
11 questions. One is in my travels and in talking with  
12 producers and so forth. There is still very much a  
13 concern about privacy of test results and safety of the  
14 individual producers. And if something in the program  
15 could be developed to ensure their safety, their  
16 privacy at least. Also, that purchased eggs -- have  
17 run across this a couple of times -- in either that ECI  
18 or purchased eggs are not required to have label or to  
19 be under program that I am aware of anyway. And also,  
20 a clarification as to who is required to be with the  
21 program and what size farm? That needs to be  
22 clarified. Thank you.

23 LOU CARSON: Thank you. Kenneth Anderson.

24 KENNETH ANDERSON: I'm Kenneth Anderson,  
25 North Carolina State University. There was a topic  
26 brought up at the beginning of this session indicating

1 that we need to evaluate husbandry practices -- I think  
2 Mike Opitz brought that up -- to reduce and get the  
3 best management practices in play that would eliminate  
4 or reduce the salmonella incidence in layer flocks.

5 I think this is a poor forum for people to  
6 push the agenda of animal rights, and molting of layers  
7 is an animal rights issue. As an individual with many  
8 of years of experience in animal behavior as well as  
9 physiology knows, it is not an inhumane practice if it  
10 is done correctly. That does not mean that it is not  
11 stressful. That's the whole idea of it. But it does  
12 extend the productive life of the flock and as the  
13 other research from Bob Eckroade and others have shown,  
14 there is no real relationship between that practice and  
15 increased incidence of salmonella-positive  
16 environments.

17 So I think this is a poor venue for that and  
18 I think we need to look at it as a husbandry practice,  
19 evaluate it, just like we need to do all husbandry  
20 practices and get the best management practices in to  
21 reduce the problem as we see it as a problem in the  
22 reduction of salmonella in eggs. Thank you.

23 LOU CARSON: Tim Davis, Fort Dodge Animal  
24 Health.

25 TIM DAVIS: Hi, I'm Tim Davis with Fort Dodge  
26 Animal Health. We are a manufacturer of salmonella

1 vaccine. I'd like to thank you for the opportunity to  
2 speak. We've heard vaccination mentioned several times  
3 today. I'd just like to make a few comments concerning  
4 vaccination.

5 My comments aren't necessarily to push for  
6 additional steps in the President's Plan, but instead  
7 to be considered as alternatives to the President's.  
8 I'd just like to say what vaccination does.  
9 Vaccination reduces the colonization of SE in the gut  
10 and in the reproductive tract of a bird. Vaccination  
11 offers the bird a line of defense the day of exposure  
12 which could potentially occur the day after testing.

13 The second thing that vaccination offers that  
14 has been talked about quite a bit less is the line of  
15 defense that it offers in the egg. Dr. Peter Holt at  
16 the University of Georgia has done quite a bit of work  
17 that demonstrates that antibodies in the egg from  
18 salmonella vaccinated chickens actually offer a line of  
19 defense to salmonella. It actually inhibits the growth  
20 greatly of salmonella enteritidis in eggs.

21 I don't have the numbers, but I think it's  
22 something like when he did a side-to-side experiment of  
23 vaccinated eggs and non-vaccinated eggs, I should say,  
24 eggs from vaccinated hens and non-vaccinated hens, that  
25 there was a difference of a 10 to the 2 and 10 to the 8  
26 salmonella populations in the eggs. So it's very

1 significant.

2 An egg antibody could be a line of defense in  
3 eggs that are mishandled in the marketplace.  
4 Antibodies in the egg could be beneficial in situations  
5 such as pooling of eggs and nursing homes and other at-  
6 risk consumer groups. Dr. Holt has done some small  
7 studies that need to be looked at further where he's  
8 actually taken an egg with antibodies from a hen and  
9 pooled it with eggs from hens that were not vaccinated  
10 and he actually saw some reduction in salmonella growth  
11 when comparing it to eggs that were completely without  
12 antibodies. So I just wanted to bring those points up  
13 and thank you for your time.

14 LOU CARSON: Thank you. That is the last  
15 person who is registered to speak. Does anyone else  
16 wish to make a statement at this time? Thank you. We  
17 are going to then move to closing remarks. Judy.

18 JUDY RIGGINS: I'm just going to speak from  
19 where I'm sitting. First of all, we really thank you  
20 for your active participation this afternoon. One of  
21 the important things for us as regulatory agencies is  
22 to gather an accurate record upon which to make our  
23 decisions in doing our proposals and going forward.

24 And so this has really been a very productive meeting.

25 And we hope that we have shared as much of our  
26 thinking with you as we could at this point having not

1 thought through all of the complexities of the issues,  
2 but we thank you for your thoughts, your ideas because  
3 it will form the basis for our being able to make some  
4 informed decisions going forward.

5 Some of the things we've heard you say this  
6 afternoon that we are going to take serious  
7 consideration of, and have a very thoughtful approach  
8 to, in our proposal based on the information you've  
9 given us are, first of all, benchmarks. We heard  
10 loudly and clearly that we need to have a very clearly  
11 defined benchmark and to have adequate information upon  
12 which to base those benchmarks, so we know where we're  
13 starting and we know what our goals are.

14 Secondly, indemnification. That's clearly an  
15 issue that's important to the industry. We know that  
16 currently the only agency within the sister agencies  
17 that are working on this is APHIS. APHIS currently has  
18 indemnification, however, we will have to explore what  
19 the opportunities might be for legislative change in  
20 the event that we can build an adequate record of costs  
21 that would be incurred.

22 But, I just wanted to mention that none of  
23 the agencies, FDA, FSIS -- I don't think AMS currently  
24 has indemnification -- so APHIS at this point -- and  
25 that's for animal health disease issues -- And so, we  
26 will explore that. We know that we would have to have

1 legislative change.

2 Then we heard clearly your concerns about  
3 testing and diversion measures. And we're going to  
4 have to seriously think how we will approach that issue  
5 in our rulemaking. Animal management practices,  
6 especially molting, is important and we will take into  
7 account all that you said, and I know that there has  
8 been numerous concerns expressed about molting and the  
9 stress factor and how that contributes to SE illnesses.

10  
11 Environmental testing, how to approach  
12 environmental testing and the importance of  
13 understanding what the public health benefit is that  
14 can be gained by environmental testing and comparing  
15 that to the costs that would be incurred by the  
16 industry. We hear that very clearly in your comments.

17  
18 The other issue of verification versus  
19 testing and diversion and making sure we, in our  
20 rulemaking, clearly define those and make a distinction  
21 between verification activities and testing and  
22 diversion actions that we might propose.

23 Vaccination is, of course, another area that  
24 we've heard many, many comments about today. And we  
25 will take that into consideration where new  
26 technologies such as vaccination and rapid cooling --

1 where they can be used on an ongoing basis and to make  
2 sure that we provide flexibility so that any new  
3 technology that emerges can rapidly be incorporated  
4 into practices by company.

5 And then we heard the concern about focusing  
6 our efforts on those areas that we know that we may  
7 gain the best bang for the buck, I guess is a way to  
8 say that. There was a discussion about the fact that  
9 there's data that shows 15 percent of the houses that  
10 are currently positive, that we might consider  
11 allocating our resources on that problem area in order  
12 to achieve the best bang for the buck and the best  
13 public health buck that is.

14 Then we heard about resource allocation and  
15 the disparity that currently exists in the allocation  
16 of federal resources with respect to inspection. But  
17 there is a heavy allocation of resources in the  
18 processing plants and not enough allocation of  
19 resources at high-risk facilities such as packing and  
20 on-farm. So we understand your concerns regarding  
21 allocation. We will work with the food safety  
22 initiative to redefine those priorities and to  
23 hopefully gain more resources where they are needed.

24 And then the last area was food service  
25 training. We heard very clearly that we need to  
26 emphasize and we need to increase the training that we

1 are getting from food service handlers. They are a  
2 very critical point in the continuum from farm-to-table  
3 whereby contamination may occur. And we know that we  
4 need to emphasize and to build upon what we started,  
5 but to strengthen our training programs for food  
6 service handlers. Lou.

7 LOU CARSON: Thank you Judy. Just a few more  
8 comments. I want to echo what Judy has said. I think  
9 this has been an excellent exchange of ideas and all of  
10 the comments have been very constructive today. I want  
11 to thank you very much. Not to dwell on the same  
12 points that Judy did, but to pick up on a few others  
13 that I thought I heard.

14 I heard clearly that we need to clearly  
15 define roles and responsibilities especially in the  
16 area of enforcement. We need to also take into account  
17 something that's not in the Plan and that's regrading  
18 of eggs and its impact on SE illnesses. We also need  
19 to take a focus with the Plan that really does identify  
20 the positive flocks and deal with those appropriately  
21 and where there are no positive flocks, then to take  
22 appropriate actions there as well.

23 We need to look for long-term solutions and  
24 not simply try to solve the problem at hand, but to see  
25 how we can best assimilate those into the best  
26 practices. It's been pretty clear, I think across the

1 board that with clear responsibilities -- what people  
2 have been asking about is strong leadership and making  
3 sure that what we craft here in our proposed rules --  
4 taking into account the advances that the state  
5 programs along with the industry have made to date and  
6 to provide a strong leadership to make sure that moves  
7 forward.

8 And lastly, I think, it's been pretty clear  
9 that we do want to have nationwide consistent standards  
10 that everyone has the same benchmark, as Judy  
11 mentioned, we have the same benchmark and the same  
12 goals that we're all trying to achieve. It's been  
13 pretty clear that everyone in the room, while you may  
14 be in the poultry or egg business has public health  
15 right behind whatever your primary duty is. And that  
16 was very reassuring and refreshing to hear. So from  
17 FDA's standpoint, I really want to thank you for your  
18 time today.

19 Okay. Are there any other comments? Then we  
20 thank you very much. (Meeting ends 4:15 P.M.)

21  
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