UNITED STATES DEPARTMENT OF AGRICULTURE

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PUBLIC MEETING

ON

IMPLEMENTING THE EGG SAFETY ACTION PLAN

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THE UNITED STATES DEPARTMENT OF AGRICULTURE

PUBLIC MEETING

ON

IMPLEMENTING THE EGG SAFETY ACTION PLAN

CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE

AUDITORIUM

1220 N STREET

SACRAMENTO, CALIFORNIA

THURSDAY, APRIL 6, 2000

8:35 A.M.

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Howard Seltzer, Food and Drug Administration

Emilio Esteban, Centers for Disease Control

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Paul Raynes, Food and Drug Administration

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Robert Brackett, Food and Drug Administration

Robert Scharff, Food and Drug Administration

Victoria Levine, Department of Agriculture

Nancy Bufano, Food and Drug Administration

Roger Glasshoff, Food Safety and Inspection Service

Rebecca Buckner, Food and Drug Administration

Moderators

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Dan McChesney

Panelists

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Carl Lofgren, McAnally Enterprises

Laurie Girand, Safe Tables Our Priority

Other Participants

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Mark Campbell, Norco Ranch

Laurie Siperstein-Cook, Association of Veterinarians for Animal Rights

Patricia Curtis, North Carolina State University

Gregg J. Cutler, DVM

John Davidson, Davidson's Pasteurized Shell-Eggs

Charles Elste, NuCal Foods, Inc.

Ralph Ernst, University of California, Davis

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David Goldenberg, West Coast United Egg Producers

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Ken Klippen, United Egg Producers

Douglas Kuney, University of California

Michael Martin, University of California, Davis

Rich Mattheis, Pacific Egg and Poultry Association

Diane Miller, Farm Sanctuary, Inc.

Armando Mirande, Biomune Company

Arnold Riebli, Sunrise Farms, Inc.

Other Participants (continued):

Hans Riemann, University of California, Davis

Jill Snowden, Egg Nutrition Center

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P R O C E E D I N G S

MODERATOR LOU CARSON: Okay. Can we please start taking our seats.

Okay. Good morning. My name is Lou Carson, I'm with the Food and Drug Administration, and I'd like to welcome you to the Egg Safety Public Meeting. We want to thank the California Department of Food and Agriculture for posting this meeting for us.

I'd like to go through a few administrative details for this meeting, just to tell you how it will progress, and also to give you a few administrative details. Perhaps the most important, the bathrooms. The bathrooms are through this door to the left, and in that corridor are the men's rooms. You go down to the first corridor to your right, you make a right, and then the ladies' rooms are there. Each door has a code. The code is 523. So take someone along who has a better memory, if you don't remember that.

The proceedings will be transcribed by our transcription service over here, Valorie Phillips. During the day, she is taping the proceedings, and so at certain times during the day as she has to exchange tapes we will have to break just for a brief time to allow her to exchange those tapes. So please bear with us when that occurs. We will -- we may have to stop you in mid-sentence, and then

we'll ask you to resume your comment, or your statement.

Each one of you should have picked up a folder at the registration desk. And in that folder is the agenda for today's meeting, and I would just like to briefly go over that.

The meeting is basically set up this way. We have an opening presentation to give you the background for the President's Egg Safety Action Plan, and what it is we're trying to accomplish here at this public meeting.

We would like to set the stage for the CDC presentation on illnesses related to eggs and SE. And following that 8:45 presentation, while it's not on your agenda, we will have a question period, a brief question and answer period, if you have any questions about the opening remarks or about the CDC presentation.

We will then proceed to the On-Farm Production section. There will be a brief presentation. Following that, there will be a series of questions that will be projected up here on the screen, which the Moderator will pose each one of the questions and then ask the Panelists to respond to those questions, one at a time.

Following the Panelists' comment on those questions, it will then be opened up to the audience for further commentary. Again, you can comment as often as you wish. We were trying to keep each section to about an hour.

So if you've made a comment at the beginning, do not feel that you can't raise your hand or approach a microphone to make a follow-on comment based on perhaps what someone else has said.

So we will have a one-hour session there, and then we will break. And as you can see, the break area is in the back of the room with coffee and pastries. And then we will proceed to the 10:25, and that will be handled in a similar manner. A short presentation, and then the balance of time for questions or comments that you may have.

We will then break for lunch, and then the afternoon session is arranged similarly.

We ask, if you want to make a formal statement, that you register at the desk out front, only so that we can organize the end of the day and identifying people to come to the microphone and make a statement, and that we approximately know how many people there are so that we can allot roughly the same amount of time to everyone so that everyone can make their statement within the allotted time.

And then at the end of the day, we will make a few closing remarks, mostly about what we've heard at the public meeting. Again, not making commentary, but simply those important things that we have heard during the day.

Again, this meeting is an opportunity for us to listen and to hear what we -- what you have as comments

based on the questions posted in the Federal Register notice.

So, are there any questions about the administrative details of how the meeting would progress?

MS. GIRAND: May I ask how are you taking this back to Washington, D.C.?

MR. CARSON: The -- the meeting is being transcribed.

MS. GIRAND: And then --

MR. CARSON: That transcription will be available within approximately two to three weeks. We will take that transcription and post it on our Web site, or it will be available for faxing or mailing out to people if they wish, by calling the contacts in the Federal Register notice.

MS. GIRAND: And are the people writing the plan or revising the plan here today, or are they in Washington, D.C.?

MR. CARSON: They are here today.

The most important thing I forgot to mention, which I was just prompted -- when you rise to speak, would you please speak your name and your affiliation clearly, so that that is properly noted in the transcript. So each time you get up to speak, do not assume people have remembered your name and affiliation; please repeat that.

Okay. Let me turn it over to Judy.

MS. RIGGINS: Good morning. I'm Judy Riggins, and I'm from the Food Safety and Inspection Service at USDA. And Lou Carson and I want to welcome you this morning on behalf of the Food Safety task force to our second of two meetings on the Egg Safety Action Plan, and the rulemakings that we're doing as an extension of that plan.

HSS and USDA are developing a farm-to-table approach to reduce the illnesses from Salmonella enteritidis from shell-egg and egg products. We appreciate the opportunity today to hear your concerns, your thoughts, your ideas on our current thinking for proposed rules on on-farm practices, shell-egg packing and breaking, and pasteurization facilities.

Last year the President's Food Safety Council initiated a process to develop a National Strategic Plan for Food Safety. As a first step, the Council identified egg safety as a public health issue that warranted immediate federal interagency action. The Council established a task force, co-chaired by Dr. Jane Henney, the Commissioner of FDA, and Dr. Catherine Woteki, the Under Secretary for Food Safety at USDA.

Lou and I served as co-chairpersons for the Egg Working Group convened by the task force to draft the Egg Safety Action Plan that was published on December 10th, 1999. The overarching goal of the Action Plan is to

eliminate SE illnesses associated with egg consumption by 2010. The interim goal is a 50 percent reduction of egg associated SE illnesses by the year 2005.

The Action Plan is based on the SE risk-assessment that indicated that multiple interventions could achieve a more substantial reduction in SE illnesses than using any one intervention alone. The Egg Safety Action Plan offers two equivalent SE reduction strategies to the industry, each delivering eggs into distribution and to the consumer at an equivalent level of safety.

Egg producers or packer/processors will determine the point at which pathogen reduction steps will be taken. Pathogen reduction steps may be taken on the farm using SE testing and egg diversion, or at the packer and/or processor with a kill-step to eliminate SE.

FDA and FSIS, in cooperation with CDC, AMS, APHIS, and representatives of the states, are drafting proposed regulations to address SE hazards on the farm, at egg packing facilities, and in egg pasteurization facilities. We published a March 21st, 19 -- no, I'm sorry, 2000, Federal Register notice, which announced this meeting, and we requested comments on numerous questions related to our interagency coordinated rulemaking. We welcome your comments, and we request that you submit them to us by April 20th of this year.

Lou will now talk to you in more detail about the two strategies in the plan.

MR. CARSON: Again, let's focus on what the goals of the Egg Safety Action Plan are.

One, the overarching goal is to eliminate SE illnesses associated with eggs by 2010, and the interim goal is to reduce egg associated illnesses by 50 percent by year 2005.

The President's Food Safety Council and the Food Safety Initiative have two goals. One is to improve the federal food safety system, but two is to reduce food-borne illness associated with microbial contamination. And that's why the Egg Safety Action Plan came under the President's Food Safety Council as one of its linchpins in reducing food borne illness. So what we're trying to do, from a farm-to-table approach, is to achieve that goal.

As Judy just mentioned, those two goals are trying to be achieved through a combination of steps. While today we're focusing at the production, packing and retail level, we have in the back of the room the Fight Back Campaign, the educational component that we are undertaking again as a collaborative effort, not only within the federal government, but with industry and consumers. That Fight Back Campaign has been extremely effective in making people aware of how to treat food and make it safe in their homes,

as well as taking on the food-handling practices at the retail area.

I think one of the things that gets lost when people read the President's plan is that the strategies one and two are really a combination of all of these areas, production, packing/processing, plus distribution, retail, surveillance, research, and education. We are not focusing solely at one level. We are looking at a combination of all of those to contribute to the 50 percent goal by 2005, or the ultimate elimination by 2010. We are not looking to each of those to make a equal contribution. We are looking to those to make a sum of that contribution.

What are the timelines for the plan? We hope to draft proposed rules this year, for comment in 2001, and to finalize the rules in 2001 based on those comments. So our proposed rule hopefully will come out by the fall. There will be a normal comment period of approximately 90 days, or whatever, for formal comment to those rules, and then taking into account those comments we will try and finalize the rules in 2001.

Based on those final rules or standards, again we're trying to develop nationwide consistent standards so that all eggs in the marketplace meet the same standards. We will try and implement those rules through funded contracts through state or other organizations that are

dealing with the farm, retail, or packer/processor community.

And then we need to measure our success with those standards by 2005, to see how well we've achieved or not achieved the goal of 50 percent reduction.

Lastly, we will take additional steps based on what our success rate is in 2005, whether we found that the standards that we've applied are working, or there are improvements that we can see that we can -- can be made to try and achieve the overarching goal of elimination of SE as a source of -- eggs as a source of SE illnesses.

So we have a lot of work to do, and we have, I think, the people here in the room that can make this a success. This public meeting, again, is an effort to get your input into how best this can be achieved.

With that, I'd like to introduce Dr. Emilio Esteban, from the Centers for Disease Control, who will talk to you a little bit about the food-borne illness data reporting and the illnesses associated with eggs.

DR. ESTEBAN: Good morning. I hope everybody can hear me clearly. As the first speaker, I -- I'm very proud to be the one to pose the first challenge.

I need these lights, not the projector, please.

Great. Thank you.

Well, as Lou said, I'm with the Centers for

Disease Control and Prevention. I would like to emphasize the word "prevention", which usually goes silent. I want to thank you all for being here, for giving me the opportunity to present to you some of the data the CDC has collected over the last, oh, decade or so.

I will be giving my talk in three sections. The first one is to present a brief overview. Then I will present some of the numbers that we've obtained through our both passive and active surveillance methods. Then I will talk a little bit about our outbreak data. And finally, I will offer some conclusions.

Okay. A little bit of the history of Salmonella in this country. Back in the 1980's, we started isolating Salmonella enteritidis, and it slowly spread towards the West Coast, to where in the 1990's it is much more common to find it here than to find it on the east coast. Since 1993, Salmonella enteritidis has been either the first or the second most common serotype isolated, only second to Salmonella Typhimurium. And through case control studies or other investigations, one of the consistent findings is raw or undercooked eggs are the most common vehicle.

Okay. Culture confirmed cases are usually reported to CDC through different state health departments or public health labs, into a system which we call P-H-L-I-S, or PHLIS, which is Public Health Laboratory Information

System. This slide shows the percentage of Salmonella enteritidis isolations that correspond to Salmonella enteritidis. As you can see -- as you can see here on the bottom, we have data from 1976 through 1998 on the -- actually, we have the percentage that corresponds to the Salmonella enteritidis. As you can see, there was a consistent increase through the years until about 1994, reaching a 26 percent of the total -- percentage of the total number of Salmonella isolated in the public health labs.

Since then it's been declining consistently, to where in 1998 we had only about 18 percent of the cases corresponding to Enteritidis.

If you look at the data reported by region, you can see the New England region, which is shown here in the yellow, increased from the 1970's all the way up here to about, again, 1994, when it started dropping quite precipitously.

Very similar, with the blue line, you can see the mid-Atlantic states corresponding or behaving in a similar fashion. And you can see then also that in around 1990, in the West Coast, in the Pacific region, that's when the increase started happening.

I would like to say also that for all regions, since '94 the incidents or numbers of cases of Salmonella

enteritidis has declined.

Okay. So how do we get all this data, which is probably more of a -- of an issue here. What I have just presented before is what we call passive surveillance. It comes -- it comes to us through the different public health labs. But we also have at CDC, in collaboration with FDA and USDA is what we call FoodNets, which is a series of sites, in this case we have -- that I will present today, is about eight sites distributed throughout the United States, that correspond to about 25 million people in the U.S., or ten percent of the population.

The labs in the FoodNet catchment areas report all cases of Salmonella as well as all the bacterial pathogens. In 1999, there were eight sites. We have added another site this year, and one other site next -- next year.

In this FoodNet, or active surveillance system, in 1996 and 1997, the rate was approximately 2.5 per hundred thousand population. In 1998, that rate dropped to 1.4 per hundred thousand, representing the decline of 44 percent.

Now, we know that for every culture confirmed case we have Salmonella, there's a lot that goes underreported. If you look at this world food-borne illness pyramid, you have the general population at this level. In order for that person to actually become part of the system the person has to become ill, then they have to seek care, they have to

get a specimen obtained, the lab has to report the organism, confirm the case, and then report it to CDC. As you can see, we're only going to get at CDC a portion of what happens out in the real -- the real world.

So, for example, in the case of Salmonella, and this is in 1998, we had about 6,000 cases that were based on PHLIS -- on that surveillance system that I talked about before -- for 1998 we had about 6,000 cases. If you applied all those multipliers that we obtained through different surveys, population surveys, doctor's surveys, lab surveys, the multiplier ends up being about 38. Not about, it is 38. Which would correspond to about to 230,000 cases of Salmonella for that year.

Since 1985, CDC has received reports of Salmonella enteritidis outbreaks -- and this is the third part of my talk, now we're looking into outbreaks -- as part of the outbreak surveillance system. As you can see, since -- from '85 to '99, which is the data that I'm presenting here updated through March of this year, the number of outbreaks total 842. They peaked in around 1990, and then have been consistently decreasing again until 1999, where we ended up with about 44 outbreaks.

This table presents the same data in tabular form, and you can -- what you can see here is that for those 15 years, '85 through '99, there have been a total of 842

outbreaks again, that correspond to about 29, almost 30-some thousand cases, 3,000 or so hospitalizations, and 79 deaths. Most of those deaths correspond to people that are hospitalized or in other type of institutions.

Again, this -- this slide then breaks that data to look at it by region. As you can see, the majority of the outbreaks have occurred in the Northeast region, which includes the New England and mid-Atlantic states. However, in recent years the number of outbreaks in this region has decreased dramatically. The number of outbreaks seen in the western states began to rise early in the 1990's, and although it has decreased slightly in 1999, the western region today represents about half of the outbreaks we have in the United States.

This slide shows the SE outbreaks by location of food preparation. Historically, over 60 percent of the SE outbreaks have involved food that had been prepared by a commercial food establishment. As you can see in that slide, about 11 percent of those are health institutions, 13 percent are at the home, and 15 percent are other sites such as schools or churches.

This slide shows outbreaks of SE infection by food vehicle. Historically, the vehicle has determined in only 45 percent of the outbreaks, so it's about 379 of the 800 outbreaks we have 45 percent that we have actually

determined the vehicle. And of those -- of those 45 percent, about 81 percent are egg associated, which corresponds to about 15, 16,000 cases.

Okay. So what about the -- where does the egg come from, you know. So we have confirmed -- this slide shows the confirmed vehicles that are egg-associated. It's -- the total samples last year is 295. As you can see, the -- about one-third of the total number of outbreaks associated with eggs or eggs products, it's about 30 percent, followed by a code for desserts, which about one-fourth, 23 percent, and then sauces and dressings.

So, in conclusion, I'd like to say that about 230,000 cases of Salmonella enteritidis cases happen every year. Both the PHLIS and the FoodNet data, as well as the outbreaks, show some nationwide decline in the cases of SE. These drastic declines in certain regions, and the numbers of -- this shows dramatic declines in SE in certain regions, but the number of outbreaks has remained pretty much constant. Of outbreaks with known source, the predominant vehicle remains raw or undercooked eggs.

I'll stop there, and, Lou, I can take questions now, or -- is there a Moderator, or should I just call on the people?

MS. BALMER: Ken?

MR. KLIPPEN: My name is Ken Klippen. I'm with

United Egg Producers and United Egg Association.

Dr. Esteban, I was glad to see how you introduced this by explaining that the Center for Disease Control is also referred to as CDC and Prevention.

Now, in the weekly Morbidity Mortality Report dated March 17th, Salmonella enteritidis declined, has been shown to decline over the last four years 48 percent, and over the last year alone, seven percent. Can you give us an explanation as to why we've seen a decline in SE, and what strategies are being looked at by the CDC as it relates to the large number of outbreaks in health facilities and schools, and the commercial venues?

DR. ESTEBAN: The way we have structured our surveillance mechanisms today cannot truly identify a single intervention that has caused the decline. But, as you are aware, there have been several things that have gone into play here. There's a lot more effort to educate the consumers, there's a lot more effort to educate the retail establishment, there's a lot more effort that has gone into working with industry to -- to make sure that we all are working in the same direction.

I think the result of that is what you see there. It's difficult, without a case control study with prospective analyses to point to any specific thing that has changed the way things are going. But I think it's the --

the team effort every area has put in that has caused that decline.

As far as strategies, or particular strategies that have done or conducted this -- or conveyed this decline, I think that a very good example we have here is this Fight Back Campaign. Things are a lot more cautious out there, and the consumers have -- hollering why they should eat eggs. I think that has helped a lot. I think that efforts that the FDA and other agencies have done at the retail level to look at food preparers, to train them, to educate them, has helped a lot.

So it's hard to pinpoint one -- one single thing.

MS. BALMER: For the record, that was Emilio Esteban.

DR. ESTEBAN: Sorry.

MS. SNOWDEN: Good morning. I'm Jill Snowden, from the Egg Nutrition Center.

I've got a question, a caveat, and a comment, and I'll try to make them short, and then we'll come back to them as the day progresses. But this'll help set the stage if we bring them up now.

The question is do we have any -- does CDC, or anybody else, have an epidemiological information on pasteurized products? Because that's a comment that's thrown around periodically, and I'm not seeing it in the

formal presentations.

And I guess a Part B on that would be, is -- if we don't have it, maybe we could work collaboratively to identify where the comments on that subject are coming from so they're substantiated and not -- not just comments, but do you know of anything on pasteurized products?

DR. ESTEBAN: No.

MS. SNOWDEN: Okay. I'll touch base with you or others on that later.

My caveat is that as these types of data are presented, is that we have to bear in mind that these are all Salmonellosis cases associated with SE that's being presented, and that five percent are not even food-borne. And at least 20 percent are not egg-related. And so if I want to be, you know, if we want to be funny about it we'll say oh, take the five percent out that's not food-borne, take the 20 percent out that's not egg-borne, and we're already halfway to the first goal.

Now, you know, I'm saying that to be funny, because, of course, you wouldn't put in the five percent that were not food-borne and the -- the 20 percent not egg-borne to begin with on your -- your benchmarks, which I'll come back to at the -- at the end of the day.

But my point is, is that when the data are presented that I think that that needs to be brought out,

that -- that that type of -- our current wonderful surveillance systems are measuring all cases in the human population, and they're not all food and they're not all -- all eggs on that.

And my comments are to put a little more detail on the epidemiological information with regards to the question of who the vulnerable population is. And the reason I'll bring that forward now is because then we'll come back to it in terms of education and -- and research as we take a look at these kinds of things.

So it's -- it's based on the previous meetings that we've had on -- on these subjects to help us start focusing more sharply, so that we can use our resources efficiently and make these target -- target goals.

If we go back and look at the outbreak information and pull out just the part that's in the healthcare facilities, that moves to the gains in that outbreak reduction. The graph is different. It's going to drop substantially. I'll put these in written comments and draw a graph for you and send it in. But if you just look at the outbreaks in healthcare facilities, that's where our drops have been on the outbreaks.

And so we're down to one to three per year, which is about four percent of all outbreaks are coming out of the healthcare facility. And certainly we want to go down --

want that to go down to -- to zero.

MS. BALMER: Jill, can we put these comments in the later session?

MS. SNOWDEN: I think it's important to do them now, Marilyn. I'll try and speed up, though.

So in addition to reinforcing the classic messages that we're going to have on taking care of the outbreaks, we probably need a new approach in terms of getting at the -- those final ones on the outbreaks in the healthcare facilities. It is all epidemiological information, Marilyn, so it fits in with -- with here.

The epidemiological information on the vulnerable populations, if we start pulling out then the sporadic information on looking at the vulnerable populations, the average, when we look at age groups, because I'm trying to get at the concept there of we keep talking about the vulnerable populations are the one at-risks, and I'm not sure that we're seeing with out epidemiological information here who those vulnerable people are.

So I'm agitating that we need to start looking at if we're going to get -- make these goals, who's vulnerable from this. And so we have some data, and we need to work with it a little bit more.

So an average, by ten-year groups, is about 11 to 12 percent in each ten-year group, zero to -- zero to 10, 10

to 20, 20 to 30, and so on and so forth. We average out about 11 to 12 percent of the sporadic cases tend to be in each of those age groups.

But your infants, like with all other Salmonellosis, are -- you have a four times higher rate in your infants, generally three to six percent of the sporadic cases, this is based on Salmonella surveillance data from PHLIS, and from FoodNet data.

Your children under age ten are a little higher, 16 to 21 percent. Your infants and children together are 22 to 24 percent of the sporadic cases. This is all Salmonellosis from SE, not necessarily egg-related.

Your elderly, the over 60 -- although I don't personally think that's very old, the older I get 60 looks pretty young -- but that's the way we break it out demographically. We're at about 11 to 15 percent in that category. No more or less than any other groups in the sporadic instances.

Your immuno-compromised, we don't have any information on, I don't have any information on that, epidemiologically speaking.

So the -- what I'm -- the bottom line that I'm trying to get across on here is that while we might need -- we certainly need more continued work on the -- the healthcare population based on this epidemiological

information.

But the control of sporadic disease, perhaps we need to be looking on the infants and children as two separate categories. We're not the least bit sure the extent of egg involvement in a baby, in infants over -- under age one, they're not typically on hard -- on table food at least until six months, if not 12 months.

So -- and certainly we have nothing on the immuno-compromised, and we may want to look at other demographic characteristics. We have a little bit of information on race, and it's dramatically different in the four categories, but the data may or may not be terribly accurate.

So we -- I think we need to start putting a little more detail in some of the epidemiological information if we're going to use our resources effectively and make our goals.

Thank you for your patience.

MS. GIRAND: Laurie Girand, STOP. I'd like to second that comment, because one of the things we've asked for over and over again is to -- for the CDC and FDA to show that the vulnerable populations are children, most often, and they are completely buried in your data. And it's -- it's not -- it's not fair, and it's a tragedy because they tend to end up being the faces that don't get mentioned.

I have a series of medical or -- or disease-related questions, and I apologize for having as many as I do. I would also like to see data on secondary infections. Infants getting SE are most likely getting them from their parents, and their parents are most likely asymptomatic because of the handling -- or a daycare provider, somebody who's handling that infant. And we'd like to see follow-up on that.

I'd like to ask why Salmonella enteritidis, in particular, is capable of setting up in the ovary, and I apologize for being the last person, probably, in the room, to understand that. I don't need very much detail. But the reason why I'm asking is I'm wondering what other organisms are capable of exchanging genes with Salmonella enteritidis, and thereby doing the same thing.

I'd also like to know, therefore, when a chicken is infected with -- or, excuse me, a layer is infected with Salmonella enteritidis, what other indicator organisms or illnesses it might have at the same time. I'd like to understand what the rate of contaminated eggs is coming out of that layer. I see lots of data on one in 200,000 eggs is infected, et cetera, et cetera, but I'd like to know when a layer is infected, how many, or what percentage of its eggs are -- actually contain Salmonella.

And the last question I had -- and you're -- I'm

sorry, really -- the last question I had was we were -- we've seen all the FDA data about how SE is going down, and I'd like to know if it's going down evenly in all regions, or if it's going down faster in some regions and rising in others, or what.

MS. BALMER: Time out.

Okay, Emilio.

DR. ESTEBAN: After all that waiting, I may not be able to answer all your questions. So, let's see. I'm going to start from the bottom.

Did the Salmonella enteritidis infections, are they going down by region in a similar fashion. You have to first understand that the data we have for active surveillance comes to FoodNet, and for the West Coast, for example, we have California, a part of California as FoodNet site, and it is hard to compare just with active surveillance whether the rates are comparable from Region A to Region B to Region C.

What I can say is that overall, regardless of which surveillance system we're using, PHLIS, or FoodNet, or any other method that we might have -- outbreak data, for that matter, that in general, the rates all point in the same direction. So even though I cannot specifically tell you the Pacific Coast is going up versus the Northeast is going down, I can tell you that in general, everything is

going down, which is -- or you can do it with EPI, with epidemiology, basically, just look at the trends.

I can probably search for very specific information and present the data about FoodNet site, but I don't have it with me right now.

As far as the question on rate of contamination in eggs. I don't know that I'm the best person to answer that. I think that will be more for the ARS-type question. I'll refer that one to some other expert, if you don't mind.

Indicated organisms. In the way you presented the question, the indicator organisms that would identify with Salmonella enteritidis being transferred through the ovaries into the eggs, and so on. I don't know of other organisms that would indicate that type of transfer. If anybody knows of any, I would be very, you know, I would love to talk to them and learn more about that. So I don't think we have indicator organisms for measuring the rate of contamination or the transfer to ovaries to the eggs.

Your question about exchange of genes, or gene exchange, the only -- the only data that I have that relates to that would be a -- and I think I have a slide on this -- is the different types of FARS types that have been detected where -- I think it's FARS Type 8, used to be much more prevalent in the -- in the Northeast region, and when you look at all -- all the outbreaks that happen on the West

Coast, it's all FARS Type 4. So I don't know that there's a lot of jumping of -- of changing in the demographics, if you will, of Salmonella enteritidis across the nation.

Did this SE sort of movement around the world, it started in Europe, then it came to the Northeast, then it came to the West Coast. I just came back from a trip to South America, and it's not moving through there. So there's a lot more that we need to do at the global level to understand how things move, much as the U.S.

As far as your first question, which was on secondary infections, we are looking into this. There's nothing that -- that I can share with right now, because we have not a lot of data that we're looking at, but we are looking at the secondary infections.

A lot of the difficulty in this is that you have to do active surveillance, a lot of interviews, takes a lot of time and resources, and it'll be a while before we can accomplish something that is representative.

I hope I covered all of them.

MS. GIRAND: I think -- Laurie Girand, STOP. I think the one question I'm still sort of asking, it doesn't sound like you necessarily can answer it, is it's believed that E. coli OM57H7 and Shigella have exchanged genes in some way that allows them to both produce the -- or Shiga toxin.

And so my curiosity is, if we go to all this great effort to cure, so to speak, an industry of Salmonella enteritidis, or find some solution for it, are we going to whack down Salmonella enteritidis and end up with Salmonella Banalitis, and it's going to be the thing that's the problem in the ovary next.

DR. ESTEBAN: I could say that there is evidence that this -- the law of gene transfer, if you will, through -- through FARS or things that jump, so it is possible. Is it likely? Gosh, I -- I don't know.

This -- there's a lot of things about competitiveness between organisms that might prevent any other type of Salmonella to come up. So it would depend on -- on so many things that, although a possibility, that we -- while we'll definitely pose to our scientists back at CDC, I have nothing to suggest there's evidence for that right now.

MS. BALMER: At this point, we'd like to move on in the program.

We have a Panel to my left. It is composed of Laurie Girand, who is an Advisory Board member of Safe Tables Our Priority. We have Carl Lofgren, who is President of McAnally Enterprises and Chairman of the Board of United Egg Producers. And to his right, we have Dave Castellan, who is substituting for Richard Breitmeyer, who is the

California State Veterinarian.

We will take each section, as Lou said at the beginning, with a presentation. Then I will go to the Panel for comments, anybody from the table here, and then to the audience.

The first presenter is Rebecca Buckner.

MS. BUCKNER: Good morning. I am Rebecca Buckner, with the FDA. I'm in CFSN, the Office of Plant and Dairy Foods and Beverages. And this morning I'm going to give you a brief overview of some of the issues that FDA is considering for its proposed rule for on-farm SE, Salmonella enteritidis, risk-reduction control.

As you heard described earlier, the Egg Safety Action Plan outlines two strategies to meet its SE risk Reduction goals. Strategy One focuses on on-farm controls, retail, and education to meet those goals. Later today you'll hear presentations on the retail and education efforts that we are planning. However, I am going to focus on the on-farm controls that are in Strategy One.

Under the Egg Safety Action Plan, it is the FDA's responsibility to develop consistent nationwide standards for on-farm preventive controls. And we plan to implement and enforce those standards on the farm through the use of state contracts.

FDA envisions that these consistent nationwide

standards will consist of two parts, the plan, and verification of the plan. The plan consists of components that provide risk reduction. The verification is the part that ensures that the plan is working effectively.

Potential components of an SE risk reduction plan include purchasing chicks from SE monitored breeders; a biosecurity program -- including things like limiting visitors or making sure you don't have stray poultry in your house, et cetera; the use of SE-negative feed; cleaning and disinfection of houses and equipment between flocks; a rodent and pest control program, because we know that rodents can harbor SE; a flock health monitoring program; and use of a monitored water supply.

All of these components are aimed at reducing the production of SE contaminated eggs.

In order to verify that the plan is, in fact, working, FDA is considering environmental testing, and perhaps egg testing, with diversion if the egg testing is positive. The verification is necessary to provide assurance that the components of the plan are effectively reducing SE.

So that's a basic overview of the issues and things that we're considering. The plan, as I have described it -- very briefly described it -- is potential, and it's under construction, and we would like your input.

Therefore, we have the following three questions for discussion that we would like comments on. And I'm going to turn it over to Marilyn to start the discussion.

MS. BALMER: The first question is, are the following appropriate and adequate components for a nationwide SE reduction program: biosecurity; SE negative feed; chicks from SE monitored breeders; flock health monitoring program; cleaning and disinfection of houses; rodent and pest control; monitored water supply.

I'll start with the Panel first, and let's start with the person on my left, David.

MR. CASTELLAN: Thank you, Dr. Balmer. Thank you for allowing me to participate in Dr. Breitmeyer's absence.

I'd like to start the discussion on this production point with a little bit of background that I've been exposed to through our Salmonella Research Project here in California. And this is an area that -- that I have some background in here, and I'd like to contribute some additional comments to the points that were put up in the slide that had a list of exclusionary measures to preempt or prevent Salmonella enteritidis on the farm.

I think it's worthy to consider that we also need to include things that are proactive and preventive in nature, such as education and training. The foundation of a quality assurance plan, and in Pennsylvania, but especially

from my experience here in California, is that education is the foundation for such a risk reduction plan, and that this needs to be included in any overreaching process to reduce SE on the farm, because changing human behavior and changing practices on the farm are -- are critical to achieving this goal.

Record-keeping is an integral part of any process control, whether it be HACCP or good agricultural practices. The record-keeping should be very, very much integrated into the process so that people can track what's going on in their farm, and that someone, as a third-party verifier, knows what's happening, so that when problems do occur they're recorded and corrective action is documented.

Thirdly, it's really important, in terms of who is qualified to help to reduce risk reduction for Salmonella enteritidis on farms, producers should be encouraged to consult with specialists who are trained, who are veterinarians or poultry specialists, who are qualified to give such advice to deal with the issues -- because every ranch is different, and it's hard to make a -- a very clear overreaching plan for everyone that's going to work. And yesterday we conducted a farm tour to illustrate some of the differences that we have here in California, in regards to the rest of the country.

So there are a lot of things that need to also be

contributed, and we'll be getting into that later in terms of research. And I would like to just raise the issue, as well, that if we're testing, why are we testing, are we testing to test the product, are we testing to validate the process. And just leave that as something to think about as we go through this discussion.

MS. BALMER: Next, can we hear from Carl on the Panel?

MR. LOFGREN: I think that the plan is very good as a start, but I think there are some things that maybe could be added to it that would be better, better serve to -- in the plan, we don't seem to have a prohibition of repacking eggs. They should -- there should be something in the plan that does not allow for any eggs to be repacked from return situation. We need to have a code dating on the eggs so that we know -- on the carton, so that there is a specific part of this plan that envisions the need for -- for code dating.

I also would concur with David that the -- one of the foremost points of this overall plan should be education. It seems like the -- the most common cause of this problem is undercooking eggs, and that's such a simple thing, with proper education, to make a correction on. I would -- I would urge that a major part of the program be the educational part, the education, both on the ranch and

to the customer, to the end-user.

That's basically all that I have.

MS. BALMER: Okay. Can we hear from Laurie next. Laurie Girand, STOP.

MS. GIRAND: Looking over this list, I think -- first of all I want to say that we're very pleased with the emphasis FDA has put on farm controls, and that especially with the rest of the work I've done with the Food and Drug Administration, I hope that we see this in other areas as well.

I think that these -- these particular items are looking pretty good. I think that we also need a trace back that associates as closely as possible a particular -- as closely as possible a particular house, or a particular layer, with the infection. And I realize that each layer probably can't be labeled, or along those lines, but we're looking for a way to identify the actual source.

And I think another very important point, along with that trace back, is that you want to have what you're referring to, I guess, is a uniform date of lay as part of the packaging, as well, so that when -- what Carl was talking about, when you're voiding the recycling of eggs back into the packages, you know where the product came from and how it -- how it got to where it was.

And I would throw in that when you identify a

house and you divert eggs, I think it's important that you somehow mark them so that there's no chance that an accidental egg strays back into the -- I'll call the non-pasteurized branch of the sale process. And I, you know, I don't know what kinds of dyes or inks, or whatever, but I would suggest that you do something to the outside of the egg so that it's visible, and not just something that's sort of invisible, you know, switched over and moved around.

MS. BALMER: When you're talking about repackaging recycling, at what point in the chain. Could you please clarify?

MS. GIRAND: It's my understanding that eggs go all the way out to the grocery store, and then old eggs come back and get put back in, and it may just be a packing house issue, I'm not entirely sure about that.

MS. BALMER: Thank you.

Are there any comments from the table here, first.

Okay. Then let's go to the floor with this question in the components of the program.

MR. MIRANDE: Armando Mirande, with Biomune.

You have questions number four, six, and seven. What happened to question number eight?

MS. BALMER: What we did was we selected certain questions from the Federal Register notice to focus in on. If you have comments on the other questions, please submit

them. The comment period, as was said at the beginning, is open until the 20th of April.

MR. MIRANDE: Okay. I have. Thank you.

MS. BALMER: John.

MR. DAVIDSON: I'm John Davidson, from Davidson's Pasteurized Shell-eggs.

One of the observations that I've had in the prior -- prior session, as well as the current one, is that there is a misunderstanding that is used by the government agencies about the term "undercooked" or "raw". The average person would not really understand whether or not they're eating a raw egg or whether they're eating an undercooked egg. When I eat a sunnyside up egg every day, I don't think of it as undercooked, nor do I think of it as raw, of course. So I think, in terms of the education side of it, public awareness of the terminology that's being used would be very helpful.

I have many more comments based on the prior section, which I'll discuss later. But on the point of public education, which, agreed, is a very important factor, the -- the definitions and the way of presenting information is very important, and I think it's lacking.

Thank you.

MS. BALMER: Yes.

MS. BARNATO: Hello. My name is Terri Barnato.

I'm with the Association of Veterinarians for Animal Rights. We're a national organization of veterinarians, veterinary students, and technicians.

I think that you've consistently overlooked the husbandry practices that are used in the egg-laying industry, specifically forced molting, which is scientifically linked to the increase in production of Salmonella enteritidis in egg-laying birds. For those in the audience who don't know what this practice is, it involves withholding all food from birds used in egg-laying production for an average of one to two weeks, typically ten to fourteen days, to manipulate egg production so that the egg-producing industry can benefit economically.

The USDA's own research concludes that this practice is a contributing factor to Salmonella enteritidis increase in egg production. Also, that the Farm Animal Wellbeing task force group has concluded that human illness would be reduced by 2.1 percent if forced molting were eliminated.

It's an extremely cruel practice. It can't be allowed in this country. It's been outlawed in Europe, the United Kingdom. They don't do it in Canada. And the egg industry should be ashamed of allowing it to continue here in this country, and it's been occurring for over 30 years.

MS. BALMER: There were other hands. Thank you.

Ralph. Can you state your name?

MR. ERNST: Ralph Ernst, University of California.

I have a question about the -- in point four, one of the points is a Salmonella-free -- free feed, and I personally don't think we have the technology at the moment to assure that such a thing even exists, particularly with the problem of recontamination that exists, even if you have a, quote, pasteurizing step for feed equivalent, recontamination can occur immediately when you start cooling after that process, if we're looking at something like pelleting.

So I guess my question is, do you really mean Salmonella-free, or do you mean some sort of Salmonella control in feed to try to reduce Salmonella incidence.

MS. BALMER: Introduce.

MR. McCHESNEY: My name -- I'm Dan McChesney, with the Center for Veterinary Medicine of FDA.

We specifically said in the plan, Salmonella negative, because we really don't believe you can have a Salmonella free feed without testing 100 percent of the feed, and we realize that's not practical.

Salmonella negative is based on a -- a sampling plan and a methodology that given somebody's taking so many samples, analyzed by such a method, you can say his feed is Salmonella negative.

And that's something that's within the capabilities, specifically when you talk -- look at Salmonella, SE. It may be a little more challenging to get a feed completely free of all Salmonella and keep it that way. But you're largely right, it's a post-processing recontamination issue.

If you look back at the data that FDA has, and a variety of other people have, SE has not -- has only been isolated from an animal feed in one case, and that was about six or eight years ago, and it was in a duck feed. Now, the caveat to that is, is yes, it -- SE has been isolated in feed when you have flocks that are infected with SE. But I don't think that's a fair choice, because you really don't know whether it came from the feed or whether the birds infected the feed.

If you just look at feed by itself, it's very difficult, if not impossible, to isolate SE from feed. And several people have looked at it, and why that is, it's not clear. If you contaminate feed intentionally with SE, you can isolate it back out. So it doesn't seem to be a method issue or an issue that something's overgrowing it. For some reason that we have yet to discern, it just doesn't seem to do well in feed.

So I think we actually can get an SE-negative feed if we agree on a definition for negative which we have used

-- FDA has used for other feeds to be ten samples testing negative by -- by a culture method.

So I would agree it couldn't be free, but I would disagree that it couldn't be negative.

MS. BALMER: Greg.

DR. CUTLER: My name is Dr. Gregg Cutler, I'm a private practitioner.

I want to talk about the issue of environmental testing and its inappropriateness as a verification step. I think that environmental testing can be useful, but I think before we address environmental testing we have to first recognize that not all flocks that test environmentally positive ever produce positive eggs. There can be many sources of SE in the environment.

I think that if we find that a flock is environmentally positive, we need to use that information to adjust our process and our on-farm activity to see what has happened to cause that organism to be present on that farm.

We are dealing with an infection rate in eggs only from positive flocks that are bird-positive, that produce positive eggs, that's a very, very low number. That number is almost impossible to detect by direct methods. So we need to use some sort of indirect method.

And again, while environmental positiveness is an indicator, it does not necessarily state that there are

positive eggs coming from a flock. When we get that, we need to go back to our educational components that exist in some of the plans that are already out there.

Earlier on, when Dr. Esteban was talking about the reductions in SE over the last five to six years, and there was a question regarding why has that happened, I think we need to take credit right now. Since 1994 there have been egg quality assurance plans that have been put into place that have been an excellent method for transmitting the current scientific knowledge directly to the producer through effective educational programs, to help them change their practices on the farm to reduce the prevalence of SE.

So I think that because of the rareness of positive eggs in that sort of situation, yes, it can be used to modify process, but it should not be anything that should condemn a flock a priori on the basis of an environmental test.

MS. BALMER: Greg, just a minute. You had said -- I wanted further clarification on this. You had said an environmental positive, and at that point you're saying you want a review of the plan? Is -- is that the action you're proposing?

DR. CUTLER: I'm saying that the action that should be taken if an environmental positive is in place is a review of your process to see where that could've gotten

in, and how you can prevent that from happening in the future.

MS. BALMER: You mean the process in the house, or --

DR. CUTLER: The production --

MS. BALMER: -- the -- the house, or the processing, or both?

DR. CUTLER: I'm referring -- right now we're talking about on-farm. So I'm talking about on-farm in the chicken house. I didn't believe we're addressing production at this point. Processing, at this point.

MS. BALMER: Okay. Thank you.

Next one. It might help, as one is finishing, if the next one could begin to come up to the microphone.

DR. HOUVE: Good morning. My name is Dr. Jean Houve, I'm a veterinarian with the Animal Protection Institute.

I also wanted to comment on the forced molting. The USDA's own task force suggested that eliminating that would reduce Salmonella illness by 2.1 percent. That, given the numbers that Mr. Esteban presented, that would be a reduction of approximately 6300 cases per year, and a reduction in deaths of two to four human lives.

I just would like to comment and say that if I were a chicken producer, I would not want to be the person who had to look that mother -- or that mother or that

husband in the eye, and say for my economic gain -- I killed your child.

I also wanted to mention, concerning the feed issue, that I don't know if this is prevalent in the chicken industry, but I know that it is allowed under the American -- Association of American Feed Control officials, of which I am a liaison member, that animal waste products can be fed back to other animals.

And I don't know if that's common in the -- in the chicken-laying industry, and I don't -- and I'm not certain whether that occurs cross species or whether fecal matter from chickens is fed back to chickens. So I wonder if somebody could address that, because it is legal, it is allowed, and it's even provided for in the AAFCO publication.

Thank you.

MR. McCHESNEY: I can -- Dan McChesney, Center for Veterinary Medicine, FDA.

I can try to address at least the last point of that. You are correct, you can feed -- actually, most of it's poultry litter back to other animal species, and to mostly cattle, provided it's been treated. And the AAFCO manual has a variety of steps and requirements before you can feed this back for treatment of the product, which is heat and a variety of other testing methods that are in

there.

And it's -- and it's a well laid out protocol in the -- in the AAFCO manual. It is not -- you don't usually feed poultry litter, poultry -- poultry waste back to poultry. It's more of a cattle feed.

Now, that doesn't say if -- if you have birds on the ground, that they don't eat each other's feces, but that's not a regulated issue.

MS. BALMER: Okay. Dave.

MR. GOLDENBERG: My name is David Goldenberg. I'm going to wear two hats right now. I am the Facilitator for the California Egg Quality Assurance Program, and I'm also the Manager of the West Coast United Egg Producers.

In 1994 we instituted the California Egg Quality Assurance Program. We have about 95 to 98 percent of our layers involved in that program, so we have a majority of our egg -- egg companies involved in this program.

One of the problems or concerns that I heard this morning was that this program that the FDA is proposing, or this SE proposal, that there's going to be consistent national standards. And what we're concerned about is that there ought to be flexibility put into this to allow for local differences in regions, through climates, or farm practices, or farm construction. In particular, such as C&D, we may have houses or farms that have cement floors,

concrete floors. We may have others with dirt floors. It's very hard to clean and sanitize dirt.

And what we'd like to do is see flexibility in the proposal to allow for differences in farm construction in regions, such as we have a very arid region out here, versus the East Coast, where you have a lot of humidity, you have freezing, snow, and just various differences there.

So we hope that there is flexibility allowed for putting a standard out there, that allow the producer to work around so that they can make it work on -- on their particular farm, because if you tie the hands, it won't work. And we found that flexibility is -- is key here in California, to work with the different variations of production practices.

MS. SIPERSTEIN-COOK: Hello. My name is Laurie Siperstein-Cook. I'm also a veterinarian. I'm an avian specialist.

I just wanted to comment that I am, as was said already, I am also dismayed that this -- these egg quality-assurance plans do not include some kind of ban on the practice of forced molting. As has already been stated, it's been shown to -- to increase the shedding in the hens, because of the immunosuppression caused by the stress of being -- being starved.

And I would like to -- well, actually, that's all

I wanted to say. Thank you.

MS. BALMER: Is there anybody else from the floor?

DR. CUTLER: Dr. Gregg Cutler, private practitioner.

I'd like to lay the molting issue to rest. We're going to debate that in another venue. Excuse me. However, one of the things that I would like to point out with regards to Salmonella enteritidis is that when a bird is placed into molt, it immediately ceases production of eggs, and does not produce eggs for approximately eight weeks, during which time it regains its weight, becomes a very healthy, nice, natural, good-looking bird, and comes back into production completely healthy. At that point, there's no reason to suspect that there is any more probability of that bird shedding SE in an egg than before the molt.

There is some scientific literature that was done. I know the scientist personally, he was with USDA at Georgia. If you discuss this issue with him he says he doesn't believe that for a minute, other than that there might be some additional shed during the actual time when the bird is fasting.

So since there are no eggs being laid, it isn't a problem. And I think anything to -- to say that health would be improved by this is mere speculation and misinformation.

MS. GEISER: My name is Phyllis Geiser. I'm from Hawaii, I'm representing the Hawaii Egg Producers Cooperative.

And I concur with the California Egg Quality Assurance Plan that we need to have flexibility in regions. Our state, we have -- we are concerned because in your two strategies, we have no egg-breaking facilities and no facilities in our state for pasteurization. And how does that impact our state production. Are you going to force us to try and ship all our eggs back to the mainland, which we could not afford, or are, you know, we forced to totally destroy all eggs from a positive environment when the layers and the eggs themselves may not be positive?

MS. BALMER: If -- one more? If there are no more questions or comments, let's move on to the next question.

Is environmental testing an appropriate verification step to ensure that the risk reduction plan is working? If so, how often and where should testing be performed to ensure that the plan is working, and that the consumer is protected from consuming SE contaminated eggs?

This time can we start with Laurie on the Panel.

MS. GIRAND: Okay. So it's how often. Okay.

We feel very strongly that testing must be done at multiple points throughout the layers' lives, and not just to depopulation. We feel that it can be reintroduced

through a combination of methods, whether it's water or feed, or what have you. And so from a frequency standpoint, we think that that's pretty important.

I wanted to ask a question about chicks being ground up into feed, which I believe used to be a practice. I don't know that it's a practice anymore, but --

MS. BALMER: Can we stay with this question at this point.

MS. GIRAND: I thought it was related to feed and what we would be testing.

MS. BALMER: It's the environmental testing appropriate for verification, and how often.

MS. GIRAND: Okay. I've concluded my comments.

MS. BALMER: Okay. Carl.

MR. LOFGREN: We believe that testing should be an integral part of a program. I feel that it should be a part of a program that verifies the -- the plan as it's exercised, and we're talking about a HACCP program, or some type of a scheduled program on the farm.

If we instigate the testing program in multiple intervals during the life of the bird, we're just testing. We're not really evaluating the program, because the program does not come into effect until a year or two later. I would feel that testing where chicks' papers come in, to make sure that you have no transport of a Enteritidis on

those papers into a sterile -- or, not a sterile, but a clean, sanitized house, is very important.

I would feel that at push out, with no other indications any place, that at pushout, about two weeks before this pushout, that a environmental test should be done. And then if you find areas where these -- where you have positive tests, then go back and evaluate the plan, re-look at your information, and re-test environmentally and make sure that you have valid, accurate tests.

If the HACCP plan, or the husbandry plan that should be in place is not working, the tests will show it up. But the tests don't change anything. The tests -- we can't test our way to negative Salmonella problems. If we were to go into the testing program that perhaps is -- has been suggested, and just summing up the number of rows and the number of flocks that are out there, it has been calculated that this would amount to in excess of $20 million across the country to do all the testing that's being proposed, and we still don't have the program in place.

I would feel that this is an extra burden that's put on the producer and the public, without making a change. So we would like to see that follow after the plan. We think that would be appropriate. The risk assessment has been determined to be one egg in 20,000. That's a .005

percent, which is several orders magnitude lower than most animal evaluations, most animal standards would be.

So we -- we think that the education part of the program, again, is where it's really at, and -- and the program that's proposed for is followed, then we do testing following that to verify that program.

MS. BALMER: Can we stop a minute, for the tape changes.

(Off the record.)

MR. LOFGREN: Okay. The -- the figures that have been used for the number of contaminated eggs have been based on this one in 20,000. It's -- it's been assumed that all the eggs then go and would be a potential consumption, but it must be remembered that there's about 30 percent of the eggs that are broken, moved to a breaking plant, and then pasteurized. So those eggs are not a part of the problem of the shell-egg situation.

A 30 percent error is certainly a major calculation difference that would really put a burden onto the producer, so I think we would encourage a valuation of these figures so that we have more -- or certainly have realistic figures to deal with.

That's all the comments that I have.

MS. BALMER: Okay. Dave.

MR. CASTELLAN: Yes, thank you. David Castellan.

I'd like to harken back to the President's Food Safety Initiative and some of the key words that he uses in it, which are science-based and risk-based. And I think that as a scientist and as a clinician, the first question I ask myself is why we're testing. I know that in -- in the program we've developed here, we have -- we use delayed secondary enrichment. We've used that technique because it's shown to be at least 30 to 40 percent more sensitive. But the reason we use it is so that the producers have the best available technique to find the organism. And I think that as part of a validation of the process, it's a very useful tool.

I think we want to use our financial resources rationally, and that ties in with the science-based approach, too, if we consider that there's an economist sitting in at this discussion, as well. So obviously that's a very important component of this.

I think that the history of a flock should be a key trigger, or the history of a building should be a key trigger for someone who's involved in managing SE. So that somehow, risk-based testing should be included, but within that setting and within that particular circumstance.

So I would encourage the development of testing requirements that are based on risk, and those risks are very individual and very specific to locations.

There are a number of places that have never had this organism, and there are some that have had it occasionally. And I think that we need to keep that in mind when we're developing testing protocols. And the key point is that the test has to be useful to the person who's doing it. It has to give you some information so that you can change something, and there are regulatory implications to testing, but I think we need to get back to the root of what a test is intended to do, and that is to give us information to act upon.

Thank you.

MS. BALMER: Any comments from the table here? Dan.

MR. McCHESNEY: Dan McChesney, Center for Veterinary Medicine.

I'd just like to make a quick comment on the chick use in feed, and we can just kind of dismiss, or go through that quickly.

It is permitted to use chicks -- or any chickens that have died -- in feed, but only after processing. So you would grind them up, you wouldn't put them in raw. That would not be -- but they could go in if they were heat-processed. Normally they would be rendered.

There is research into some other areas on fermentation, but none of that is approved yet. So that

could be -- and I can understand how you could see that as an environmental testing issue.

MS. BALMER: Okay. We'll start with the floor.

MR. KLIPPEN: I'm Ken Klippen, with United Egg Producers. And I just wanted to echo the comments that Carl Lofgren just made about the testing protocols that are in place already.

The egg industry is making adjustments in its testing, but if you test without a specific purpose, all you're doing is you're raising the cost of food, and you're not really protecting the public health. Whereas if you can see what we're trying to do as an industry, we're taking birds from SE monitored breeders, and before we actually have them move out of the house, a depopulation, we test them.

Now, if there's a positive in that situation, well then the -- the whole program is ratcheted up to a much more extensive testing requirement, so they even test at 30 weeks of age when it's a peak period for the shed of SE.

But the egg industry has come a long way in trying to adapt to a testing regimen, but just testing for the sake of testing itself, you can't test your way to safety. So we're trying to be responsible in -- in responding to this, and at the same time trying to provide a safe and wholesome product for our nation's consumers.

MS. BALMER: Anymore comments from the audience? If there are -- okay.

MR. GEMPERLE: My name is Stephen Gemperle, with Gemperle Enterprises.

Environmental testing is a very effective tool to check on the quality of management in a company, and all of the -- the assurance programs that they're using. If someone's following an effective assurance program and they're buying NPI chicks and all of the different steps in the quality program, environmental testing will tell you if there's any missing holes in your management style and your entire program, your housing, and all of the different issues that can come into the picture that could introduce SE in your farms.

And a lot of farms have been testing for a number of years and have never found an SE on their farm. And in a situation like that, and you continue to do environmental testing and you're never finding them, it's telling you that you're being effective in the management style and all of the different programs that you've elected to use in your farms.

Thank you.

MS. BALMER: We were scheduled for a break at this time. Why don't we break for -- why don't we just take the break now. We were scheduled for a 15 minute break. Let's

be back here, the clock in the back says about one minute after ten. Let's be back here about 10:15, and hopefully the mechanical parts will be fixed.

(Thereupon, a break was taken.)

MS. BALMER: With the second question that was on the overhead -- that question, again: "Is environmental testing an appropriate verification step to ensure that the risk reduction plan is working? If so, how often and when should testing be performed to ensure that the plan is working, and that the consumer is protected from consuming SE contaminated eggs?"

I believe we had finished the Panel. We were on the floor. Were there any additional comments from the floor?

Don.

MR. BELL: Thank you, Marilyn.

My name is Don Bell, I'm a poultry specialist for the University of California.

My comment has to do with the frequency and number of tests. The California Quality Assurance Program at the present moment makes one test in the life of a flock. We've heard proposals for three or four tests. We've heard proposals for every-row tests. We've even heard proposals for twice-per-row tests. I think that's currently on the table.

My question has to do with sampling, as opposed to total coverage of a facility. And in particular, twice-total coverage. When we're talking about resources or limited facilities, limited number of people, funds, what have you, I think we need to get back to the scientific concept of sampling, that we sample every day the quality of the eggs, we sample the size of the eggs, the performance of the flocks, and so on. But at the present moment, for some reason, we're thinking in terms of every single house, and we have chicken houses, individual chicken houses in the United States that have 400,000 chickens. And in California, we have farms that have those same 400,000 chickens in 200 houses.

So we have a marked difference in what we are sampling, and I hope we can get back to the scientific concept of scientific sampling to tell us what we need to know. We do not have the resources to totally sample everything, nor do we have the resources to do it twice.

Thank you.

MS. BALMER: Are there any other comments on this question?

Greg.

DR. CUTLER: Yeah. My name is Dr. Gregg Cutler. I'm a private practitioner. And somebody asked me to tell you that I also have an MPVM from the University of

California. Dr. Esteban and I are alumni and I am a Diplomate in the American College of Poultry Veterinarians. I have 20 years experience in poultry practice.

I agree with Don that we need to look at a sampling regimen. I think any of us who are epidemiologists or scientists who have studied statistics have heard of something called the "central limit theory". I think we all have to agree that it holds, and that when you're dealing with large populations, reasonable sample sizes can be determined based on predicted prevalence and the level of confidence you want to have in your sample, and that to sample 100 percent is a waste of resources, a waste of time, a waste of money, and serves no purpose to reduce the -- the amount of disease that we are looking at.

The disease has already been reduced substantially, particularly here in California, from a high of over seven per hundred thousand at the peak, down to less than two per hundred thousand in the most recent data that we have. And there's every indication that that will continue.

I believe that the reason for that decrease has been in all of the implementation of information that has been garnered from the scientific community, and passed directly to producers and put into place in their environments. I believe that by sampling the environment,

at least at the end of production, to make sure that their process has worked appropriately, continues to be the most important factor in reducing the amount of disease. Again, you cannot test out of a disease that is as rare as SE is in a population.

I think that the testing might also include making sure that the chicks that are brought in to that environment are clean by means of testing chick papers, as Carl Lofgren has also indicated earlier on. And I think those are probably the two most important points to test. Basing the results of what you do on those tests you know that you have a clean flock starting. You're doing everything that we know how to do during the life of that flock to keep it clean, and then we're evaluating at the end of that flock that you indeed have kept it clean.

One confounding factor that I have found personally in testing chicken houses over at least the last 12 years, is that this can be an extremely intermittent problem. You can test one day and find it, and go test another day and not find it, particularly in houses that are probably not shedding SE in the eggs. I don't know where these samples -- where these positives are coming from. There is a lot left to be learned about the ecology of this disease, and I highly recommend that we spend a lot of our efforts, if not the majority of our efforts, to further

understand this disease, rather than waste a lot of money trying to test out of a disease that you cannot test out of.

MS. BALMER: If there are no other comments, let's move on to the third question.

In the event that an environmental sample for SE is positive, what, if any, additional steps should a producer be required to take with the positive flock house, and with the next flock that will be placed in that house?

Let's start with Carl this time.

MR. LOFGREN: If a flock is determined positive, and it's required to be moved out, I believe that the requirement for a thorough cleaning and disinfecting, and a sanitation program would be reviewed again.

What -- when did that get into that house should attempt to be determined. If it just happened on -- at the end of the flock, or if it happened back in the -- examining the records, looking at the performance of the birds. But at any rate, that house should be thoroughly cleaned and -- and disinfected.

The new flock that's placed in that house should be a absolute clear flock, and it should have no positives. And that flock should be sampled, then watched, and if it's -- if it's -- turns positive, then you have to take a major step and -- in that house again.

It's my understanding that this has happened in a

couple of situations where a house has been negative, turned positive, they cleaned it up, disinfected it very thoroughly, and then it turned positive again. So we don't know where -- where it's coming from, but we feel that the program of disinfecting and cleaning is an absolute must.

That's pretty much my comment.

MS. BALMER: Okay. Dave.

MR. CASTELLAN: Yes, thank you.

Our California Egg Quality Assurance Plan proposes as part of its plan that when -- when something like this should arise, and there is a positive, that the producer is responsible to consult with an expert initially. Someone who's qualified to educate and correct -- help correct the problem, to identify it, first of all, through review of the process. Going through -- painstakingly through the plan to determine where the system broke down, and make the appropriate correction.

It seems that one of the issues that comes up in this regard, as well, is lag period after discovering something. And it seems that in terms of research needs, there is a need for a rapid test which will allow everyone to be able to react quicker. At this time we -- we do not seem to have that, but that would seem to be a very high priority in terms of research needs.

MS. BALMER: Okay. Laurie.

MS. GIRAND: Laurie Girand, STOP.

We believe strongly that you have to disinfect the house if this is going -- if you've got an SE positive from an environmental sample. I'm sort of concerned about the idea of taking a flock that might be infected and putting it back into a disinfected house, and I don't understand how you're going to prevent that, and would like to see that prevented.

I think we probably also ought to be testing eggs from that house, or from the -- the batches that occurred prior to finding the SE positive.

MS. BALMER: Comments from the -- oh, Dan.

MR. McCHESNEY: Can I ask a clarification question of Mr. Lofgren?

Were you -- did you provide -- you may have said this, and I apologize if I missed it. After the house is cleaned, do you propose testing the house again before you place the birds?

MR. LOFGREN: We would follow the California program, but I would tell you that if we had a positive house, as a company we would test that house environmentally again. You bet.

MR. McCHESNEY: After the cleaning?

MR. LOFGREN: Yes. Not necessarily before we put birds back in there, but we would test it following our

cleaning, and then we wouldn't have the results if we were -- you don't have very much time until the next flock comes in, so we might be afterwards -- after the birds have been put in that house. But we would test it.

MR. McCHESNEY: Well, as another follow-up. What -- I understand how there's a short timeframe there, but what would happen if you tested it after you placed the birds, it was positive? Playing devil's advocate here.

MR. LOFGREN: Well, we would be sitting down with our California Quality Control people that really have good suggestions and good ideas, and we would be examining this very closely, trying to determine how it happened, the history, what -- everything that had been done, to make sure that we hadn't missed something.

MS. BALMER: This is Marilyn Balmer. One further, would you do any additional testing? If you -- you're saying you would review your program. Would you do any additional testing on that flock that was subsequently put in there?

MR. LOFGREN: Well, I believe that we would test according to what the information that we had. If -- if it looked like there was a problem that was not being identified, then we perhaps would do some more testing. But as a routine, we would not test as often. Only if there's a real break in our program, and we see that we're having a

significant problem here and a follow-through was another positive test.

MS. BALMER: Okay. Open up to the floor.

MR. MIRANDE: Armando Mirande, Biomune.

What steps can be performed after a flock has been found to be positive in the environment?

I don't know if you're aware, but Canada, the Province of Ontario, which represents over 40 percent of all the layers in Canada, makes mandatory to vaccinate the incoming flock of pullets. Originally, if the pullets were already positive they had to be vaccinated. They eliminated that, now they have to be killed. They set aside money for compensation of -- of the producer. But if a negative flock of pullets is going to a previously environmentally positive house, must be vaccinated. It's mandatory.

What is ironic is the Canadian government took the field evidence from our country to make that rule. And our government has not looked into it. That's one intervention that can definitely be of help.

The other intervention that they make mandatory is the cleaning and disinfection of that positive house.

MS. BALMER: Any other comments from the floor?

DR. CUTLER: Dr. Gregg Cutler.

I think that it's really essential that if somebody gets a positive environment, and they clean up that

environment, that they contact a professional who can help them with further understanding the reasons for that positive, and also strategies and activities that can be taken to reduce the possibility of additional shed of eggs from a flock if it happened to turn bird positive.

I think, as Armando indicated, there are some strategies that are available. There are some live vaccines, there are some killed vaccines. And I certainly think those would be some of the options that might be taken in the presence of a positive house, even though that positive house were thoroughly cleaned and disinfected, which I heartily support.

MS. BALMER: Are there any additional comments? Any from producers in the audience?

MR. GOLDENBERG: David Goldenberg, California Egg Quality Assurance Program.

I guess I would like to see some research done from the universities or from the government to look at action levels. When you -- if you have a positive, is there just one positive sample, or is it 50 percent, or 75 percent that are coming back positive, and what does that mean? Does it mean if you have one positive environment, was that a rodent drop and it was picked up, or does it mean that the flock is infected.

So I think there needs to be a correlation between

the environmental samples coming back positive versus what it would mean in -- in flock infection.

MS. BALMER: If that is it for comments, before we go to the next area, we'd like the table to first introduce themselves such that people are aware of who is here from the different federal agencies, listening to your comments.

Can we start with Howard.

MR. SELTZER: Howard Seltzer, FDA.

MS. WORKMAN: Martha Workman, USDA, Food Safety Inspection Service.

MR. RAYNES: Paul Raynes, Food and Drug Administration.

MS. KUX: Leslie Kux, FDA, Office of General Counsel.

MR. BRACKETT: Bob Brackett, FDA, Center for Food Safety and Applied Nutrition.

MR. SCHARFF: Robert Scharff, FDA, Office of Scientific Analysis and Support.

MS. LEVINE: Victoria Levine, USDA, Food Safety and Inspection Service.

MR. GLASSHOFF: Roger Glasshoff, Food Safety and Inspection Service.

MS. BUFANO: Nancy Bufano, FDA, Center for Food Safety and Applied Nutrition.

MS. BUCKNER: Rebecca Buckner, FDA, Center for

Food Safety and Applied Nutrition.

DR. ESTEBAN: Emilio Esteban, Centers for Disease Control and Prevention.

MS. RIGGINS: Judy Riggins, USDA, FSIS.

MR. CARSON: Lou Carson, FDA, Center for Food Safety and Applied Nutrition.

MR. McCHESNEY: Dan McChesney, Center for Veterinary Medicine, FDA.

MS. BALMER: Thank you.

The next area to be covered is packer/shell-egg Processing. And I believe this will be given by Roger Glasshoff. It is a change in the program. Alice Thaler could not be here.

MR. GLASSHOFF: Thank you, Marilyn.

Previously this morning we've heard from the Food and Drug Administration about various components that are being considered in regulatory rulemaking under Strategy One, which is basically the producer level. We're going to move on now to the packer, or the shell-egg processing portion of the -- or scope of the industry.

And as we envision a rulemaking, we anticipate that-risk reduction for Salmonella enteritidis may include several of the mandatory components of a risk reduction plan, a national work group for the development of standards to address risk reduction of SE in-shell-eggs, considered

that the best way to address Salmonella enteritidis reduction would be to consider the implementation of a HACCP based system for shell-egg processing, which would also include prerequisite programs to reduce the risk of SE in-shell-eggs.

At the packer level, we would also envision the implementation of components to address cost of developing these type of HACCP based systems that would involve various aspects of record-keeping and the monitoring of the process from the farm label -- from the farm level to the transport of eggs to the consumer. We anticipate good manufacturing practices to be identified to prevent cross contamination.

We've heard earlier from those people at the microphones, as well as from our Panel, that recordkeeping is essentially a key component of a HACCP based system. The producer would be identified, dates of production for each lots that are transferred to the packer would be maintained, temperature may be key as an intervention. That may be monitored again to prevent the growth of SE in eggs. And if transportation is key, of course, storage temperature is key prior to processing.

Controls at receiving would be a method by which the packer or the processor can determine how old the eggs are. We're not familiar with any scientific methodology that is currently used. We would suggest that if anyone has

information on that, that they submit that with their comments.

Additionally, as controls at receiving, measures would be taken to ensure that eggs from SE positive layer flocks which are diverted from the table egg market, are properly identified. The processor would maintain usage of those eggs for verification purposes to assure that they were pasteurized.

Additionally, identification of the producer with certification of conformance with the prerequisite programs which we have been discussing this morning. We talked about the National Poultry Improvement Plan, and purchase of SE free chicks, biosecurity programs, pest control, rodent control, and other aspects of the prerequisite programs. This would be available on documentation for review under verification by the agency.

Again, as part of controls at receiving, storage pending processing would involve the handling and the processing of eggs from SE positive flocks diverted for the production of liquid and frozen dried egg products. I alluded to that earlier, and this would involve principally record-keeping.

Refrigeration from the time of gathering to processing, which is also under consideration. What type of temperatures should be involved to assure the safety of eggs

and the reduction of risk associated if eggs are exposed to elevated temperatures prior to processing. Currently, the temperature for the transport of eggs to the consumer is 45 degrees ambient temperature. This might be taken under consideration as a guideline for refrigeration of eggs pending processing. And we would again urge your feedback on that topic.

The cost of maintaining refrigerated storage would have a major impact, no doubt, upon the industry. And as I stated earlier, the eggs that are destined for the consumer are stored at ambient temperature of 45 degrees or less. In this case, the eggs that are received for processing, destined for grading and packaging, would be considered subject to refrigerated storage if they were in excess of 24 hours of age from the date -- from the time of laying.

Other prerequisite programs which would be developed by the processor/packer, would involve basic sanitation of the premises, a facility plan to describe sanitary standard operating procedures. It would address the food-handling practices, cleaning and disinfecting of equipment, maintenance, again, of the facility grounds. That seems to be in sync.

Again, prerequisite programs, facility rodent and pest control program, monitoring frequency would be part of the documentation indexing the type of insects or pests that

are caught or destroyed. Potable water source. Many of these were mentioned earlier this morning as prerequisite programs at the producer level. Under a HACCP-based inspection system, it would be the responsibility of the processor to determine that the cleaning, de-staining, sanitizing compounds, as well as shell-egg protecting oils, marking inks that are being used are acceptable for the intended use.

There are guidelines available that are currently published by FSIS under the Sanitation Performance Standard, which give processors the guidance on how to secure a letter of guarantee from the manufacturer. Again, there would be an education factor, not only on various types of programs as they are developed, but we would envision a continuing education as we evolve through these type of HACCP based inspection systems.

Another concern that was identified by the work group was the possibility of cross contamination as it relates to washing eggs. We've heard comments that there are several pre-wetting practices that exist within the producer/egg processor industry. We would also recommend adopting washwater temperatures and criteria that would inhibit or reduce cross contamination. Many of the producers here in the room today are probably familiar with the USDA voluntary shell-egg grading program, which has

developed guidelines with regard to washing of eggs to prevent cross-contamination.

Another intervention step may be the consideration of maintaining a pH level in the washwater reservoir to keep the bacteria load down. And in many cases, if that pH is maintained at a high level, it can destroy some pathogens.

Process control, of course, here we're talking about grading and sizing eggs. But some concerns have been expressed about the number of under-grade eggs that are allowed under the tolerances. Of course, at this time FSIS does not have the authority to change any of those tolerances. It was just brought up as a concern.

We've heard this morning on several occasions about elimination of the reprocessing of returned eggs for table use. Again, in the record-keeping that would be established under a HACCP based system, it would be evident as to how those returned eggs are being handled.

We've mentioned potential cross-contamination. One of the topics that has also been taken under consideration is the re-use of packaging materials, whether it be at the producer or the packer level. Now, most of the industry that I'm aware of, of course, uses new material to send eggs to the table market. However, in the transport of eggs from the producer level to the packer, we find a high degree of variation and quality of the packaging material.

In considering rulemaking, then, we are concerned about what would be the impact upon the industry if only new materials or good used materials -- as I was saying, we were concerned about the costs that may impact the industry if only new or good used materials were allowed. This would also apply to maintaining the sanitation of various types of transport mechanisms, such as dollies, the palettes that are used, and various other types of means of transporting the eggs.

Labeling. We would envision a HACCP-based system to identify company records that would explain the codes that are used on all products that are packed. This, again, would be important in the correlation of a trace-back or of any problems that were sighted by a consumer. This, of course, would apply to bulk pack as well as cartons. Maybe even overwraps, in some situations. That labeling, of course, would comply with FDA as well as FSIS labeling requirements.

Currently, the requirements for shell-eggs destined for the ultimate consumer require that they reflect that the product must be kept refrigerated, and the other labeling requirements that are to be applied to product that is displayed at retail have not been concluded yet in rulemaking. That is under the jurisdiction of FDA.

Another strong portion of this program would be

the monitoring of temperature. If it is considered to be an important intervention in reducing the risk associated with SE from the producer level to the processor, then there would be incorporated in the plan a monitoring frequency to demonstrate conformance. Again, in a rulemaking we would be focusing on ambient storage temperature.

I noted in the discussion at the microphone also that there is much concern over research. We would like to also present some questions. What research on SE and eggs would assist the packer and the processor in identifying and implementing proper risk reduction programs?

With that, I believe I'll wrap this up and we'll address the individual questions.

MS. BALMER: Okay. The first question in this part of the program is what is the cost of maintaining refrigerated storage maximum temperature 60 degrees Fahrenheit for eggs received that are destined for grading and packing, or in-shell pasteurization, when time to processing will exceed 24 hours from time of lay.

Let's start with Dave on the Panel, first.

MR. CASTELLAN: Thank you.

A number of process -- or producers do have onsite storage facilities to maintain lower temperatures. Some do not. And so that is an issue that, in terms of the economics, that needs to come out of this discussion. What

are the implications along that line, too, for inline production versus offline production practices. And I -- I'm just raising several questions that perhaps we might want to discuss during this segment.

And -- and also, to take into account that currently the California Agricultural Code does have a 45 degree limit temperature requirement. The California Uniform Retail Food Facilities Law has a similar type of requirement. They do allow up to four days of unrefrigerated time from time of lay. So in -- in the CURFFL. So I just thought I would bring these points out as -- as some of the background for some of this discussion.

MS. BALMER: Dave, could you clarify. You're saying if it's offline that they have a four day grace period, but otherwise, in a processing house if it's prior to processing, the temperature requirement is 45?

MR. CASTELLAN: Well those, and I should qualify that a little better. Some of those are -- that four day window is -- is for market, direct marketing at the farmer's markets, for example, that sort of provision is there for that.

But our -- our California Ag Code does stipulate that the temperature requirement is 45 degrees as soon as -- as possible after eggs are collected. And I think we did our farm tour yesterday, which illustrates to some of the

Panel Members, at least, or some of the Committee Members, that the demand here -- and certainly Carl and a lot of the producers can speak to this -- the demand for eggs here in California is quite high, so that will also need to be taken into account in terms of how fast the eggs are turning over, and influences this temperature requirement.

MS. BALMER: Thank you.

Carl.

MR. LOFGREN: Yes. Refrigeration has been a point that we have felt very strongly about for a long time, and we feel that refrigeration is extremely important as soon as that egg can be brought into refrigeration.

We have both inline and offline facilities. In the offline facilities, we move those eggs into a -- approximately a 50 degree cooler that holds those until they can be moved into the packing facility. Some of those small cooler rooms will even come down to 45 degrees, but in that area quick refrigeration we feel is important. If these eggs should be SE positive, we think they ought to be brought right into refrigeration without any time, if they're going to a -- a breaking plant for pasteurization.

The cost of maintaining a cooler, this is going to vary so much with the facility. If you take a new facility and you amortize the cost of the building and the refrigeration equipment, and the best we could do was

estimate, but it's going to approach approximately $100 a week to refrigerate a thousand cases of eggs. Now, that's just a rough figure, and it's going to vary considerably. But we think that's pretty much an average. Others may find that that is different, but that's what we have come up with.

Eggs do not wait long in California. They move out very quickly. There's very little holdover. Many times we're going down and collecting those egg rooms a second time a day to have enough eggs to process. So the holding time is not a big factor.

I think that pretty much concludes my remarks.

MS. BALMER: Okay.

Laurie.

MS. GIRAND: No further comment.

MS. BALMER: Okay. From the floor. Any comments about refrigeration?

I guess we'll take Don first.

MR. BELL: Don Bell, University of California.

First of all, there are no requirements in existence of pre-processing. The USDA recommends -- recommends is the word -- 60 degrees. I think, David, I think you misspoke that our 45 degree California egg program is prior to processing. It's only post-processing, our 45 degree requirement. We do not have a requirement before

processing.

The other thing I'd like to -- to make you aware of, that we don't want to take this temperature too low, and I think that's why the recommendation is at 60 degrees, is because the -- the greater the difference between the washwater temperature and the incoming egg, the more these eggs are vulnerable to what we call thermal crackage, or breakage.

And these eggs -- these are sometimes microscopic fissures in the shells, and these are not good for SE free eggs, or any contamination of the eggs. So this temperature that's been used for -- forever, for a long time, has been recommended at 60 degrees.

MS. BALMER: Okay.

Arnie.

MR. RIEBLI: Arnie Riebli, Sunrise Farms, Northern California.

On the issue of refrigeration before processing, my experience has been -- and it's over 35 years -- is that there really isn't a magic number to use. It really depends on relative humidity in conjunction with temperature. My experience has shown that if you use 60 degrees in the summertime and you've got a -- you've got fairly dry humidity, 60 degrees will not be a problem.

If you were to use 60 degrees in the winter

months, and you have a relatively high humidity, you have -- for instance, in the valley you may have fog, fog over on the coast. You will have growth of -- a mold growth taking place on the outside of the egg probably within 48 hours. It's just a contamination that appears to be on the shell or -- or in a piece of broken egg, some feces matter that's out there. It will propagate the growth of the product.

Thank you.

MS. BALMER: Were there any other comments on this question?

MR. McCHESNEY: Can I ask for a clarification on that? So would you recommend a higher or lower temperature?

MS. BALMER: That was Dan McChesney.

Can you come to the mike.

MR. RIEBLI: If you have high humidity, the lower you lower the temperature. The drier the humidity, the higher the temperature can be. And as Don said, you want to try and keep the differential -- you want to -- you want the temperature to be as high as it possibly can to preserve the product, because you -- because of the differential between the product temperature and then the wash temperature, that will get it.

MR. McCHESNEY: So my -- you would like to see this written as a range?

MR. RIEBLI There has to be a range. There is no

-- there is not a magic number.

MR. McCHESNEY: Okay.

MS. BALMER: Okay. The next question is, are there any methods by which a packer/processor can determine how old eggs are when they are received?

Start with Laurie.

MS. GIRAND: I have the impression that most of these questions are really directed at packers and processors who would understand that -- how they actually receive them. But my suggestion would be that the people that have that information are the people that have the eggs laid in the first place, and if we could make sure that that information followed the eggs and the batches were consistent, then you would have that information without the packer/processor having to do chemical analysis.

MS. BALMER: Carl.

MR. LOFGREN: I think a lot of experience here is one of the best second protections against old eggs. The first one, of course, would be the transfer of the actual date, and to track those eggs so that you know what the date is from date of lay. Eggs are purchased many times from outside sources through egg-clearing house. They usually, in California, anyway, they guarantee a certain percentage of double A eggs. You would not be able to make that guarantee if you had older eggs. It'd be very unlikely.

So by the normal methods that the AMS has used for years, looking at the -- the HAUS units and -- and the standard way of measuring eggs, plus where you buy the eggs and following with the -- with the date that the -- that they were laid. And -- and a lot of good experience on those eggs.

MS. BALMER: Do you have any experience -- I mean, you're talking about double A eggs in California, when they trade them. Do other -- do you know, have any ideas on other states, when there's trading of eggs is it strictly double A, or is it A/B grade?

MR. LOFGREN: I believe that many of the other states only use the A grade, but in California we -- we use double A and A.

MS. BALMER: Dave.

MR. CASTELLAN: I have only one comment regarding this issue, and it came to light yesterday when we were discussing age of eggs at a processing plant, where the story was recounted that stock rotation, as well, in stores or retail facilities was an issue in terms of uniform control of the product age through the food chain. So I -- I would just raise that as an adjunct idea to add to this particular point in the food chain.

MS. BALMER: Okay. Any comments from the floor? Ralph.

MR. ERNST: Just a quickie. There is no --

MS. BALMER: Name, please.

MR. ERNEST: Oh, Ralph Ernst, University of California.

There is no magic test that we can run that's quick and easy. There's no such thing as chemistry. We all know that USDA graders can -- can look at eggs and they can guesstimate how old those eggs are. But I'll tell you that I can fool them, because I can preserve the albumen quality longer if I cool the eggs faster, and if I package them or hold them in a controlled atmosphere storage.

So it is -- there is no -- it's not normally done in channels. I -- I'm not suggesting that it is. But it is done with hatching eggs, and it could be done.

So you could be fooled. There's no hard and fast rule just looking at eggs that you're going to be able to tell how old those are. You have to depend on the integrity of the source, and that the eggs are properly marked and identified.

MS. BALMER: Don.

MR. BELL: Don Bell.

The NAHMS group of APHIS has done an extensive study of the way eggs are handled in the United States. And the numbers of direct inline processed eggs is the dominant amount of eggs that are produced in the United States. In

other words, these eggs are within hours of processing when -- of lay when they are processed. The percentage of this is basically a hundred percent of everything new that is being built is inline processing. So this will automatically answer the question in -- in the very near future. And I think the number is something like 80 percent today that already answers that the eggs are hours old.

The other thing is that the older the egg is, of course, the downgrading of quality and the value, and the egg weight occurs. So these are all factors that are -- that the processor is -- is trying his darnedest to preserve the quality and the weight of his products.

So the only place where this really is a problem at the present time, especially the 24 hours, is the weekend in an offline situation, where we have only offline processing available, and we have a weekend or a holiday situation where the processing may be a five-day operation as opposed to a seven-day operation.

So I think the problem, if it is a problem, is rapidly being corrected by the use of inline technology.

MS. BALMER: Arnie.

MR. RIEBLI: Arnie Riebli.

As a practical measure, all eggs that are produced are offline -- in an offline facility, are picked up, and most of them are committed to a processing plant. The eggs

are picked up either by the processing plant or they're delivered by the producer. There's a tag that goes for those eggs. Believe me, no producer gives his eggs to a processing plant. If they have, they're on my case.

(Laughter.)

MR. RIEBLI: And the producer wants to see the grade out for that lot of eggs. There's a tag that's written for the -- for the lot that's delivered to the processing plant. That tag goes along with the lot. The lot is processed and graded. There's a grade-out sheet run, and that grade-out sheet determines what the producer is going to be paid for the product.

So as a practical matter, this is already being covered today. There is -- I don't believe that there are loose eggs -- when I say loose eggs, I mean eggs that are out there floating that don't have some kind of identifier with them.

Thank you.

MS. GEISER: Phyllis Geiser, Hawaii Egg Producers Cooperative.

Forty percent of our industry in Hawaii are inline. Sixty percent, maybe 70, are offline. But because of our economy and scale, I think we have better control over the age of our dates, because a lot of our producers are also their own packer/processors. And so even though on

some of the smaller neighbor islands where there is less population, they process maybe only three times a week, but those eggs are refrigerated and processed within six hours of collection.

So as far as any methods, we know when our eggs were laid, even though we do not process the eggs six or seven days a week.

MS. BALMER: Could you please clarify at what temperature?

MS. GEISER: Most of them are refrigerating their nest run eggs after collection less than 24 hours between 50 and 60 degrees.

MS. BALMER: No other comments?

The last question is when packing shell-eggs for the consumer, will the use of only new primary packing materials increase your marketing costs? If so, what is the estimated cost? Is there a way to clean plastic containers to prevent cross contamination so they can be re-used?

Let's start with Carl this time, from the Panel.

MR. LOFGREN: I'm not aware of anybody that's packing eggs now that's not using new material for the consumer. It may be happening, but it's not an issue in the average California market. All material going to the -- to the consumer is new material. That's a price that's built in to the cost of the egg, and so used material is not a

problem there.

Used material on the ranch would be primarily plastic material that is brought in to the processing plant from the ranch, and in all the cases that I'm familiar with, those plastic flats are immediately, after transferring the eggs, are immediately washed with a sanitized solution and spun dry, and then taken back out to the ranch.

It's difficult to judge the quality of washing on the plastic containers. It's probably very effective, but I don't know that it will take care of all of SE or not. And I guess we would say that would depend upon how well they were cleaned, and if there was any organic material left on the flat. But they are washed as thoroughly as -- as the machines that we have, and then taken back out to the ranch.

MS. BALMER: Further clarification. On that washing process is the water recycled, or is it changed at any point during the washing of the plastic flats?

MR. LOFGREN: I believe that water is -- is new transferred and then new water put in from -- from a boiler. And it is sanitized with a -- with a chlorine solution.

MS. BALMER: Thank you.

Dave.

MR. CASTELLAN: I would just like to comment that California, as well as other state departments of agriculture, promote biosecurity for a variety of reasons,

of which SE is one of them. And that it is -- SE is a component of a flock health plan that we certainly promote, and we work with the industry to promote cleanliness and tracking of materials that leave and come on to farms.

That's my comment. Thank you.

MS. BALMER: Laurie.

MS. GIRAND: How big are the flats, these clear plastic containers you're talking about in this question?

MS. BALMER: How big are the plastic containers they're referring to in this question.

MR. LOFGREN: They are just -- they are plastic flats that the eggs --

MS. BALMER: Two by two?

MR. LOFGREN: -- fit in.

MS. GIRAND: Then if it were possible to introduce some type of a heat treating dishwasher style solution, I think that would be preferable over a sanitation solution which would be less perfect, just from a temperature standpoint, and be more likely to just reduce pathogens as opposed to eliminate pathogens.

MS. BALMER: Any comments from the table here?

Any from the floor?

MR. ELSTE: My name is Chuck Elste. I work with NuCal Foods in northern California. We're an egg marketing and distribution cooperative, representing a number of

producers in northern California.

In our company's case, before I make a comment regarding the question, one of the things that I haven't heard mentioned this morning by the industry is that we are proactive in food safety, and we don't want to put any product out there that is going to be negative to food safety and human health.

And so we want to work with the government, whether that's state or federal, in putting together practical solutions to present safe products for consumption anyplace in the United States, and for our company particularly here in California.

With regard to packaging of eggs for the consumer, in our case we use only new material, and to the best of my knowledge that's a very common practice, probably 100 percent, but it is a very common practice.

And in -- in the case of the plastic material that we can only be talking about here is the flats that bring the product in from the farm, if it's an offline operation. Those are plastic flats that hold 30 eggs on each flat. If, according to the California program, if they are returned to the same farm, they are not necessarily washed going back to the same farm that they came from, if they're recycled from the same operation.

However, in our case, we do sanitize the flats,

and they are washed with a dishwasher type detergent in a machine that cleans all the flats. They're air-dried, and then they go back out to the farms.

Thank you.

MS. BALMER: Any -- okay. Arnie.

MR. RIEBLI: Thank you, Marilyn.

Well, I have a -- a basic question of Roger Glasshoff. Roger, we talk about washing eggs. My question is this. Is there scientific data that says that eggs shouldn't be washed before they are presented to the consumer? When we go to other countries in the world, we find that eggs are presented to the consumer unwashed. It's my understanding the only reason that we wash eggs in this country is because they look better to the consumer when the consumer is purchasing them at the retail level.

So my basic question is, is there a difference in Salmonella enteritidis between washed eggs and unwashed eggs? Are we trying to put a band-aid on a problem that doesn't exist? And I ask this in the same vein that -- and forgive me, Marilyn, but the cholesterol issue.

Some 50 years ago someone said cholesterol causes heart disease; ergo, eggs contain a significant amount of cholesterol, they are a cause of heart disease. It's taken the egg industry 50 years to disprove that mythology.

So my question now becomes of egg washing, where

is the scientific data that says that eggs should be washed before they are presented to the consumer?

Thank you.

MR. GLASSHOFF: This is Roger Glasshoff, with FSIS.

There has not been any research done recently, but we can go back to the 1950's, 1960's, and there are a number of projects that were completed by USDA, ERS, a gentleman by the name of Moats, and he did not specifically study SE.

However, he did study the migration of microbes through the shell and the membrane. And yes, foreign countries do not require the washing of eggs. There's an argument that once you wash the egg you remove the cuticle on the exterior of the shell. But in the same respect, if a -- the eggs are not handled under the proper relative humidity and temperature as was being discussed previously, that if there's sweating on the surface of the shell microbes will also begin to enter through the porosity of the shell, through the membrane.

I cannot be specific about Salmonella enteritidis. However, if it's present I'm certain that it would migrate as well as any other specie of Salmonella.

MS. BALMER: Okay.

Pat.

MS. CURTIS: Pat Curtis, North Carolina State

University.

We have recently, in the last nine years, done some research on washing of eggs, and we have found that washing does remove several layers' worth of growth off of the shell of the egg. If you look at the countries who do not wash their eggs, they also do not refrigerate their eggs and they're using their eggs up in a very short period of time.

You -- we -- both North Carolina State University and the University of California have done studies on egg sweating, and we have not found that egg sweating has caused an increase in contamination of those eggs.

If you look at the information that was just discussed in the 1950's and 1960's, and look at the way that the eggs were washed, they were using immersion washers and temperature of the egg washwater was a very important point. One of the things that we might want to consider when we're talking about if we're going to be cooling the eggs down is do we really need to wash those eggs at the high 115 to 120, which is what most of the processors are currently using to wash eggs.

The biggest problem with washing eggs in cooler water is that we don't currently have sanitizers and detergents that are dissolvable in that cooler water. We could solve that problem. We found that if you immersed

eggs that's where the problem occurred with the new spray washers. The washing, all the washing research that all of the regulations are based on was based back when we were doing immersion washers, and they just started looking at spray washers.

I think that we need to reevaluate some of that research that was done with the current process that we're using today.

MS. GEISER: Phyllis Geiser, Hawaii Egg Producers Cooperative.

I think less than ten percent of the packing material for the consumer is used -- re-used in Hawaii. And I think the re-use of packing material for consumer is limited to direct walk-in home use sales at the processing and distribution level. As far as re-using material for nest run, I think about 65, maybe 70 percent of the nest run eggs collected in Hawaii are used on fiber flats, and they're re-used. And I think the reason why is because there is no facility in Hawaii that produces packing materials. Everything comes in on the ocean from mainland United States.

So if you were to subject us to be using new material at the nest run level, I think we estimated that our cost of production would increase between 15 to maybe almost 30 percent because of our economy of scale. And our

inability to get new material in a timely manner.

MS. BALMER: One further clarification. You use the fiber flats, you do not use the plastic ones?

MS. GEISER: I'd say maybe 35 percent of the nest run eggs are collected on plastic flats. The majority are collected on fiber flats, and because we don't have clear -- major clearing houses, we have no -- we haven't had any documented biosecurity problems with returning the flats back to the source of origin, because they're not commingled between, you know, the location that they originated from.

MS. BALMER: Jill.

MS. SNOWDEN: Jill Snowden, Egg Nutrition Center.

Quality and food safety often mingle together. And washing eggs is certainly going to remove other pathogens that could be present on the -- the outside of an egg. The reason I'll emphasize that point is simply that -- that that has been a control step for, oh, I don't know how many decades ago now, that was implemented in order to make sure that other types of diseases were not transmitted in association with eggs.

And as we think about Salmonella enteritidis, which we mostly think about in terms of the interior of the egg, although I think for other reasons we need to be thinking exterior also, but we shouldn't lose sight that there are other opportunities for food-borne disease that

are currently under control, have been under control because of practices set up by the egg industry and the government.

And so an integrated approach on this whole issue is important. Although we're looking at SE reduction, we certainly wouldn't want to lose any of the ground that we've gained in terms of protecting the food -- protecting the egg supply and protecting public health.

So we need to make sure that we don't drop out any concepts here, such as washing eggs and -- and other things like that, that protect the food supply.

MS. BALMER: If there are no more comments at this time, we still have a little time on our schedule, and we might want to look at Question Eight in the Federal Register, and that was, where vaccines have been used, is there a correlation between vaccines and reduction of SE in eggs?

Can we start with the Panel first. Dave.

MR. CASTELLAN: I think that I'll not comment on this, but leave it to some of the experts in the audience for right now.

MS. BALMER: Okay. Carl.

MR. LOFGREN: All I would say is that we're very interested in what the vaccines may provide for us. At this time it seems rather uncertain, and enough work hasn't been done on it, and we have not started using it. But we

certainly would keep that as an option open, and undoubtedly if we had a recontamination we probably -- I shouldn't say we probably, I'm quite sure we would test it out and see what it would do for us.

The records, the information that I have seen indicate that vaccines appear to be quite effective, and there's a lot of difference in the cost. The difference between maybe three cents for a live vaccine to ten cents for a dead vaccine, and so that's -- that's quite a significant. We don't -- we don't have that information yet to use it at this point.

MS. BALMER: Okay. Laurie.

MS. GIRAND: Sounds as though we should be looking for data -- for data from other countries at this point.

MS. BALMER: People on the floor.

MR. MIRANDE: Mr. Lofgren is right.

MS. BALMER: Name.

MR. MIRANDE: Excuse me. Armando Mirande, with Biomune.

Vaccine usage definitely has correlated with the decrease in SE in eggs. That's the question number eight. The company I represent developed a vaccine that was licensed in 1992. There was a similar meeting to this when the pilot project was originated, when a panel like yourselves asked the allied industry to develop an effective

SE vaccine.

The vaccine was developed, was licensed in record time by USDA, APHIS, and has been used on and off. Originally it was used by some companies on an ongoing basis from the -- from '92 on. In different regions it took, you know, a little bit longer for the usage. In Pennsylvania it started being used at very significant numbers until 1997. It was used before in the Midwest.

And believe me, just like the Statue of Liberty says "give me your tired, your oppressed, your persecuted", we've been giving the worst flocks that you can imagine, the ones in houses that have always been SE positive, and the vaccine has been tested under all possible circumstances and the results are extremely positive.

To the best of my knowledge, there's yet to be SE positive eggs detected coming from vaccinated flocks. The number of SE positive environmental samples coming from vaccinated flocks are incredibly low, which is what the producer wants to know. Whether is that relevant or not of the issue of egg safety, whether positive environment correlates to positive eggs, that's another issue.

But that's how the egg producers are being regulated, based on the environment. And even in the environment the results are extremely positive. Of course, this is coming from a guy who works for a vaccine company,

but the data comes from egg producers themselves, it comes from the Pennsylvania Department of Agriculture. They do the testing, they do the monitoring. You don't have to listen to me, you can ask the producers that have used the vaccine. Believe me, this is a very competitive industry which would not spend a single penny for something that does not work.

We have repeated customers that have used the vaccine. They know what kind of problems they had before they were vaccine users, and what kind of problems they have now. And the vaccine usage increases every year.

MS. BALMER: Okay.

MR. MIRANDE: Thank you.

MS. BALMER: Ken.

MR. KLIPPEN: Ken Klippen, with United Egg Producers.

MS. BALMER: Okay. Could you start again?

MR. KLIPPEN: The journal is Food Microbiology, 1996. The article is entitled "Growth of Salmonella enteritidis in egg contents from hens vaccinated with an SE Bactrine." The primary researcher was ARS, Dr. Peter Holt. He was assisted by Drs. Stone, Gast, and Porter.

And what this study did was, it compared eggs from vaccinated and non-vaccinated hens, and they took eggs from each group and then they pooled those eggs, inoculated them

with a low level of viable SE organisms, and then incubated them for growth. And after incubation, there were a hundred million SE organisms per milliliter in the non-vaccinated group, and only 100 SE organisms per milliliter in the vaccinated group.

So that demonstrated a one-millionfold reduction. So we see this as promising research, and we're looking for more development.

MR. MIRANDE: Again, Armando Mirande, Biomune.

I'm very familiar with that study, and the -- I have nothing against in-shell pasteurization, but it's a process offered in the Strategy Two, and they talk about a five log reduction. I do not know the scientific validity of requesting a five log reduction when the most probable number of SE organism in a naturally contaminated egg is ten. Below one log, I don't know, you know, why you need five.

But that study showed that vaccination, because of the activity of antibodies, reduced the growth of SE by six logs. And yet it's not mentioned as an intervention in the plan.

Thank you.

MR. GEMPERLE: Stephen Gemperle.

I have a limited knowledge on vaccines. In our company we currently do not use it. If it becomes part of a

national program, it's probably an effective step in reducing the problem on an infected farm, but I believe it would be a costly mistake if it became mandated that, as I heard happening in Canada, where all farms were forced to do the vaccination.

In a poultry farm there's a number of things that you vaccinate birds for, and you vaccinate them for the challenges that they receive in their life. And in a lot of farms, SE is not a challenge that the birds are being introduced to.

So to have a blanket vaccination policy for the entire U.S. would be a mistake, if that's what came out.

MS. BALMER: Okay. Carl.

MR. LOFGREN: I would concur with that. It may be an effective tool, but I would not encourage mandatory across the line vaccination use. I think it could be very effective at some time.

MR. MIRANDE: Yes, Armando Mirande.

In Canada, the mandate vaccination is only for pullet flocks going into a previously positive environment. That's -- that's the only mandatory vaccination step.

MS. BALMER: Are there anymore comments?

Okay. This will conclude the morning session.

We'll take an hour for lunch. Somebody in the department supplied us with a list of restaurants in the

area.

There is Vegas, which is an Italian restaurant at 14th and O. Looks like Vallejo -- Vallejo, which is a Mexican, at 14th and O. And also at 11th and O, there's a deli at 11th and O, a deli at 13th and O, a Japanese at 12th and S, and apparently there are many on K Street between 7th and 12th. The quickest way to get to K Street is to walk through the park.

We will reconvene at 12:35.

(Thereupon, the luncheon recess was taken.)

AFTERNOON SESSION

MR. McCHESNEY: Well, good afternoon, and welcome back from your lunch.

I'm the Moderator for this afternoon. My name is Dan McChesney. I'm with the Center for Veterinary Medicine of FDA.

And the format we will follow this afternoon is the same as this morning. There'll be presentations this afternoon on Egg Products Processing. Then we'll have an open discussion period. Retail/Food Service and the Consumer, then follow that by an open discussion. Then Regulatory Impact Analysis, which is an economic presentation. Then we'll have a break. Then we'll have some -- a section on Research, then we'll have open discussion on research.

And we'll end up the afternoon with an open microphone. And currently, there's a list of -- I'm not

quite sure how many, but it's -- it's two columns on a sheet of paper of people wanting to make presentations at the end of the day. So it's probably going to be about five minutes a statement, or less. I haven't looked at it very closely yet. And then if we have more time at the end, we can, you know, you can come back and make a follow-up statement if you want.

But I would ask you just when we're having the open microphone this afternoon to limit -- to respect everyone else's presentation time, and to limit your remarks to whatever time we have to set. And the time is -- we're going to set the time by just doing the math, taking the total time available and diving it by the number of presenters. So everybody'll get an equal time.

Our first presentation this afternoon is on Egg Products Processing, and it's by Roger Glasshoff of FSIS.

Roger.

MR. GLASSHOFF: Well, I'll try to pay more attention to the slides this time.

This morning we spoke about Strategy One within the Egg Safety Action Plan, and this afternoon we're going to address Strategy Two. And, of course, the principal difference is that under Strategy Two, the eggs are processed in a manner to destroy Salmonella. Of course, the Egg Products Inspection Act, which was implemented in 1970,

requires that all egg products be pasteurized.

As part of the Egg Safety Action Plan, FSIS is proposing to convert its egg products inspection program to a HACCP based inspection program. We're currently in the process of developing proposed regulatory changes, and it's likely that the timeframe will follow much as the proposed regulatory changes for Strategy One, which addresses the production of eggs at the farm level, as well as the shell-egg processor.

The approach which the agency is taking with regard to incorporation of HACCP into the egg products inspection program is to focus more upon the development of regulations which include performance standards and are science-based. These proposed rules will focus principally on allowing the processors more flexibility and innovation. They will change from prescriptive requirements. Under HACCP, the focus is directed upon verifying effectiveness of the processes and the process controls to ensure food safety.

With the revisions to the egg products regulations, and incorporating HACCP as part of the inspection program, FSIS will correlate meat, poultry and egg products inspection. The entire agency will then utilize HACCP in its inspection program, and have a correlated process and consistency and uniformity for

interpretation throughout its field operation staff.

Under HACCP, each company will be responsible for developing a HACCP plan. That plan will also include addressing prerequisite programs such as a sanitation standard operating procedures. Those procedures, or that particular standard was written and is available on the Web site of FSIS. It addresses things such as maintaining facilities, equipment, use of various cleaning and sanitizing compounds, and health and hygiene, as well as many other items. Each HACCP plan will be tailored to the individual company, and the processes utilized at that company. As I said earlier, it provides for a flexibility and innovation, and it is not prescriptive.

In development of a HACCP plan, a hazard analysis is conducted. There's an identification of critical control points necessary, establishment of critical limits to determine that those control points remain under control during processing, establishing monitoring and frequency, documenting corrective actions, establishing verification procedures, and, finally, one of the most important aspects of HACCP is record-keeping and documentation.

The agency is interested in the cost of implementing HACCP, including documentation to demonstrate compliance on a continuing basis with Sanitation SOPs, and established performance standards. For development of

performance standard for the pasteurization of egg, we are still seeking information on the enumeration of Salmonella in liquid eggs prior to pasteurization. There is some research available which we're currently evaluating. It's being conducted by United Egg Association. And we're also utilizing the risk assessment that was developed and published in 1998 by the agency with regard to the risk of Salmonella enteritidis in eggs.

This is perhaps the best example of eliminating the prescriptive aspects of the regulations. Currently, we have time and temperature requirements for pasteurization. Upon revision, it will be determined that there is a performance standard to be met to destroy Salmonella in egg products, and that performance standard may say, for example, that the product must be treated in a manner to destroy seven log, or demonstrate a seven log reduction in Salmonella. And then the company would be at liberty to implement whatever processes are acceptable, and demonstrate scientifically that they are producing a safe product.

The producer is responsible for implementing the components of the prerequisite programs. And with regard to prerequisite programs, we are seeking information on whether or not environmental testing would be a valid component when eggs are to be diverted to egg products processing plants.

Refrigeration as an intervention for microbial

growth when eggs are not processed within 24 hours from the time of lay. Currently there are no refrigeration requirements from the producer level to the processing plant. Would refrigeration temperature be necessary to reduce the risk associated with Salmonella enteritidis.

We are also interested in the impact of eliminating the re-use of fiber and pulp packaging materials. I think we heard this morning that in many situations, it is good used or new packaging materials. However, there are other situations where there are carts, pallets, and so forth, that are being utilized. Each plant will be responsible for addressing the cleanliness of that material in their HACCP -- or their hazard analysis.

The Egg Safety Plan as described will require diversion of eggs from SE infected flocks. Those eggs, of course, would be destined for some type of a pasteurization process. It would require notification of USDA at the breaking or the processing plant for monitoring purposes, to assure that the lot that was identified and the quantity shipped to that processing plant was, in fact, pasteurized. We are aware that there exist some customer specifications which restrict the use of eggs from SE infected flocks even in the production of egg products.

With the timeline -- the proposed rule, as we heard earlier, should be through clearances and published in

the Federal Register by the end of fiscal year 2000, which would be October. Then a final rule would follow. Of course, implementation would be defined in the final rule. That is projected for 2001.

We wish to urge industry in their assessment of HACCP to utilize the publications that are already available from FSIS. In many cases, egg products will, in essence, be incorporated in some of the performance standards that already exist for meat and poultry are generally applicable to the entire processing programs.

As I said before, the Internet is accessible. The Internet is listed here, and a good example to begin evaluating is the Sanitation Performance Standard. As we proceed with the rulemaking and implementation of HACCP, it is not entirely unfeasible that we will develop some generic models as guidelines. Many of the materials that exist today that are prescriptive, such as the instructions for inspectors in the field, will also be rewritten or revised to reflect more or less a guideline on how to process egg products.

With that, I would like to move on to the alternate procedure at this point, that we are aware of, that will allow the destruction of Salmonella in-shell-eggs. That is referred to as in-shell pasteurization.

Again, we would envision through rulemaking that

this would be a HACCP based system, utilizing the components to maintain sanitation in facilities, food-handling practices, et cetera. The eggs that are diverted to this type of operation would be shipped under refrigeration. The proper controls, such as written description of the identity and the lot, would be necessary to maintain its processing and identity as finished product.

Again, a science-based valid process would be applied that would meet the performance standard established for the destruction of Salmonella enteritidis, and would assure no microbial growth subsequent to processing. The integrity of the product must be maintained during distribution. This could be maintained by placing the product inside of a container that is sealed in some manner, and/or identifying each individual egg. Other concepts, of course, could also be considered.

We want to ensure that those eggs are not mixed once they reach the retail level, that they maintain their identity for the consumer. And, of course, the package would meet all labeling criteria necessary for shell-eggs as defined by the Food and Drug Administration and our agency.

I mentioned proper controls. Part of that responsibility would be the documentation by the company, which would assure that it is being processed properly. Conformance on a continuing basis, which would be reviewed

for verification purposes by the FSIS field operations staff. The oversight of the HACCP based system would be maintained, of course, by the company. USDA would monitor these type of operations to assure that the product was properly pasteurized. The frequency of determining such oversight and verification by USDA at this time has not been determined. Under our surveillance program, these type of operations, as well as shell-egg packers, would be subject to the minimum requirement as stated in the -- the statute, which is a visit quarterly to demonstrate conformance.

With that, I guess we'll turn it over to the questions which were selected. If there are any further questions, I would urge you to present them during our discussion later this afternoon.

MR. McCHESNEY: Thanks, Roger.

What we're going to do, just so there aren't any real surprises for people this afternoon. In this section there are three questions we're going to deal with. And in your -- in the rule, they're questions nine, which is the one you see up there now; question eleven, which says do customer specifications exist that prohibit the processing of SE eggs or for-egg products, considering your production volume and available market for egg products, will this influence the price of eggs; and 17, are the proposed comments on the national standards for packaging and

processing of shell-eggs and egg products appropriate and adequate to reduce the risk.

And what I would like to propose that we do is that initially we allot 20 minutes to each of these, so we won't really short-change any. And then if we have time left over at the end, we can go back and discuss any question you'd like. But we'd like to get as much -- we'd like to get input, all your input on all these questions, but we'd like not to short-change any particular one.

So it's 1:00 o'clock, if I can see the clock correctly there, so we have until about 2:00. And I'll keep a rough track of time so I'll -- may ask someone who's up there at the end of 20 minutes to -- if we could just hold the question, or if they could hold that question.

So the first question here, which is number nine.

"In the event eggs from an SE positive flock -- layer flock are diverted from the table egg market, what measures should be implemented to ensure those eggs are pasteurized?"

Let's start that one, which is in my mind sort of a regulatory type question, we'll start with Dave, over here on our Panel.

MR. CASTELLAN: Thank you, Dan.

Some of the issues that this problem raises will include the following. Which agencies take the lead? This

will be different in different states. And how to ensure that these eggs are being diverted is certainly a key question, and that assumes allocation of resources and personnel.

But I'd like to focus on responsibilities in two different situations. One would be an on-farm testing situation, where -- where a positive comes up. Obviously, there is a lag period with our present technology, in terms of our isolation of Salmonella, and I think I'd like to return to a point I made earlier about the need for a rapid test on-farm to allow people to react quicker. But this is one of the -- one of the lag periods we have to deal with at this point, and take that into consideration with some of the interpretations of what a positive means on the farm, and the need to follow up with corrective actions and repeat testing.

The second situation really deals with a trace-back situation, and I get involved in these from time to time when they do occur. And timeliness of reporting by public health is not an insignificant issue. If we're really concerned about public health protection that has to be addressed, and I think that that is -- that is a question that needs to be taken into consideration along with what goes on at the farm, in the big picture.

Thank you.

MR. McCHESNEY: Thanks, Dave.

Carl.

MR. LOFGREN: I think that there is a question as to what will be the standards for diverting the eggs, and if -- if these are truly positive flocks and established without any question, then I think there should be no question that those eggs are tagged and moved into the breaking plant, and they're followed all the way through -- there shouldn't be any gray area here -- to eliminate any liability they might have.

The question would come up if you don't know for sure, and you move some of those to a market, then you have to have a trace -- a recall, or a trace-back, and that adds a lot of extra work to the program.

So going to the breaking plant labeled, tagged, restricted, is the measure that we certainly believe should be done.

MR. McCHESNEY: Thanks, Carl.

Laurie.

MS. GIRAND: Laurie Girand, STOP.

As I had mentioned earlier, I think these eggs should probably be marked externally, because one of the biggest problems that I see with the invisible pathogens is that people can't see them and so they don't know which ones are which ones, which eggs are which ones, necessarily.

And I would -- I would include that we really do need trace-back mechanisms through pooled eggs of any sort, and that manufacturers of pasteurized eggs, or pasteurized and/or pooled eggs of -- of whatever manner, need to be keeping track of their batches and what the sources of those batches are.

MR. McCHESNEY: Let me ask the Panel a question here, just as a clarification. I mean, you -- I think you've all answered the questions from the point that these should be sent to a breaker. But the question really says to ensure these eggs are pasteurized. Would anyone be opposed to in-shell pasteurization, if that was a feasible means?

You don't have to answer in sequence. Anyone can jump right up over there.

MR. LOFGREN: I would say that if that becomes an established, proven, effective economical way to do it, yes.

MR. McCHESNEY: Go ahead, Laurie.

MS. GIRAND: Are you expecting that -- are you expecting that standard -- let me ask you a question back. Are you expecting that standard to be equivalent to other types of pasteurization? In other words, if you're getting -- I think Roger had mentioned the seven log kill was what you were looking for. Is that what you're expecting to see in the in-shell pasteurization, or the equivalent level for

the size of the egg, and what-not?

MR. McCHESNEY: It's -- yeah. Pasteurization is normally defined as a five log reduction. So the answer to your question would be yes, we would think as equivalent pasteurization.

MS. GIRAND: I'm sorry, what --

MR. CARSON: The in-shell pasteurization is a five log kill.

MS. GIRAND: Okay. And the other eggs are being done to a seven log kill; is that correct? That was -- or is this a volume issue?

MR. GLASSHOFF: The egg products, research that was done many years ago projected seven to nine log reduction in many areas of -- or, I should say, categories of egg products that are produced. That including the plain eggs, as well as eggs with non-egg added ingredients. Current research has shown in some areas that we're not achieving that high of a reduction. And we're utilizing that research data to make a determination in development of performance standards for the future.

There is some concern with respect to two categories of egg products, and although that particular research has not been completed, the performance standard to be achieved for the other categories of products, as they are currently processed, would be adequate to destroy

Salmonella.

MS. GIRAND: Part of the reason why I asked is I had a conversation with a former FDA person about three weeks ago, about -- actually, I guess it was three months ago, about pasteurization of eggs in particular, and he indicated that it was five log that was the standard nationally. But at any rate, my -- my point would be just along the lines of what Carl said, that we'd like it to be equivalent to whatever the higher standard is, and that we would support something that was of a higher standard as opposed to something that was sort of yeah, it worked a little bit, but it wasn't quite the same.

MR. McCHESNEY: Okay. That's a good point.

MS. RIGGINS: This is Judy Riggins.

Just to add to what Roger just said. We are looking at the current scientific information in order to make a determination about how we would propose the performance standard for pasteurization of liquid eggs. However, keep in mind that seven to nine log kill that Roger spoke about is for all organisms. The five log kill that we've referred to, which is the current state of the science, is for SE alone. So you have to take into account all the other organisms that might be present in a liquid -- in the liquid egg after breaking.

MR. McCHESNEY: Are there any other comments from

the Panel?

Okay. Let's open to the floor for comments. Don't everyone jump up at once.

Please state your name.

MR. DAVIDSON: My name is John Davidson, and I'm with Davidson's Pasteurized Eggs.

On the subject that you were just discussing regarding seven logs for all pathogens, versus five logs for SE or any other of these strains that may be significantly heat resistant. Our process is established at the five log level. For everybody's information, we will be going to market for the first time in two weeks in Ohio and Pennsylvania, followed by going to market in several major retail chains between New Jersey and Georgia immediately thereafter. We'll also be in the food service market through SYSCO and various others at the same time.

The -- the process produces an egg very inexpensively, in relative terms, we believe less expensively than liquid product. We use only prime eggs. We do -- at this time we're not even considering using any diverted eggs. The -- the process includes maintaining a zero bacterial count in the water bath. It is a water bath we use. It includes putting a protective sealant on after pasteurization. It includes chilling the internal temperature of the egg immediately after pasteurization. It

includes using only graded eggs, USDA grade eggs initially, and then recandling them afterwards, and then it puts a mark on there to make sure that they are not switched in the marketplace.

We intend to do all sizes. We've built in a profit center for egg producers. We've built in a -- an agreed upon low markup with the retailers, voluntary. And we believe that we can deliver product at a value added that will give the consumer a choice as to whether he wants to eat only a liquid product, or a hard cooked product, and run a risk or inexpensively have the minimum risk that a pasteurized product will provide.

That's the essence of our plan. Everyone here is welcome to visit the joint facility of ISE and KoffKoff Egg farms, in Newberry, South Carolina, anytime. We'd like to know you're coming, but I think you'll find it very interesting.

Having said that, I want to question this group about raising the bar too high. Pasteurization of shell-eggs has taken us ten years to develop, and we've come out with a very good product. We've got a product that maintains its functionality, its aesthetic appeal, is low priced, and works. If you raise that bar unnecessarily to seven logs, then you are defeating the whole purpose of it, unless there is a scientific foundation for doing so.

As I understand it, all the worst eggs in the world go into liquid product. They fill in with the good eggs. The track record of liquid product, even though my understanding is that the standard is 4.4 logs, is excellent. I don't know -- I think the CDC has stated that there is no trace-back ever attributed to a liquid egg product source in 30 years. Considering all the raw product source, and the 4.4 log standard that they seem to be operating under, I think that's a superb record. And I think that shell-eggs at five logs should not be whimsically changed unless it is a good reason for it.

I know that this is not the format, but I'm going to sit down now, and I would like to hear more about the President's proposed warning labels on the egg cartons, which has not come up today. It seems to me a straightforward statement as to giving the public a choice of -- through knowledge, as opposed to some language that may not disclose an awful lot would be appropriate for the egg cartons. If the egg cartons were to simply say that eggs may contain harmful bacteria, and unless hard-cooked they may cause illness, it's a fair statement, it's an accurate statement, and it should be considered carefully.

Thank you.

MR. McCHESNEY: Thank you.

I assume we'll touch on that in some of the

consumer discussion areas.

Other comments in this area?

MR. MIRANDE: Yeah. Can Mr. Davidson define relatively inexpensive?

MR. McCHESNEY: Could you state your --

MR. MIRANDE: Yeah. Armando Mirande, Biomune.

How much does it cost to pasteurize a dozen eggs?

MR. DAVIDSON: The -- as I said, we take not discounted eggs. We take market eggs. We pasteurize them, and we provide the producer a five cent profit per dozen. We consider breakage, every cost, including amortization of the machine, and at the end of the day it -- we'll sell the egg wholesale to the food service supplier at about 25 cents, and at 28 cents to retail.

MR. MIRANDE: That's per dozen?

MR. DAVIDSON: Per dozen.

MR. McCHESNEY: Thank you.

Other comments, other questions?

If not, we'll move on to the second question here.

The next question is Number 11. Do customer specifications exist that prohibit the processing of SE positive eggs for egg products? Considering your production volume and available market for egg products, will this influence the price of SE positive eggs?

To me, this sounds like a producer question, so

Carl, you get the first shot.

MR. LOFGREN: I am not aware of any customer that would not accept properly pasteurized eggs as -- because it had been SE positive. There may be some, I'm not aware of them.

The influence on the price, if there happened to be a lot of diversion and breaking plants were not available for taking those eggs and running them through, there might be some reduction in the value of breaking stock if there was a large quantity. A small amount would not affect any, in my opinion.

MR. McCHESNEY: Thank you.

You're up.

MS. GIRAND: Well, I'm actually afraid I'm at a loss, because I probably don't eat this style of egg often enough to really understand where it would be served. I'm assuming that if it were properly pasteurized, that consumers would probably eat it. But beyond that, I don't really have a sense for where it would be served or how it would be served.

MR. McCHESNEY: These are largely, I believe, the liquid egg products we're talking about that may be institutionally used, or sold in cartons in food stores.

Dave.

MR. CASTELLAN: Yes, Dan. I don't have any direct

comments in this, but I'm sure there are some people in the audience that are some of the people who deal in the -- this area that would have some comments about it.

MR. McCHESNEY: Comments from the audience. Would someone like to make a comment?

MR. BELL: Don Bell, University of California.

As you know, we've been gaining about one percent more of our eggs going into breaking products of this type every year, and we're now a little over 30 percent. And the existing breaking plants, of course, have a certain capacity. And we might look at the fluctuation in monthly breaking is less than five percent, so it's a fairly uniform monthly occurrence of breaking so many eggs.

The problem is that the breaking industry is geographically concentrated in the midwest. And in a great state like California, the one that you're sitting in today and enjoying the weather and everything, we are limited in our breaking capacity. We import liquid eggs, and so on.

So if diversion became a geographic problem, such as in the state of Pennsylvania, when -- in the heart of this thing, or in southern California, whatever, and we got into a very heavy diversion situation, there physically would not be enough facilities to break these quantities of eggs. There's not that much flexibility in the entire system.

MR. McCHESNEY: Could I ask a follow-up question, Don, while you're there?

The -- would there be concerns by processors, do you think there would be concerns of processors of these products that they might contaminate their plants?

MR. BELL: Yes. We are very concerned about vectoring disease from one site to another. People are concerned about trucking, about the racks, about these filler flats, and what have you. And they may be -- they may be justified in these concerns, or maybe not. But they are still going to be based upon what they think. And we have, in recent weeks have had to deal with avian influenza, a small outbreak in southern California, and this did affect the acceptability of these products from one plant to another.

And so you cannot blame a breaking plant in a isolated area just to say no, that we will not accept these regardless of what you tell us or what you -- what safeguards you've taken, just say no. We have enough eggs already, we don't think we should be into this loop, and the last question about affecting price, obviously, it will. If you can't sell eggs, it will affect price.

MR. McCHESNEY: Thank you.

Other comments?

MR. LOFGREN: I would like to add that if a

breaking plant would not take those eggs, and the producer then would be stuck with them, in the California scene you cannot just put eggs in any landfill. It's very difficult to find a place that will take liquid eggs, or broken, discarded eggs. So that would really create a problem for the person who was near a breaking plant that would not take them.

MR. McCHESNEY: Would they -- since I spend a fair amount of time dealing with animal feed issues and pet food issues, would that be an -- would you see that as an outlet, maybe thinking ahead on the question, instead of trying to send these to the human liquid egg market, that they might go directly to pasteurization for animal feed uses and pet food uses?

MR. LOFGREN: My belief is that the current market for pet food is saturated, and there's very little that can be done. It costs about as much to handle it and get it to them as it's worth. If it were developed it might be an opportunity, but I think it'd be difficult.

MR. McCHESNEY: Thank you.

Other comments? Something from anyone around the table?

Moving right along here. We'll go on to the third question.

Question 17, are the proposed components of the

national standards for packing and processing of shell-eggs and egg products appropriate and adequate to reduce the risk associated with SE? And we're asking you here to all draw on your fabulous recall memories and think of all the points Roger put up here this morning in his two presentations. So if you have something, you may want to ask Roger to, you know, come back with a couple of points.

But this, I think, is, of the series of these three questions, is probably more a consumer oriented question, because it's largely -- there's truly a science component to it, but it's one of -- it's also an issue of perception. Are we doing sufficient.

So, Laurie, you get the first shot at this one.

MS. GIRAND: I'd say the answer would be no, and based on what I know of HACCP and how it's been -- or it's been proposed in other areas, I'd have several concerns. The first would be that we need mandatory minimum standards across all states. Granted that Hawaii seems to be a very special case amongst the -- the 50 states, or 49 states. One of the biggest problems that we see when we look at HACCP regulations is that the SSOPs usually get this sort of brush-off, like well, you've got SSOPs in place, now let's talk about HACCP. And we find that frequently in processing plants, that's the place where things fall down and introduce contamination or contribute to the spread of

contamination.

And so we would like to see mandatory SSOPs, not every state gets its own favorite flavor of an SSOP. And we'd also like to see, like I said, that all standards be applied equally across states.

As somebody said, it's very hard to sanitize a dirt floor. Well, you know, I'm sorry, but it doesn't sound to me like that's a very sanitary operation, and if you continue to allow that because the state of -- I don't want to pick on any state, but some state in particular allows dirt floors and others don't, then you don't have minimum standards across all states.

I think also fundamental to all of this is incoming product testing, because just as you were saying about the plant, if you find a large volume of product is coming in that needs to be pasteurized, or a rather large volume of contamination is coming in, it's possible that seven will never be successful, log seven wouldn't -- process wouldn't sufficiently meet the needs.

On the other hand, if you're using some new fancy pasteurization method and you're taking the eggs instantly and they've all come -- and they've only got ten organisms per egg in them, then you've got a different level of contamination you're dealing with.

So I think that incoming product testing is really

very important. And then, of course, final product testing, as well, would be -- would be critical in order to determine whether or not the pasteurization method was working.

Lastly, I think one thing that hasn't been introduced in any of the industries that I work with is some level of inspection, or a heightened level of inspection for repeatedly -- repeated failures within any particular program or processor, what have you. And we believe you need to be inspecting where there is a lot of failure.

And when we've got people that at least say they're never seeing a negative and hopefully they're testing according to what the recommendations have been, we're hoping that you're going to be inspecting the people that are dirty, and not just sending one in to every plant every ten years, regardless of what the quality of product is.

MR. McCHESNEY: Thank you.

Dave.

MR. CASTELLAN: I think, in terms of something I haven't heard addressed here, is just what is the effectiveness of our current washing and sanitation, and I suppose that ties in with the performance standards that you're hoping to develop in this area. And are improvements possible, and are they needed. And in terms of looking at all options, and not just in-shell pasteurization, but

really assessing what we do -- do right now.

And -- and I think in terms of setting priorities, if we check eggs have come up a number of times today -- and there are Canadian studies and a number of studies overseas that indicate that these are at a high risk -- and so do we need to prioritize in terms of addressing some of these issues that are there and obvious, and tackle those in -- in the first place.

And, yeah, that -- those are my comments. Thanks.

MR. McCHESNEY: Okay. Carl.

MR. LOFGREN: Do I assume this correctly, that this is a question asked of a monitored type of HACCP program, that this will be different than the program we're on now?

MR. McCHESNEY: Well, the answer is it doesn't have to be. We're still in the process of developing this.

MR. LOFGREN: I find this question extremely hard to answer, because I don't know what the -- the ramifications are going to be, how it's going to be set up, and then if we violate or get out of the control standards, exactly how it's going to be administered once we find we're out of conformity. And so I -- I don't know. I think it's adequate to reduce. I mean, I think that statement if correct.

MR. McCHESNEY: Okay.

MR. LOFGREN: But whether it's going to meet all of our requirements, I -- I guess I would not be qualified to comment on that at this time.

MR. McCHESNEY: Okay.

Someone around the table from USDA want to take a shot at this one?

MR. GLASSHOFF: This is Roger Glasshoff, with FSIS.

I think the intent of this particular question was again to focus on the components that will be used in the development of performance standards, and what is anticipated in development and assessment doing a hazard analysis, put a hazard-based inspection program in place. And with that, coupled with the components that are utilized at the producer level, would that, in fact, allow for reduction of SE.

MR. LOFGREN: Well, I believe that it will reduce the SE substantially, and I think it's a program that must be administered equally across the country, as it's been already discussed. I think that is a very important factor in it. If it would be administered by states that are allowed leave-way, then -- to do things considerably different, then that would probably be a difficult thing for the producer in other parts of the country.

We've seen the standards and the continuity that's

been demonstrated by AMS as a grading type of operation, and we think that is very good. It's very steady. I don't know how that would fit in to this program, but it needs to be some kind of a program like that that gives us a equal playing field across the country and is effective in its Salmonella reduction.

MR. McCHESNEY: Thank you.

Other comments from the floor -- not other comments, but comments from the floor? Have the mike.

MR. DAVIDSON: We -- we have conducted --

MR. McCHESNEY: Excuse me. Could you identify yourself.

MR. DAVIDSON: I'm John Davidson, of Davidson's Pasteurized Eggs.

We have conducted extensive studies with regard to the European standard of not using water and washing eggs first, as well as our own, as well as using chlorine or ordinary solutions, and done a comparative analysis on them. And one of the specifications that we will have for our licensees as a result of those studies is that they have to change the water more frequently at the wash cycle in the grading plant, because the bacterial counts that we're experiencing on the shells prior to pasteurization are higher than they need to be. And they vary quite a bit, depending on the -- the protocol of the producer, but in

general, it's a risk that can be avoided, and is unnecessary to take. And it's a very simple change in -- in your work to consider that as a beneficial change.

Also, I might add that we've been talking about everything that really creates cost to the producer. And the more eggs that are diverted by that producer, forced into liquid, such as eggs that are the result of avian influenza, infected flocks, or anything of that nature, all cost the shell-egg producer substantial sums of money. With in-shell pasteurization, they can maintain their -- their current pricing and not have to wholesale them off, as they frequently are forced to do. So when you're doing your cost analysis, there is all sorts of offsets that should be considered in what you come down to.

With regard to the -- the cost of product, we -- we've got to consider the $2 million that the -- that your own agencies consider the cost of illness from SE. And we've got to consider whether SE is the only strain. Suddenly we've forgotten about all the other strains that existed before 1985. And -- and we've got to focus on the language we use being understood by the public in general, and whether we're leading them down a primrose path as to what it is they're really eating and what the degree of risk is. There's much clearer language available.

But that -- thank you.

MR. McCHESNEY: Thank you.

Other comments from the floor?

I think a couple of things struck -- just a second. There's a couple of things struck me here, while it's still on our minds, is that it seems like we've heard some real opportunities for research here for our university types. Heard looking at washwater and the effect of it, and different compounds in it to be more effective. And also, there was question over here of just what is the load in an egg that's infected, is it ten organisms or is it a hundred organisms, or is it 10,000 organisms, all of which could really impact the need for -- the stringency of the pasteurization.

So I think there's some good research opportunities in there.

MR. ELSTE: Chuck Elste, with NuCal Foods here in northern California.

This question deals with the standards for packing and processing of shell-eggs and egg products, and asks are they appropriate and adequate to reduce the risk associated with SE.

For years, the egg industry has brought to the attention of regulatory agencies, including USDA, the issue of the use of centrifuges to break eggs. In the centrifuge process, the whole egg is put into a tub, broken through a

centrifuge process with the liquid extracted. That puts the liquid egg in contact with potential contaminants on the surface of the shell. Twenty-two states have outlawed the use of centrifuges. I'm sorry to say that California is not one of them, and we have a centrifuge right here in this city that is operating in their baking plant.

There are several of them in use. Two weeks ago, at a retail bakers trade show in Washington, D.C., a centrifuge was displayed as an item for sale for use by the baking industry.

My question, I guess, directed to Roger or whoever, is, is the issue of centrifuge going to be covered in this protocol that is going to be established?

MS. RIGGINS: Judy Riggins, USDA.

I think Lou and I will do a one-two step on this one.

With respect to the use of the centrifuge in situations where they're being used to pool eggs that are going to go into pasteurization, which would be USDA's jurisdiction, we are -- when and if we institute HACCP, the microbial contribution that would be contributed by the use of that technology, of that centrifuge machine, would need to be taken into account at the time that the company does its hazard analysis, and its HACCP plan, would then need to reflect the steps that it needs to take in order to validate

the temperatures and the times that it is -- that product would be exposed, you know, to the thermal step in order to kill any bacteria that might be there.

So in -- in the pasteurization plant, if that's -- if they're being used there, they would be covered under HACCP in the hazard analysis, and in the HACCP plan.

Now, with respect to its use in bakeries and other manufacturing processes, and in institutions and restaurants, that would be FDA, and I'll let Lou speak to that.

MR. CARSON: Yeah. Lou Carson, FDA.

Our next segment, which will be taken on by Nancy Bufano from FDA, will talk about retail and the standards which we are going to propose at that level.

Basically, the standards there would require that pasteurized product be used unless there would be an immediate use of those eggs that are broken. So in the case of centrifugation and pooling we would require pasteurization, and that's what we're going to be proposing so that we would eliminate that possibility. I don't think we're going to per se talk about centrifugation. We're going to talk about all pooling of eggs.

And so that's how -- we're going to be proposing that, and Nancy will detail those points in the next segment. So we are trying to take that into account at the

retail, as well as what Judy just said, at the processor end. So I think we will be devoting some attention to the points you just raised.

MR. McCHESNEY: Other questions?

And I think what I heard Judy and Lou say really go back to the question that was asked earlier over here, what level do you need if you've got a low level of contamination in an egg, that may be D-5, or whatever D value you pick is fine. If you have a high contamination level put in, then it may not -- may not be adequate. You may have to look harder at it. And that's in your hazard, it would have to be something in your hazard analysis.

Roger.

MR. GLASSHOFF: I just wanted to clarify one thing. In egg products processing plants, we have restricted the use of centrifugation, and that is principally because the statute requires inspection of individual -- the contents of individual eggs. So we -- we don't allow the use of the centrifuge for production of human food at this time, in egg products plants. However, that's not to say that there isn't technology out there that can be developed that some time it might be presented for evaluation. But currently, it's not allowed for use in USDA egg products processing.

MR. McCHESNEY: Okay. Thank you.

Other questions or comments on this area?

Yes. Please state your name when you get to the mike.

MR. KLIPPEN: I'm Ken Klippen, with United Egg Producers.

Going back to the question on the proposed components of the national standards for packing and processing, are they adequate to reduce the risk associated with SE. If I understand the promulgation of the rules, you do have an exemption for flocks of less than 3,000 hens.

Now, that being the case, there are a number of eggs that are sold that would be exempt from any of these proposed standards that are going to be applied to the bulk of the industry. And that doesn't represent the large number of layers, but it represents a substantial number of eggs that actually make it into the marketplace that won't have these same sort of rules.

And so the question is, is this -- by allowing this exemption for the 3,000 or less layers, aren't we opening ourselves up to potential problems associated with that?

MR. McCHESNEY: Someone around the table want to take a shot at that one?

MR. CARSON: This is Lou Carson, at FDA.

Within the Egg Safety Action Plan, and using the

mass data from 1997, we looked at what represented approximately 98 to 99 percent of the industry in-shell-eggs. And in all cases, they exceeded 3,000 layers or more. We recognize that it isn't 100 percent. We would offer at this time that if you do not believe that it's an appropriate cutoff, then to make comment that we should cover all egg producers, and that's certainly something we will take into account.

In discussing that with a number of professionals in the industry, that becomes a real numbers nightmare as to the number of very, very small producers who probably do not have a commercial output, but perhaps a very small mom-and-pop operation for themselves, or neighbors.

But nonetheless, that's certainly an appropriate point for you to consider and make additional comments as to whether that break point should be there, or should not be there.

But in our consideration of how we can address the problem and get a 50 percent reduction by 2005, we felt we were addressing the majority of the industry. Granted, not 100 percent of the industry.

MR. McCHESNEY: And as a follow-up comment to that, the plan doesn't -- well, I would put some numbers out there, the plan puts numbers out there. It's also there's an education component in it that's directed at everyone.

So there will be a -- a role for extension veterinarians to try to find and educate these people, as well as the local state ag associations. And it's going to be an educational program for these smaller people, maybe more so than an -- than a true regulatory program.

And in the past I've done a lot of work with bovine spongiform encephalopathy (phonetic), and we had the same issue. There's lot of small producers in that area, and the approach to get to them was not necessarily to inspect everybody but to try to get out and educate these people. So I think a big component may be educating these smaller producers, even though the number, as Lou said, is surely open for discussion.

MS. GIRAND: Laurie Girand, STOP.

I'd just like to say that we're very strongly opposed to these kinds of distinctions between smaller operations and big operations, that food safety is something that the consumer doesn't look at an egg and go, oh, it came from a small company or a big company unless there's a real investment reason, like the small company, they know the small company and they trust the small company. And so we find these types of distinctions to be very distressing, and I would argue, Lou, that if they have 2,999 layers, that doesn't make them a backyard egg producer.

MR. McCHESNEY: We surely have noted that.

Other comments?

All right, I think we can -- last chance. We're on to our last segment here.

The next presentation will be by Nancy Bufano, of Center for Food Safety of FDA. It will be on the Retail Food Service and the Consumer.

Nancy.

MS. BUFANO: I might need some help putting up my presentation.

(Off-mike discussion.)

MS. BUFANO: Thank you.

Okay. The last, but certainly not the least important of the segments from the -- of the farm-to-table continuum is the retail food service and consumer segments. And I will present those issues.

First I'll tell you about the retail and food service -- retail and food service segments of the farm-to-table continuum for eggs. FDA is considering mandating, by way of regulation, certain egg-related provisions of the 1999 Food Code to cover this segment. And I'll go through some of these provisions that we're considering.

First one involves temperature and condition of shell-eggs upon receipt at retail. If -- if FDA were to codify this provision, shell-eggs received at retail would have to be at a temperature of 45 degrees Fahrenheit or

below, would have to be clean and sound, and would not -- would not be allowed to contain more restricted eggs than are allowed in U.S. Consumer Grade B.

The provision for holding -- the provision for temperature for holding shell-eggs at retail will be addressed by FDA's final rule on labeling and refrigeration of shell-eggs at retail, which will be published later this year. And I'm sure most of you know that in the proposed rule, the temperature specified was a 45 degree Fahrenheit ambient temperature.

Another provision of the Food Code we're considering codifying that liquid frozen and dry eggs and egg products would have to be obtained pasteurized.

For retail establishments that specifically serve at-risk consumers, for example hospitals, nursing homes, and daycare centers, they would be required to substitute pasteurized eggs or egg products for raw eggs in certain menu items such as menu items that typically contain raw egg ingredients, or items that are prepared by combining and holding eggs prior to service, also often referred to as pooling eggs, and/or menu items that are prepared by holding eggs following cooking and prior to service. Additionally, in these establishments soft cooked eggs and meringue made from raw shell-eggs would not be allowed to be served.

For retail establishments that do not specifically

serve at-risk consumers, raw shell-eggs would have to be served fully cooked, or pasteurized eggs or egg products would be -- would be required to be substituted for raw shell-eggs in the preparation of foods that typically contain raw or undercooked eggs, or the retail establishment would be required to inform consumers of the increased risk of consuming foods containing raw or undercooked eggs poses to at-risk consumers.

FDA will craft consumer advisory language for retail establishments -- retail establishments that do not specifically serve at-risk consumers, to use to inform consumers of the increased risk that consuming foods containing raw or undercooked eggs poses to at-risk consumers.

The final segment in the farm-to-table continuum is the consumer, and while FDA does not regulate, nor do we intend to regulate the consumer, I do want to make you aware of several food safety education efforts that are currently underway that have been underway, and that we will continue with and continue to strengthen.

FDA has published two fact sheets, one for consumers, one for food service. Both those fact sheets, I believe, are in the packet that you picked up today. They're also available at the Fight BAC display at the back of the room. These fact sheets explain salmonellosis

associated with fresh eggs and who it at high risk. They outline safe buying, handling, preparation and storage of shell-eggs and egg dishes. And they explore the hidden risks in foods containing raw or undercooked eggs, and how to avoid them.

These fact sheets have been distributed to the media, to 83,000 daycare centers, to 22,000 school district food service directors, to 13,000 nursing home directors. They're posted on FDA's Web site, which is FDA.Gov. They're available from FDA's food safety hotline, which is 1-888-Safe Food. And the consumer fact sheet was included in the 1999 National Food Safety Education Health Consumer Education Planning Guide.

We have also developed a video news release which alerts consumers to the potential risks of undercooked eggs and egg foods, and the simple steps they can take to avoid these. This was produced and distributed when FDA's egg labeling -- proposed egg labeling and refrigeration regulations were published back last July, and to date the video news release has been carried by 18 stations with a viewership of 2.5 million.

We have also developed two feature articles on egg safety, one in English, one in Spanish, which have been distributed to print media nationwide. They've appeared in -- I think that number is now over 1200 publications, with a

readership of over 74 million.

And the Fight BAC brochure, which should also be in your packets -- if not, it's available at the Fight BAC display at the back of the room -- also includes safe egg cooking information. It's been widely reproduced and distributed both in English and in Spanish as part of the Fight BAC campaign. It's also available at the FightBAC.org and FoodSafety.gov Web sites, and also from FDA's food safety hotline.

And lastly, we have developed a patient handout for physicians, which is currently under review, which includes both the safe cooking information and identification of persons at-risk of food-borne illness from undercooked eggs and egg containing foods, and this handout was developed for the American Medical Association, FDA, USDA, CDC, Physician Food Safety Education Initiative.

And with that, I'll turn it back to Dan, and I'll leave you with our retail food service consumer discussion question.

MR. McCHESNEY: Thanks, Nancy.

And the one thing Nancy didn't mention about the Fight BAC program, and there is a big display on the back there, that it also comes with a costume and you can actually call up our local districts, and maybe Howard's office over here, and get -- get a costume someone can jump

into and do the school routine or the State Fair routine, or something like that. And that's a big seller.

So before we go to the Panel, do you want to say something about that, Howard?

MR. SELTZER: Yeah, we have two costumes, actually. I just bought another, because the old one was so popular. But I just want to warn you, you can't be too tall or too short to wear it, and it is extremely uncomfortable.

(Laughter.)

MR. McCHESNEY: So that generally means you need to be an intern or a graduate student to be -- to be pegged for this job.

So that's our first question in this area, and we have about 30 minutes for this question, since there's only one question in this area.

And the question is, do the provisions of the 1999 Food Code which apply to shell-eggs adequately protect at-risk consumers in the retail establishments? If not, what other provisions are necessary for their protection?

I'm not going to pick of the Panel. Whoever wants to jump up with this one first can go. It's got components of regulatory, producer and consumer in it, so whoever wants to be first can go.

MR. LOFGREN: Well, I believe that it's pretty adequate, providing that the message gets across completely

to the consumer. I really appreciate this last presentation here on educating the food service and educating the consumer. In food service you have once removed customer many times, so it's hard to get that message across. And I think that the FDA and USDA can do a lot to make sure that that message gets across. If it does, then I think this program will be very effective.

Certainly the biggest problem that we see, we've had it mentioned several times here, is proper handling of food and sanitation. And that's education. So I think it would work if it's effectively presented clear through to the all -- the consumer.

MR. McCHESNEY: Thanks, Carl.

Laurie.

MS. GIRAND: I might have a few comments on this.

I was thinking before I came to this meeting about all the times in the last week or two, and in the next few weeks in which my family will be coming into contact with shell-eggs, and I wanted to remind you of some of them because I think sometimes we get away from the reality of what consumers really do with eggs when we think about protecting them.

You know, I bake cookies with my children, and of course I'm actually one of the most highly educated

consumers, you know, I think at least in the state of California. And so, of course, my kids are not allowed to crack eggs into dough, and they're not allowed to eat cookie dough raw, and they're almost not allowed to come near the counter when I'm baking cookies.

I've been taking a cake decorating class for the last five weeks, and many of you are probably highly aware that most of the old recipes for cake decorating involve the use of unpasteurized -- uncooked egg whites, in particular, for creating the best and most tasty frosting, which are no longer frankly available to consumers without a lot of other odd chemicals.

I was in a restaurant and ordered -- and taking my life into my hands -- souffle, and we've ordered eggs at restaurants, and we were always very clear that they have to be heavily cooked to the person that's taking the order. And my children -- who, before my daughter was hospitalized, used to eat French toast -- no longer eat French toast.

In addition, as an example of raw eggs, my two-year old is in nursery school right now, and he was invited to see chicks hatch and hold chicks at his nursery school. And we have a major egg holiday coming up, which -- for which, in my family, we used to decorate eggs by blowing the egg white and yolk out through the tiny hole that was created by possibly a pin or a needle. So we've got a lot

of behaviors here that are not entirely addressed by the Food Code.

And I think as a -- I want to come at this from a marketing perspective and point out that to truly educate the world to stop doing things that they've been doing for years and years, and not -- not just one thing, I mean, at least perhaps with ground meat, we're talking about just don't eat your hamburger raw, or undercooked -- we're talking about eggs that are used in hundreds of recipes that have been pretty much the same for years and years and years.

And in -- from a real marketing effort as opposed to the -- the underfunded effort that FDA puts on, it would take millions -- tens of millions -- of dollars to adequately inform consumers about the risks across all products, that they're saying tens of millions of dollars.

And when I look at the 100,000 data sheets that you've managed -- one hundred, maybe 150,000 data sheets that you've produced -- I think that there are 200-plus million people in the United States, a bunch of them are children, and we're talking about maybe, let's say five cookbooks a family that are still in existence and still in those people's homes that produce recipes incorrectly from the standpoint of egg safety.

And so we'd be talking about replacing cookbooks

at a rate of $15 or $20 a cookbook, ten million families. I mean, we're -- we're still talking tens to hundreds of millions of dollars to correct a problem that starts at the egg, and not really at the consumer.

I think the Food Code, some of these ideas do address the problems by asking that people use pasteurized eggs in place of -- in places where they're going to be served, and I applaud the idea that you'll actually put a warning at retail, and I'll hope to talk to some other people about that, in other areas at FDA, as well.

I think that efforts like Fight BAC that are directed at school children are preposterous from a marketing standpoint, since school children don't cook eggs.

And yes, they can go home to Mom and try and convince Mom to cook them differently, but they're really the wrong audience altogether, and spending money on educating school children, to me, seems to be a -- not a good use of taxpayer money.

We want warning labels on shell-eggs that have not been pasteurized. We want them to be very clear about the risk, and we want the at-risk groups mentioned on the package so that it's clear to parents that they can poison their children. We want accountability, and so we really do want these codes and the trace-back codes on the package, so that in fact -- I don't want to call them dirty producers,

but the dirtiest producers will be identified in the cases where they cause outbreaks.

And frankly, I think that the egg industry should want that, too, especially if they're going to go to all the effort that it seems like they're going to be going to, to try and clean up the situation. They should want to get rid of the producers or push the producers that are doing hazardous things into less hazardous behavior.

And lastly, this is an idea that I don't think has been suggested, at least based on my conversations with people about Ohio. But I think it's really -- it was sort of alluded to by the gentleman with the pasteurized eggs. In the end, when I go to the grocery store I don't want to see any eggs that are contaminated with Salmonella, and I would like you to let me know if they are not contaminated with Salmonella, and I realize you can't do that until you've cracked them open, unless we've got some super x-ray technology.

But what I want to see if who are the good producers, and I want it stamped on that box. And what I would like to see is this -- these eggs come from a farm that has tested Salmonella negative for a year, for two years, for three years, for four years. And if it's Olivera or it's any of these other people who are here today, I want to know that they have been delivering on the promise of

what all this technology is supposed to be delivering on.

And I think that's often lost, because we sort of say well, we've got to raise this bar, and that's sufficient, and there are no rewards for industry beyond just not causing a problem. And there needs to be a reward where there is a higher bar and a higher standard, that the people meeting it, they don't get out of the warning label but they get the reputation of having tested negative because they have been. And those are the people I want to buy eggs from.

Thank you.

MR. McCHESNEY: Thanks.

Dave.

MR. CASTELLAN: Yes, thank you.

Well, that kind of leads into this -- this topic is very, very important, because the risk assessment did come to the conclusion that more than one point in the food chain is necessary to mitigate the risk of SE in humans if that is the outcome variable that we're measuring. And in every institution, in every kitchen is the opportunity to control that, and certainly we need more education, and I -- and I applaud the efforts that are going on in this regard. We need better risk-communication. I'm aware of some studies that have -- that are underway through FSIS and some of our researchers at UC Davis, as well.

But I would like to pose several questions to several people, and one would be to Dr. Esteban. Regarding, if you could just give us an idea as to what proportion of outbreaks in institutions are related to food mishandling? Just to give us an idea of what the time temperature abuse, how important that is, or other human factors.

But also, I have questions -- a question regarding if -- if, Nancy, if you could answer this, how egg temperature is measured. Are you measuring internal temperature or ambient temperature in the truck in which it is received? Because I have seen some training information for retail food preparation managers that indicates that they are to measure internal egg temperature, and there doesn't seem to be, from what I know about it, but maybe you can clarify this, a synchrony between what public health is expecting and what a producer or processor is expected to do.

MS. BUFANO: Are you talking about the provision for temperature of shell-eggs received at retail?

MR. CASTELLAN: Yes.

MS. BUFANO: Since we're still in the stage of crafting those regulations, that's certainly open for discussion. We haven't -- obviously we haven't specified whether it would be ambient or internal, or -- I mean, that's part of what we need comments on.

MR. CASTELLAN: I -- I guess I'm alluding to the fact that in the Serve Safe program, which is a program given to food -- retail food managers, that internal temperature is recommended, so it is recommended that the manager, or whoever is receiving the product, crack two eggs in a glass and put a thermometer in a glass and measure that. And I'm just -- I guess I'm wrestling with the incongruity with ambient temperature being measured to the point at which the eggs arrive in the truck, and then -- and then having that as perhaps one of their SOPs at the retail level, expecting that.

MS. BUFANO: As you're aware, our final regulations for temperature of shell-eggs, for holding of temperature of shell-eggs at retail, the final regulations will be published later this year. And I'm sure whatever temperature is specified for holding, and I know in the -- in the proposed regulations that was a 45 degree ambient temperature, but only -- we would probably be leaning towards that same temperature for receipt at retail.

MR. McCHESNEY: That last comment was Nancy Bufano, from FDA.

DR. ESTEBAN: This is Emilio Esteban, from CDC.

David, your question about the proportion of outbreaks or illnesses associated with food service, roughly 61 percent of the outbreaks that we've seen between '85 and

'99 are associated with eating at either restaurants, delis, bakeries, cafeterias, a vending truck, or a catered event. So a little bit over half of them are associated with commercial venues.

You had another question about what we're doing at the retail side about training. We've -- as of this year we have added to FoodNet sites, to selected FoodNet sites, a component. We're still trying to figure out the details, with FDA and USDA, but a -- several training programs was surveys that will allow us to pinpoint more carefully where all the risk factors or risky behaviors that cause people to, you know, expose people or consumers to contaminated food. So give us a few more months, if you will, and we'll sort of have some numbers on that, answers to those questions in particular.

MS. GIRAND: May I ask one more question?

MR. McCHESNEY: Sure.

MS. GIRAND: I'd like to understand how the Food Code -- you know, I think California, if I'm not mistaken, has had a refrigerated retail, this being grocery stores, rule for a little while, possibly a couple of years. And I personally came across a situation where it was just being blatantly ignored, and asked a couple of people in the grocery store what was going on. And they gave me lots of you're a dumb consumer kinds of looks and stories, and what-

not, and went away.

But my question is, how are you going to really enforce the 1999 Food -- whatever this is that's coming up, how are you going to make sure that it's really enforced and that on average they aren't leaving the eggs outside the case, in the case of a grocery store or retail establishment?

MR. McCHESNEY: Fair question.

MR. CARSON: This is Lou Carson, at FDA.

As I mentioned, we're going to be proposing the standards in 2000, finalizing in 2001, and then implementing them in 2002, 2003. Currently, the state's local jurisdictions have primary responsibility at the retail. FDA, in establishing a nationwide consistent standard at retail for eggs through the Food Code provisions that are in the final rules, we would look to the states, and we would try to probably fund as a one-time deal a -- an effort for implementation.

The normal retail inspection process would then include a temperature monitoring or audit of those cases to make sure, and to see if the food store is doing that in an appropriate manner. If not, then to take appropriate remedial action.

So, again, I think we will be using the existing retail inspectional force at the state level.

MS. GIRAND: I'd like to comment that that force at this point is not adequate, and would need to be substantially greater funded. I've been to grocery stores where they're not using the warning labels on unpasteurized juices, and I've seen unrefrigerated eggs sitting outside cases. You know, this is the state of California. They've had these rules for a while, and they're still not able to keep up with every one. So we really need better enforcement.

MR. McCHESNEY: Thank you.

Other comments in this area from the audience? Or comments from the audience?

We'll let Howard go first, while you're getting to the mics. Howard.

MR. SELTZER: I just wanted to --

MR. McCHESNEY: Could you identify yourself?

MR. SELTZER: Oh, Howard Seltzer, FDA.

I just wanted to respond to a couple of the points that Laurie made.

One is that when we mailed, as we did, our egg consumer fact sheet to 83,000 daycare centers, we didn't mail it for the kids at the daycare centers. We were basically -- we included with it a letter to the directors, asking them to reproduce it and send it home.

Most of the -- particularly the direct mail things

we do, are to multiplier organizations. Our whole thrust is to get this into the hands of parents, or other kinds of caretakers. We also go to various hotlines, like the HIV hotline, the federal hotline, cancer hotline, and that sort of thing.

And the other thing I wanted to mention is that the Fight BAC campaign is not -- it does utilize a sort of comic strip character, but it's not really directed at children, towards school children. Most of the materials are directed at adults.

On the Web site, we've instituted -- about a year ago -- a virtual tool kit. These materials that are put on there are used by state and local health educators, our own public affairs specialists in our field extension. Anybody, really, who has access to the Web site, which is virtually everyone with a computer.

And, for example, we are in the process, probably already up, putting up an Easter egg tool, I guess you would call it. It's basically a lot of information about eggs, egg safety, coloring eggs safely, dealing with Easter egg rolls and hiding eggs, and making sure that they're not out there longer than two hours before eating. That sort of thing.

It would be nice, it would be terrific, if we had the hundreds of millions of dollars necessary to go to every

single individual in the country, but that's not likely to happen.

MR. McCHESNEY: Thank you, Howard.

On the right over here, my right.

MS. BRADLEY: Francine Bradley, Poultry Specialist, University of California.

It sounds as if Mrs. Girand has had a family member who had a food-borne illness, and that's most unfortunate and I can understand your concern about that.

However, I do take exception to the criticisms of the Fight BAC program and the expenditure of government dollars to educate children, and the comment that children don't cook eggs. I can tell you, as an educator of everything from students who are 60 year old poultry producers to 20 year old university students, to 4-H'ers and other youth organization members who are between eight and 18, that the most receptive group and the most educable group are the children. And that's whether you're teaching them about safe food-handling practices or learning a foreign language. And there's very good peer review research to back up that statement.

There are some very simple things that all children can learn, such as keep cold foods cold, hot foods hot, and wash your hands. Unfortunately, those good practices and things that were taught in the first pages of

some of those cookbooks, whose other contents -- the contents of which you may have criticisms of other chapters, those things are no longer given in school.

And unfortunately, home economic classes are all but extinct. So children are not being subjected to that type of educational information as to how to properly prepare their food, and how to -- to take care of it once it's cooked.

I think that's very unfortunate, but it's a -- it's an issue that we can't solve here. Therefore, they're not going to get it later on, so they need to be getting it in daycare, starting in daycare, primary school, and following.

The comment that children aren't cooking eggs, if you look at the demographics, especially here in California, you'll see the increasing number of latchkey children who, when they return home from school, they're in a parentless house, they're often preparing snacks for after school. They may also be starting dinner, and you may have one child cooking for several other children in the family. If you're at home with your children, I think that's wonderful, and your children are benefiting. But unfortunately, many households don't have a Mom or Dad who are there between three and six, and preparing the food for the children.

So I think it's an excellent use of government

dollars to ensure that children know food safe handling practices.

Now, something that you might be concerned about and maybe don't know is that there is no government requirement that there be hot running water or soap in any school lavatory, in public schools in California. Now, to me, that's a travesty, and that's something we could all work to correct, and something that would have a great effect in ensuring that whatever you're eating, whether it's peanut butter or jelly, or an egg salad sandwich, isn't contaminated.

With respect to the upcoming holidays, whether one is celebrating Passover or Easter, you should remember that the egg has always been a symbol of life, that's been celebrated for centuries, and I think it's most regrettable if we're becoming so paranoid a society that our children and all citizens are deprived of the joy of a chicken and egg.

Thank you.

MR. McCHESNEY: On the left.

MR. MATTHEIS: I'm Rich Mattheis, Pacific Egg and Poultry Association, Sacramento.

I think this would be a good time, with response to this question, to cover what the laws are here in California, and there was allusion to it here earlier, one

of the laws regarding retail facilities.

It was mentioned earlier by a speaker that the industry's been quite proactive, and that's certainly true here in California. It'll address some of the issues that are in the Food Code, and some additional things that are being done here.

We have passed legislation recently, which the industry worked on, to require that eggs and foods containing raw eggs be heated to a minimum of 145 degrees. I don't know if that was addressed here. That legislation has been passed and is in place here in California.

Additionally, our association sponsored and gained passage of legislation that requires refrigeration of all eggs from the time of pack to the time they are delivered, so there is some retail aspect there on the tail end.

Once those are packed, they must be held, stored and displayed at that 45 degrees, which you mentioned the 45 degrees in -- in your proposal here. But it also requires conspicuous labeling of words to the tune of keep refrigerated, or keep under refrigeration. That is currently required here. We also have a sell by date.

Additional legislation passed by the industry requires a dual end dating system and a specific identification plant system so you can trace back, which was brought up one of the Panelists here. That has been put in

place here in California. We also worked, the egg industry, with the grocery industry to require that eggs be refrigerated at all times while they are at retail.

There was reference to the problem of -- by our Panelists, of having enforcement of that law. And it is true that the Department of Health Services has had some funding problems. However, last year, working with industry, those fees paid by food facilities were substantially increased and there will be more moneys for enforcement. And the County Health Departments in some areas do do a very good job. I know this from experience, because we get calls on a regular basis about actions they're taking at retail establishments regarding the 45 degrees.

We also have in California, which they don't have elsewhere, a County Ag Commissioner system. We have an ag official in each county, and they inspect eggs at retail facilities to make sure that when they're delivered they're meeting the requirements of all these laws.

Additionally, we have legislation recently passed here in California that requires that you have a certified individual at each food facility, institutional, restaurant, whatever, who has taken and passed an approved course in food safety handling. That person is charged with the responsibility that making sure that everybody who handles

foods knows how to properly prepare and serve those foods to avoid contamination. So that has also come in line in the last couple of years here in California.

With regard to those few exceptions about eggs that can be served in a raw or undercooked form in certain foods like sauces and salad dressings, and the like, we also have new legislation that requires consumers be notified, and that was mentioned here, that before those products can be served in that way, consumers must be notified of the risks. So that's in place here.

These programs working together have been significant in reducing Salmonella. We think it also, and we'll get into this in later discussion in the open mic, but it, I think, paints a picture of why perhaps there ought to be regional difference in the program that you finally approve.

MR. McCHESNEY: Thank you.

MR. MARTIN: Michael Martin, University of California at Davis.

I was just going to add my voice also to Francine Bradley's comments as far as education. I think that education is a significant portion of what we should be considering as far as any funding, and that also that education directed towards children is an excellent use of funding in general.

I base this on when I was in private practice as a veterinarian, we actually did lots of outreach programs to children in schools, as did other veterinary clinics in our area, and we had a significant portion of people who got talked in, that's parents, by their children to come in for annual vaccinations and annual examinations for their pets.

So children do play an influential role in the family, as far as influencing parents. And also, I believe that children are at an educational level more than adults are. You can teach children. They can carry it through to their adulthood, all these good kind of practices as far as food-handling, and just general good, safe food -- you know, food consumption. And so I think that that is an excellent plan to use children as far as an educational tool.

Thank you.

MR. McCHESNEY: Thank you.

Jill.

MS. SNOWDEN: Jill Snowden, Egg Nutrition Center.

In specific response to the question you've got, the questions you have up on the screen, the egg industry supports protecting a vulnerable population through the use of pasteurized products, and using these products in particular with the at-risk population, especially at healthcare institutions. And the Food Code addresses this, but it's got a major limitation, and that is enforcement.

So saying what needs to be done and getting it done are two different things. So we need more effective food protection at the retail level to match the food protection that's going -- that's provided by producers.

And so this needs to be executed, not only listed but actually followed through, these types of practices, as well as the other food-handling practices that we need to protect all the food supply are actually executed, actually done.

My third point is that we really don't know who's at-risk from SE in eggs, at retail. We know the at-risk population for food-borne disease, generically. We know that the outbreaks in nursing homes, for example, from SE are down, and the few that are left tend to be associated with very egregious food-handling practices that are going to be unrelated to a provision of the pasteurized egg product.

I'm going to repeat the examples that I shared with -- the example I shared last week, because it's so important. The nursing home that was involved with an SE outbreak, and the inspector walked in, the individual was using gloved hands to cut up raw animal product, and walking over and tossing the salad, the green salad, with those same gloved hands on.

Now, that type of thing is not going -- the

consumer is the at-risk consumer in the nursing home situation is not going to be protected by a code like that, that those are the types of things that we -- the few that are left, the few outbreaks that are left in nursing homes, have to be addressed from a different angle in order to protect the rest of those vulnerable populations.

The case control studies don't reveal the relationship between the at-risk population and retail. So we have -- the case control studies have identified eggs and their role, the types of eggs served at restaurants. But we don't have a sense of who's eating those eggs based on those studies. And so at the very least, I'd say that we need to look at the data that we currently have from the outbreaks, from the case control studies, from FoodNet, from Salmonella surveillance, and start looking at the demographic characteristics to see who is -- who is actually getting sick and what are they getting sick from.

And I think we'd also need to consider additional research studies so that we can identify who's at-risk, and what are they at-risk from, and then how do we stop it.

MR. McCHESNEY: Thank you.

One final comment in this area, then we need to move on.

Don.

MR. BELL: Don Bell.

In reviewing the cases that we've seen in the last, what, 15 years or so, I think we can see a common thread through all of them. There's an awful lot of group preparation. There's the so-called mishandling of eggs. The products seem to be all over the place. They're not concentrated in scrambled eggs or things of this type, but a rather exotic list.

If you think about it, who actually handles eggs, physically handles eggs. I'm not talking about egg handlers, but people who physically handle eggs. Probably no group is more represented than the homeowner, the person that prepares the food in the home. But the secondmost group -- I didn't really see on the screen much emphasis on -- and that's the food preparer in the restaurants, in the mass system. It was referred to, referred to, but I didn't see any educational materials, 20,000 of this, 15,000 of that.

It's a very big group. As I understand, it's in the half-million range, or something of that type. Every restaurant that you go to has several so-called chefs, because they have a hat. You know, they have a white hat on their head, and they're called chefs.

Now, all I'm getting at here is that there seems to be a high incidence in this group. I do not see a real formalized educational effort in this group, and I'd just --

just like to make one reference. State of Oregon certifies all egg handlers. People in the fast food system, and the restaurant system. Please use this as a model. I mean, we're talking about 50,000 people educated specifically so that they can handle food for you. If you ever cook eggs in your home, in the kitchen, I dare you to come out with a dry thumb.

I don't think any of us break eggs with a dry thumb. We all stick our thumb into the egg, and then we prepare the egg. And I don't think the restaurant chef is any different. He does it two or three eggs at a time. He's pretty good at that.

But the message is, is that I think this is a -- the second most common handler of eggs, physical handler of eggs. The poultryman doesn't even handle his eggs. The bulk of the eggs that are produced are not touched by humans on the farm, or in the processing plant. The food preparer in the home and the food preparer in the restaurant are the people who handle eggs. They pool the eggs, they transfer whatever they -- they find on the eggs onto the next egg. They're the people who need to be educated.

Thank you.

MR. McCHESNEY: Thank you.

We move on to our next presentation this afternoon, and it's the Regulatory Impact Analysis, Role of

Economics. And it's by Robert Scharff, of FDA.

It may be a technological challenge to get --

MR. SCHARFF: Okay. Well, we've heard a lot of comments here today, and believe it or not, many if not most of these comments have had relevance to economics. Economics is not just dollars and cents, although sometimes it seems that way. So what I'm going to do now is I'm going to talk a little bit about what we do in the agencies with economics, how we use it to analyze regulations, and how you can be helpful in giving us some of the information that we could use to conduct our analysis.

Okay. There are a couple of requirements that the agency has that are pertinent to economic analysis. And this is true for every agency, by the way, in every major rule. And this has been deemed, I believe, to be a major rule. So the first of these is the Executive Order 12866, and I'll go a little bit more into that, and that basically just says that we have to do a regulatory impact analysis.

And the second of these is the Regulatory Flexibility Act of 1980, which has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996. And now, I know we've had some comments today saying that small businesses should not be looked at differently. I understand where that comes from, but by law we are required to at least look at the effect of any regulation on small

business. And so we are going to do that.

Okay. Now, what I have here is a number of quotes from Executive Order 866, and this is -- this is why we have to do -- why we do what we do, and why we're, you know, what we are required to include.

First of all, each agency, as it says, each agency shall assess the costs and benefits of the intended regulation. Well, we -- we often think of economics as dealing just with the costs, just with how much is this going to cost our business to -- to have to meet this regulation. Well, when we look at it from an economic point of view, we also look at the benefits. And in this case, the benefit of a quality assurance plan would be the reduction in SE that we expect to come from it. And so we will look at that as well.

Also, each agency shall base its decisions on the best reasonably attainable scientific, technical, economic and other information. And that's one reason that we're having this meeting. We're trying to get information from you about -- about the industry. We have our own information, as well, but we want to hear -- hear what you think.

Each agency shall identify and assess alternative forms of regulation. Once again, this is something that we get from these meetings. We hear a lot of proposals for

well, you shouldn't be doing it this way, you should be doing it some other way. And we -- we take that to heart and we look at it, and we analyze whether that does, in fact, make sense.

And finally, each agency shall tailor its regulations to impose the least burden on society. So basically, what we're saying here is that we are trying to get to a certain point in the least -- using the least cost method. It's basically cost-effectiveness.

Okay. Now, one thing that's required by Executive Order 86 -- I'm sorry, 12866, is the regulatory impact analysis. And any of you who have looked at proposed rules or final rules, there usually will be a regulatory impact analysis attached to that. And that's something that I'm going to end up writing for the FDA, and then there's going to be somebody for FSIS who writes their portion.

And what the regulatory impact analysis does is it assesses the positive and negative impacts of the rule. And as I said, it's written by the economists, and we do get input from -- from other agencies, scientists and policy-makers.

Now, for the Egg Safety Action Plan, the RIA will talk about, as I said, both the benefits and the costs. And as I said, the benefit of the plan is the reduction of illness due to SE in eggs. The costs of the plan, however,

are going to be the increased expenditures due to the implementation of the plan's components. So what -- basically what we're looking at here is what will you have to do as a producer, or as a packer or a processor, to reach the level that this plan is going to require you to reach. And it's the increased expenditures.

Now, that's not to say that those of you who have already implemented quality assurance plans, that we're ignoring you. We want to hear from you, and we want to hear what it has -- what it has cost you to -- to implement these different components. And a number of the components I've listed here.

I've listed record-keeping, testing, written control, refrigeration. One thing we heard earlier today, which is excellent in terms of the type of thing we like, is we heard from Carl Lofgren about the cost of refrigeration. And he put it into -- into terminology that is great for economists. The amortized cost of refrigeration is $100 a week. That's perfect. So that's basically what we're looking for.

Okay. As I mentioned, we also have to look at small businesses, and we do this through the Regulatory Flexibility Act of 1980. And this requires that agencies assess the impact of a proposed regulation on small businesses in a Regulatory Flexibility Act.

This is written at the same time as the Regulatory Impact Analysis. And the RFA provides for the participation of small business in rulemaking through notice in the Federal Register' public hearings, such as this one; review and response to comments received by the regulatory agency.

So if you look at the -- the notice that we sent out for this meeting, one of the things you'll see is that in the back, under Section 5, public dockets and submission of comments, we clearly tell you how to make comments, and we want to hear from you. We want to hear whatever it is that you have to say about the economics of this rule, and about all other aspects of this rule, as well.

Okay. Oh, I think I missed one. No, that's not what I wanted.

Okay. Now, one of the things that we have included in your packet is "Guidance for Small Businesses". I'm not sure how many of you would fall into that category, although small business has been variously defined by the Small Business Administration, and a lot of businesses that may seem to be large are also -- are actually, in fact, small. But in any case, this guidance is valid for people who are large businesses, as well.

And so the question is, how should small businesses comment, or all businesses, for that matter. First, you should submit detailed information that will

assist us in assessing the value of a proposed rule. Okay, so anything that is once again going to get at how -- how much is this going to cost your business, what is going to be the result of this, what -- what, in your experience, has been the result of anything you've done on SE, for example. Those would all be good -- good comments.

Now, we want you to submit detailed information about your company. However, we want to make this very clear. Anything that you send to us is going into the public docket, so it will be publicly available.

So anything that's sensitive, don't send us. But anything that you can send us beyond that, we'd love to hear about it.

Okay. And comments, getting back to comments, what kinds are useful. Well, comments that provide little detailed information are not useful. This rule will put us out of business. We hear this all the time by small businesses. Well, that's not something that, I mean, we -- we take that into account, but it's not something that's really as useful to us as other comments, such as the one about refrigeration or about any specific costs or -- or benefits that are going to come out of this.

And once again, in this Guide for Small Businesses, which is one of the resources to help you make comments, we tell you exactly what types of comments are

useful. So if you look at this chart on the back, it goes down and gives you several examples of things that would be useful.

So we do have this brochure. This brochure is also on the Web, so if you know anybody else who might benefit from looking at this brochure, you might want to refer the to our Web site, which is as I've listed here.

We also have something, a small business hotline. So any of you who fall into the category of small business, if you could -- if you'd like to, you can call us at our hotline, and we will tell you what types of comments would be useful.

Now, I do have to tell you that you -- this hotline is not for registering comments. We cannot use it in that way. So anything that you tell us will not be recorded, and we will not be able to take that into account. However, if you're unsure about what form we'd like the comment to be in, or what would be most useful to us, then this would be a good number to call. And the number is listed there, and it's also listed on the back of the small business guide.

Okay. I guess that's it.

MR. McCHESNEY: We don't really have a follow-up question on this for you to speak to, per se, but I would encourage you. This, of all the things that's probably out

here to write today, this may be one of the most difficult sections to write, because the information is only what you supply. It's very difficult to come up with some of this. So I would encourage you to supply the information.

So I'd like to open this up to our Panel first, for comment, if they'd like to comment, and then we have time for about two questions from the floor. So whoever wants to start up here. Laurie.

MS. GIRAND: I'd like to be sure when you produce the economic analysis for this, that you include long-term illness data from -- as a result of SE. Often, when we read economic analyses from FDA they say the person was sick or died, and they were hospitalized for this long, and therefore the costs are this. And it excludes people who have to have their gall bladder removed, it excludes people who develop chronic arthritis, and what those long-term costs are to those people.

So please -- and we do not have that data. The CDC would be the people to ask for that data.

MR. SCHARFF: Right. Actually, we have been. I'm not sure about in the past in this agency. I'm -- I'm relatively new with the agency. But I know that in the recent past, when we've looked at Salmonella, we have included some of those chronic conditions in our analysis. And if you want to look at something that would be relevant

and would use the same benefits types of numbers that we would be using in this, there's the -- the labeling and refrigeration rule, which has recently come out. And that has an RIA attached to it.

So you might want to look and see what we've done there. And if you do not like what we've done, please send us comments.

MR. McCHESNEY: Can we just hold that for a second, and we'll get --

MR. LOFGREN: I have no comment.

MR. CASTELLAN: I just have one question for Bob. In terms of the total process, where does the cost benefit analysis and the economic analysis fit in to the total scheme of the Egg Safety Plan, in terms of timing and --

MR. SCHARFF: Well, we are trying to -- I'm doing the research on it at the same time that we're trying to develop it. Obviously, I can't come up with final numbers until the plan has been put in, you know, has been written. However, I am doing enough research that I can -- I'm trying, you know, it's -- it's an interactive situation where we talk to each other, and I give them feedback, they give me feedback. So it's -- it's a good process, I think.

MS. KUX: The regulatory flexibility analysis accompanies the rulemaking process. So it -- it's part of the proposed rule, and part of the final rule.

MR. CASTELLAN: So they're parallel processes.

MS. KUX: Yes.

MR. McCHESNEY: That last commenter was Leslie Kux, of FDA.

MS. KUX: Sorry.

MR. McCHESNEY: The question I believe that was asked by the gentleman back there was how would they submit new information. Was that the question?

MR. DAVIDSON: Yes. In all of these discussions --

MR. McCHESNEY: How do we do that? Can you get -- if the question is how do you submit -- is that -- if that's the only question, then I can answer that for you. Or if you have more, you need to use the mike.

MR. DAVIDSON: The -- all the discussions today seem to, as everyone already knows, be centered around cost and cost effectiveness, and if a significant cost has not been raised for discussion prior to today, something that may contribute to illness that has not been covered in the discussions, how would one get that to your attention beyond today?

MR. SCHARFF: Beyond today, what you would want to do is you would want to submit any comments you have that we -- that you haven't talked about today to the public docket, in the way that it's described in Section 5 of -- of this

that you got in your packet, this -- the notice for this meeting.

MR. DAVIDSON: Let me -- if I may, I'll give you one illustration. In the grading process of eggs, the -- a Grade A -- and I believe I'm right, and I know there are people here that know all about it -- the setting on the grader which cracks, dents, checks, can be three, four, five, six, seven percent. All standards for food safety look for a sound egg, no cracks, no dents, so forth. Therefore, the public is being provided with your -- within your standards currently, seven percent product that is substandard, and more able to cause illness.

The question is, how would you propose, or would you propose to make it a level playing field, make it zero, and how would you handle that as a cost?

MR. SCHARFF: What we would do, when we look at any cost all we do is we look at what people are currently -- what people are currently doing, and if there are some players who are not doing what the rule is going to eventually require them to do, we're going to look at the -- what that cost would be for them to adjust their behavior accordingly.

MR. McCHESNEY: One -- let me -- one -- would someone else -- since we only had two questions, if someone else would like to ask a question before you get back up,

and if they don't, you have the mike. We have an opportunity for one other person to make a comment, and then we need to probably take a break. I think our break material is here.

MR. RIEBLI: Arnie Riebli, Sunrise Farms.

In response to Mr. Davidson, I think that Mr. Davidson makes -- is a misstatement. He said that the consumers are presented seven percent product that is not conforming. That isn't true. There may be -- there are tolerances for products, but you've got to remember we're handling fresh shell-eggs. You're not buying golf balls. We can't put the egg on a tee and hit it 250 yards. We are handling something that is probably the most volatile product for handling that you're asking.

Mr. Davidson, you -- you are -- you're making a case to have all eggs pasteurized. Which maybe in my lifetime may happen. It may happen. That may well be. But I think that the -- making a statement that says that seven percent of the product that's presented to the consumers is not conforming, is a -- is a misleading statement. There may be some product that is out there, there are tolerances for product, but I believe that, Mr. Glasshoff, that virtually all the product that gets into the hands of the consumer, it is probably within tolerance. And, you know, it's in -- it's in the hands of individuals -- people,

people cause the problems. And I think that we have to remember that, you know, all of that.

And then Robert, when you do your -- when you do your analysis, one of the things you have up there was what's the cost to eliminate a rodent. Well, on the other side over there is after the rodent's gone, how much less chickenfeed will that rodent eat? What benefit will that producer gain?

The cost of refrigeration, Robert. If you don't have refrigeration, how long can you hold your product? If you do have refrigeration, how long can you hold your product?

So for all the things, and I've heard all the stories, all the horror stories, because the little guys are always going to get put out of business. It isn't true. The little guys are going to gain just as much economically, maybe more than the big guys will on this one. What it's going to mean is you've got to pay attention to your business, and all it does, it helps them to become a better producer.

MR. SCHARFF: I think those are good points, and if you -- if you could, if you have information on that, I'd like to hear everything you have to say. And that -- that is one of those things that we do want to hear in the comments, what -- what these trade-offs will be. I've heard

that one, those before, and -- but if you -- especially if you have any data supporting that, that would be great.

MR. McCHESNEY: That's the final comment. We -- the table here had the final comment for this section.

We can pick this discussion up again in the open discussion, if we need to.

So we'll now have a -- it says a ten-minute break. And I will tell you here that the longer you take for a break, the less time you have in the open comment period, so I would encourage you to be back in ten minutes. We'll start up again in -- five to three.

(Thereupon, a break was taken.)

MR. McCHESNEY: Could everyone please take their seats?

Okay. Our next presenter today is on -- we have a presentation on Research, and the person doing the presentation from FDA is Bob Brackett.

Bob.

MR. BRACKETT: Thank you, and good afternoon.

In your packet, I'm sure you've all noticed already, is a copy of the -- of the plan, and in that is some information about the research that has been proposed, and I'm going to just discuss a little bit about that. But I think also addressed in there was the fact that the -- the plan was designed with the goals in mind that they would be

based on sound science, and sound science data.

In order to develop an effective policy it's important to have the right information and the right data, and so some of the research that has been suggested is geared towards going at that.

What I'm going to do is start off a little bit by sort of reiterating what Lou Carson said in his opening comments, only maybe perhaps from a little bit different perspective than he did that, and sort of to provide the context for the comments that will follow on research.

As was discussed, there are really two facets of the plan, one of which is Strategy 1, Strategy 2. Strategy 1 deals primarily with on farm, or production type issues and the way to control SE in eggs, whereas Strategy 2 is more after the farm, or technology based applications.

Now, this is important in the terms of research as well as trying to strategize on how it should be regulated, because there are fundamentally different approaches that one takes towards research, depending on which of these strategies that you're addressing.

Now, generally we can find that there are different issues in solving the problems in Strategy 1 versus Strategy 2, and also when you will often see a different philosophy in the way that researchers will address these two problems. In the case of on-farm, you

will have perhaps poultry scientists or veterinarians that have become involved, and they will look at things quite differently than the technology based scientists, like food scientists or engineers will look at. And this is a good thing, because you get, I think, a little more diverse ideas and creative ideas on how to adjust this.

The overall goals of the program were also addressed earlier, and that is the overarching goal of eliminating egg associated Salmonella enteritidis illnesses by 2010, and the more immediate goal, which -- or the interim goal, which is to reduce illness by 50 percent by 2005.

The mechanisms that this is going to be done is addressed in the plan in eight different objectives. It's Objective 7 that ends up dealing with the research component of this. And the research has to fit into this -- these same constraints here; that is, the research has to be addressed at eliminating SE from eggs by 2010, but we also have to have some more immediate goals that we need to achieve.

Objective 7 states that what we want to do is ensure an adequate current information is available to make decisions about SE preventive controls, as well as surveillance, and education based on sound science, not just somebody's ideas or whims.

And basically, what the writers did is came up -- and the scientists that were involved in this, came up with four sub-objectives. And if you read through this, it might initially look like this is just a list of sub-objectives, or of research projects. But in fact there -- there's some order to them, and they are grouped.

The first sub-objective, what I've -- which I've numbered 7.1, is to develop and evaluate on-farm intervention strategies or technologies. Some examples of projects that have been proposed under this -- and these are not in any of these subobjectives -- are not the only things that research would address, but these are some starting points, would be forced molting and other stress factors that would lead to enhanced SE in eggs. Vaccines and immunomodulators, competitive exclusion or other competition for other organisms, and such technologies as ion scrubbers in the hatcheries.

Now, one of the things you may notice about this particular subobjection -- or, objective, is that it addresses such things as husbandry issues, immune state of the chickens in the -- on the farm or ranch, and also some of the physiological differences between the animals themselves. So it almost directly addresses Strategy 1.

The second subobjective, 7.2, is really geared more towards addressing the questions and solving problems

in Strategy 2, the technology-based type of problems. Provide additional information about commercial processing technologies and practices, and these include such things as in-shell pasteurization of eggs, rapid cooling before and after processing, continuous rewashing of the eggs, repackaging, and pasteurization of egg products and their additives.

As is the case with all research, this tends to be a moving target, and, in fact, what you've probably already realized is that several of these subobjectives, or these research projects have, in fact, been accomplished. And so what will happen is researchers will sort of reprioritize or come up with new ideas to build on what's been found so far. But what you basically see that these are mostly technology or handling based, as opposed to husbandry type of questions.

The third subobjective is improving testing methodologies, a question which has come up today, for Salmonella enteritidis on the farm and in eggs, including the identification of virulence factors and development of rapid tests, screening tests, sampling protocols for subtyping SE isolates that we -- we obtain. This particular subobjective actually is something that both Strategies 1 and 2 could use. It's really geared towards providing tools for the researchers, rather than just answering specific

questions. So regardless if it's an on farm strategy or a processing strategy, these are the type of research gaps that we need to get at.

And then, finally, research objective -- subobjective 7.4 is really understanding the ecology and the epidemiology of SE in the hen in the farm environment. This includes such things as the sources of SE in the environment; that is, where is it coming from and how is it being transmitted around the environment. Mechanisms of colonizing the layer house; characteristics of SE that promote infection in the hens and in humans; biochemical characteristics of Salmonella enteritidis strains causing variations in virulence -- and this is important to know because these things do change.

The immunological and other factors in humans that also affect infectivity, not only characteristics of the strains themselves, but of the consumers that might make them more susceptible. And then risk factors associated in humans that affect infectivity, which is an important issue.

So these, again, subjective 7.4, these type of research projects would again be common to both Strategy 1 and Strategy 2, but these are much more fundamental questions. These are issues that would take longer to gain, they wouldn't provide as much of an immediate answer, and they're also a little bit more difficult to get at than some

of the earlier questions that were asked, and consequently they will take a little more time, they're going to be more expensive, and they also have the greatest risk. That is, if you do an experiment and research you may or may not get as good an answer as something a little bit simpler.

Regardless of which of the research subobjectives you're talking about, or where the interest lies, there are several research issues that serve as constraints, or at least the type of effective research program we have will need to take into consideration these issues. The first of which is, is the question that you're asking going to provide an immediate versus long-term result. And this is, again, the question of applied versus fundamental research, applied being a much quicker answer to get, fundamental research taking a little bit more time.

And then you also have to take into consideration the practicality and the economics of solutions. That is, getting questions that are -- or doing research for information that's nice to know, versus actually getting information that's going to fill in the necessary gaps that we need to solve the problem. And it's also important to realize that when we're doing this research, that, as was mentioned earlier also, Salmonella enteritidis is not the only pathogen that the industry has to deal with, so we have to take in what effect this is going to have on other

pathogens, as well.

With that -- the other thing is that there's always the question of who -- the practicality and economics of the solution; that is, how much is it going to cost to implement a particular research result, and will the results actually be something practical that can be used by the industry, or is this more of an ivory-tower type solution that will never be used. And, of course, these are issues that need to be considered.

And then, finally, the whole problem is a huge one, and there are many partners involved in the type of research, including government, both USDA, EPA, and FDA, as well as many of the universities who are working on this -- who have been working on this -- and also industry, who has provided a lot of very good research and also actually applies the research that both government and academia has provided.

With that, I'll put up the questions and return the podium back for answering of questions.

MR. McCHESNEY: Thanks, Robert.

As you can see, the two questions we have here for -- on the research side -- and we have about 15 minutes to address these -- are, rewashing of shell-eggs is a widespread industry practice; are there data or research to support it. If it is disallowed, what economic effect will

it have on the shell-egg industry.

And then, sort of going along with -- at the same time. What research on SE in eggs is already underway and what additional research is needed to assist producers, packers, processors, retailers in the proper practices.

The first of that, I'd ask you to focus on the rewashing issue. We've heard a lot today about washing, and the pros and cons of it, and what's in the washwaters, and things like that. This is a separate issue. This is rewashing something that's already been washed.

So I'll turn to the Panel, first, and go with Carl, who's the industry person here.

MR. LOFGREN: I believe that rewashing of eggs is appropriate. If you are washing eggs until they're clean, it seems to me that's our goal, is to get a clean egg that's in there, as long as it doesn't take too long and it's not economically a burden to continue washing.

But to bring eggs around and rewash them seems practical. If you didn't do that, you'd have a large number of eggs that would be diverted to the breaking plant, or discarded. The difference in that is probably somewhere in the vicinity of maybe 15 cents immediately lost because of the egg that would be diverted to the breaking plant, and sometimes maybe even more.

So I feel that it's an important step, if it's

properly handled, and should continue on.

MR. McCHESNEY: Okay, thanks.

Dave.

MR. CASTELLAN: I have no comment.

MR. McCHESNEY: Laurie.

MS. GIRAND: I apologize, but I don't understand enough about rewashing as an issue. The eggs are coming through, they're being washed, and then they're just being washed again? Is that all we're talking about?

MR. McCHESNEY: If they are pulled out when they go through the line, they're identified as still having some dirt or something on them, they can be marked and pulled out and sent back through the washing system.

MR. LOFGREN: Actually, in many operations, newer operations, there's just a return conveyor and that egg goes back around, comes back through the washer again. And it seems like it's a practical procedure.

MS. GIRAND: Okay. I don't know that I should comment on that. I'm presuming -- I have too many assumptions, so --

MR. McCHESNEY: Okay.

Comments from the floor on this question.

Please state your name when -- and your organization when you come to the mike.

MS. CURTIS: Pat Curtis, North Carolina State

University.

We've done a number of research projects on washing eggs, and one of the questions -- I'm not opposed to rewashing eggs, at least, you know, a couple of times. The question that I pose is, would the new equipment where it washes and it automatically sends it back around, it can get it indefinitely, and sending it back around until the egg breaks or until it gets clean. And the thing that I raise about this is every time the egg goes through the washer it's raising temperature, and it's going to stay hotter longer. And if you look at the time that it takes an egg to cool down, that's the only issue that I raise with the rewashing system.

MR. McCHESNEY: Thank you.

Other comments.

All right. Move on to the next question. Oh, I'm sorry, I didn't see you.

MR. RIEBLI: Arnie Riebli, Sunrise Farms.

From an economic standpoint, if you do not rewash eggs it will cost about three-and-a-half percent of your total production. Dirty eggs will cost you approximately three-and-a-half percent.

It's my understanding that right now, dirty eggs or stained eggs go to an egg products plant, and go into the product line. It's my understanding that after the first of

the year, FSIS is going to take the position of no longer allowing quote, unquote, dirts, into a products plant. Roger, I see your brow rolling. This -- this is something that I have been told, that FSIS is taking a position that they will no longer allow dirts.

You take the three-and-a-half percent number and it goes to a products plant, the differential in -- in paying price is 25 cents a dozen. That -- you can just figure -- you can extrapolate from there what the cost would be. If you go from -- if you don't allow it into an egg products plant, then it has to go into loss. And for three and-a-half percent of eggs produced, goes to a store to pet food, with absolutely no value.

Thank you.

MR. McCHESNEY: Thank you.

Other -- one other brief comment on this. Roger.

MR. GLASSHOFF: Roger Glasshoff, FSIS.

Just for clarification, all dirts, cracks, and under grades are to be diverted to egg products processing plants for breaking -- segregation, breaking, and pasteurization. There's been no change in that ruling. I think what you're hearing in the field is that we're encountering some problems with conformance regarding eggs that are entering the breaking room. At that point, all ineligible eggs should've been removed from the conveying

system. Dirts are not eligible for breaking at that point.

MR. McCHESNEY: Thank you, Roger.

Jill.

MS. SNOWDEN: Are you ready to move on to the second of your two questions?

MR. McCHESNEY: Well, we can. We'll give our Panel -- did you want to comment on that one first?

MS. SNOWDEN: No. Actually, I'm on the second. I just got a little disorganized.

MR. McCHESNEY: Okay.

Anymore comments on this first one, first.

All right. We'll move on to the second one. You'll be the first commenter after our Panel, Jill.

On the second question, what research on SE in eggs is already underway, and what additional research is needed to assist producers, packers, processors, and retailers in proper practices?

I'm not sure where to start on the Panel, so anybody who -- it's obviously you, Dave. They've got it down.

(Laughter.)

MR. CASTELLAN: I'd like to comment on a few of the areas, but specifically about the production area.

Strategy 1 and Strategy 2 both encompass the production component to some degree. And in order to make

sound decisions we need to have sound information. And that's been the rationale in this state for conducting studies. There's been considerable investment of time and money by our department, and by the industry here, to try and approach some of these questions that need to be answered.

Epidemiology -- in that area there are some badly needed studies, and some -- in the area of pathophysiology of the disease, and there's a lot of work going on across the country. But a better understanding of its occurrence, because we know it's spatially and temporally clustered, and that it can be here today and gone tomorrow.

We need to understand what it lives with and where it coexists, and what the environment is, what is the pH, what is the ammonia level of that manure. These are important variables that hopefully, through some of our research, and hopefully in the future we can continue to address, but we need to understand these things.

Eliminating everything is not necessarily the solution, because we don't understand enough of the ecology of these organisms to be able to say anything that might appear to be common sense without really looking into it further. This is crucial, because with the right answers we can develop performance standards that mean something. Something that's going to mean something to the producer,

and he's not just walking through steps, but he's doing something that makes sense to him because it's been verified and published.

Much has been said about vaccines and competitive exclusion products. That's certainly something that needs to be borne out more. I would just add, and I didn't add this comment earlier, that we need to -- we need to define when and how to use these vaccines. There's so many things that need to be in place before vaccinations should be considered, or in conjunction with vaccination.

Prevalence studies are an initial step, and the SE risk assessment used the Pennsylvania data primarily. We now have a prevalence statistic for California, and we need that to fill in a lot of the holes in the big picture. But these are cross-sectional studies. And they're limited, because they only give you a snapshot in time on many, many different places. When you amalgamate information such as cross sectional studies, you're missing the continuum, the day by day change that goes on on an individual farm. We need longitudinal studies to determine what happens in flocks that do have this as a problem.

In the other areas of packing and processing, I think we've touched upon them in terms of the -- what we're actually doing right now, do we really understand, do we really have a good sense of what the performance standards

are and what they should be, can they be optimized. And in terms of the retail end, which Emilio alluded to, I was glad to hear that there is some research going on into food-handling practices. That was a very -- very curious result a few years ago, when you did a study that educational level is actually inversely proportional to the level of risk people are -- are willing to assume -- are directly related, I should say. So that it's -- there's so much more we need to understand about food-handling behaviors and food risks, and food risk communication, as well.

So, in total, I would like to see the risk management approach of risk-assessment and risk-analysis and risk-communication from farm to fork, with an emphasis at all points in the food chain.

MR. McCHESNEY: Thanks, Dave.

Jill. You're up.

MS. SNOWDEN: Thank you. Jill --

MR. McCHESNEY: Oh, I'm sorry. They were just starting. I thought -- I thought we had consensus among industry and consumer groups, since they both pointed to the regulator there immediately.

MR. LOFGREN: I can be brief, because I think David, and Jill, at the Egg Nutrition Center, probably know more about what's going on in the research than I do.

I have a real interest to know more about how

Salmonella can be introduced into an egg, and there may be some interesting facts that will come out of some research that indicates that it may be difficult to get Salmonella into an egg. And I -- I'd like to know more about that. I think I understood that there was some of that kind of research going on.

Also, the difference between transovarian and through the shell entrance, there's so many things in there that I think are not clearly understood, and that would be I think a very important area of research.

Other than that, I'll just let these others comment on the research.

MR. McCHESNEY: Okay. Thanks.

Laurie.

MS. GIRAND: I'd agree about the transovarian issue, and I'm also interested in understanding whether other organisms are capable of achieving this -- the same feature, so to speak, through some type of -- of evolution that would cause other problems with other pathogens in addition to Salmonella enteritidis.

I think we need to see data on SE rates in southern California as opposed to SE rates in northern California. I think we should be watching whether those rates are going up or down or sideways, and I don't believe we have that data right now because it's not the part of the

state that's under surveillance.

And lastly, I'd like to see data on incoming rates of contamination for the processing plants. I think that's very important for determining final performance standards.

MR. McCHESNEY: When you're talking about incoming information, are you talking about eggs that are coming from SE positive flocks, or --

MS. GIRAND: Whatever eggs are coming into the processing plant, we should know what level of contamination they contain.

MR. McCHESNEY: Okay.

MS. GIRAND: Not every single egg.

MR. McCHESNEY: Right. I understand.

Other things from the Panel?

Now you're up, Jill.

MS. SNOWDEN: Okay. Jill Snowden, Egg Nutrition Center.

I'd like to support the current objectives, the research objectives that are being put forward as part of the plan. And in the interest of time, I'll cover industry research areas in written comments, and I'll just take a minute or two here to highlight a couple of gaps that I'm noticing.

And I'd say the biggest gap on research is in the social science research. How do you motivate people? And

we can use research in order to identify tools whereby which we can ultimately motivate and change behavior.

We also need social science to identify the cultural practices that are risky. What are the recipes or the habits, or what-not, and who is practicing them in what part of the country. To what extent is a raw egg in a Coca-Cola (sic) -- or like in orange juice part of a habit of a particular group of people -- and what might that contribute or not contribute to this type of situation.

Part and parcel of this is risk-communication research. How do you tell people what they need to know so that they change their behavior without frightening them away from the great nourishment provided by an egg? That's -- where is there risk, and where is there not, so that we can all go on eating, because not eating is not an option. So we have to get the risk-communication in such a way that we're nourishing ourselves safely.

We have tons of opportunities for research to determine if we've been effective with any of our plans. Communication is the big one. If we put messages out there, have we succeeded. What was the behavior before we started an education program, and then what's the behavior afterwards, as an example. Have we been effective. We very rarely check up on ourselves to see if there's been a change in what's going on in that area. Do the messages that we

put forward actually work.

Another area is human epidemiological research. I touched on that that earlier in the day in terms of how we can use the information that's out there to better craft more effective programs, particularly our communications programs.

And I'd like to conclude with the need for molecular biology research, that to be able to greater characterize or discriminate amongst Salmonella enteritidis would be of tremendous help at all levels. They've done some fantastic work with campella bactor lately, indicating its movement from the farm to the ecosystem, not the reverse. It'd be great if we had a molecular biology tool to work on that with Enteritidis.

The California Egg Commission, in association with the California Department of Food and Agriculture and Lawrence Livermore Laboratories, the Commission providing the funds as well as I think CDFA, also spearheading the work and Lawrence Livermore doing a lot -- doing some of the work, the work being split, have got some work going, looking at the genetics of SE, and are making good progress in that area. So there's an opportunity for collaborative work on what they're doing in that area.

Thank you.

MR. McCHESNEY: Thank you.

Gregg.

DR. CUTLER: Yeah, Gregg Cutler.

I first want to compliment Dr. Brackett on really an excellent list of things that need to be done. In my work over -- in this area -- excuse me, in the past 10 to 15 years, those are the questions that have come to my mind about what we need to learn about this. Excuse me.

We need to commend the industry for some of the work that's already been done. In California, the California Egg Commission has already spent over $300,000 on research projects related to SE, and we've gained some wonderful information from that. We need to know much more about the ecology and epidemiology of SE. We really don't know how it transmits, we really don't know exactly the mechanisms by which it moves around. It's extremely fickle. It is extremely intermittent, and it's hard to predict where it's going to go.

We need to learn about the pathobiology of this. You know, what are the mechanisms that cause it to infect chickens. When I went to school I learned about SE as a disease of rodents. Was there some change in this organism over the years that caused it to then be infectious to chickens, and why did it decide that it could go to the ovary and be transmitted. These are outstanding questions.

We're sitting here today talking about developing

guidelines on how to prevent this disease, with really very little knowledge. And we need to develop this knowledge before effective guidelines can be established. I'm recognized as a fairly skilled and knowledgeable person regarding driving horses, and I really think that we're putting the cart before the horse here.

MR. McCHESNEY: Thank you.

Are there other commenters?

MR. KUNEY: Doug Kuney, with the University of California. And Dr. Cutler just kind of stole my thunder.

But California and several other states have quality assurance programs in place, and it appears from -- from the data that -- the epidemiology data, that they're working. And in fact, maybe by the year 2001 we will have achieved that 50 percent reduction in the incidence of human SE cases.

And since there is so much that we don't know about this -- this bacteria, its ecology, the epidemiology, and all, I agree with Gregg. I think that we would be implementing a plan based on historic information, old information. I think that these research ideas ought to be implemented, and disease studies should be conducted. And then implement a plan, a national plan based on this new information, plus the historical information.

Thank you.

MR. McCHESNEY: Thank you.

Is there someone else that's hiding back there?

MR. BELL: Yeah, a couple of us hiding back here.

Don Bell, again.

Relative to research needs, I think we have a untapped reservoir of data on the flocks that have been declared SE positive, either in the egg, in the -- in the earlier days, in the Pennsylvania data, and also in the environment. We have not gone back to those flocks and looked for common denominators, as I see it. There have been enough of these flocks on a national basis, if they were pooled, I think we would find answers, some negatives and positive answers to this.

Dr. John Mason, who is heading up the -- a project in Pennsylvania, tried to -- attempted to do this on many, many, many, many questions, and very well-thought out questions.

One that is coming back to haunt us, I believe, is the question of age or molting history. I didn't want to bring the subject up, but I think it needs to be said. Is the incidence, the tested incidence of SE more present in molted or older chickens than it is in younger or non-molted chickens? This, we -- we should expect a certain proportion, if -- if the molt itself was not responsible, we would expect a certain proportion of this.

To me, this is -- this could be determined within weeks or months of research, and we could lay to rest -- I think that's the term that Dr. Cutler said, we could lay to rest this issue and not indiscriminately do away with a practice which is worth so much to the industry today. It is -- it's a practice that is pro-welfare, it lengthens the the life of the flocks, it rejuvenates the flock.

I think we would all like to be rejuvenated the way a molted chicken is rejuvenated. And I think it could be laid to rest if someone would just take a look at the data.

I believe Pennsylvania is trying to do this, but it surely needs a hurry up before we disallow the practice.

Thank you.

MR. McCHESNEY: Thank you.

Another commenter back --

MR. KINDE: I am Hailu Kinde, from the California Animal Health and Food Safety Laboratory, University of California at Davis.

I have a few comments to make here in regard to SE research. The poultry industry in California has been very proactive doing, first of all, participation over 95 to 98 percent in the California Egg Quality Assurance Plan. And secondly, they funded the largest project looking into the prevalence of Salmonella enteritidis in big ranches

throughout the state. Probably this is the most well-thought, well-studied surveillance study.

Similarly, I would like to see a similar effort from the public health and also the restaurant industry to see -- to do something like that. A few years ago, we anticipated to do some research in the environment, in the kitchen environment of restaurants, to see the -- the status of environmental contamination in the kitchens. I think it's -- this is very important, especially when we look into food handlers and the way -- the behaviors in doing business in the kitchen. I think it's very important. That's an added value to the overall understanding of Salmonella enteritidis in human infection.

Secondly, we see the predominance of Salmonella enteritidis Type 4 in southern California, which we don't see it in the northern part of the state. What other factors are playing a role there? Of course, eggs are shipped up and down the state. The same eggs are consumed in Northern California as are in Southern California. But I think there are other issues which we don't know in regard to the ecology and epidemiology of Salmonella enteritidis. We need to study that.

And we have already established that Salmonella enteritidis is well-established in the environment, including drinking water reservoir, and other surface

waters. So I think these are the issues we need to see in the overall picture of the Salmonella enteritidis problem in human infections.

Thank you.

MR. McCHESNEY: Thank you.

Other commenters?

If not, we'll move into our open comment period. And there's a list of 22 people that have signed up that I have up here. And we're going to shoot for about three minutes apiece, and -- three -- three to four minutes. It's going to be three minutes, and I know you're going to talk longer.

Now, what I would ask you to do is I was thinking of how I was going to get people to talk just three minutes. And initially I thought I would get some eggs and throw them at you if you went over, but --

(Laughter.)

MR. McCHESNEY: -- we learned that's an unsafe practice. And I probably couldn't hit you.

So given that we can't do that, we're going to have to take the be responsible adult approach, the responsible adult approach, to respect those that have yet to comment and try to limit our comments. And we will come back -- if we have time, we will come back to you. And I would encourage you to make the salient points that you want

to make to keep the time down. And also remind you that we -- we really put up here about, oh, I don't know, 15 questions today, for your comment, out of a total of something like 21.

So it doesn't mean you just have to limit your final comments to what was already up here. If you'd like to comment on any of the other ones, I would encourage you to do so.

If you have a lengthy comment, I would encourage you to give us the three minute salient version of it, and submit the rest of it to the docket in writing. Even if you give us a three minute comment, I would encourage you to submit that to the docket so we have a record, and you can really get down what you wanted to say.

Now, I have a list here, and I will read this list off. And if we want to make this go rapidly, we kind of need to be up at the microphone. So I'll do the first four people, and as one person sits down, I'll announce the next one. We kept this list to ourselves here, but everyone has signed up.

So the first person on here -- and just because your name's on here, you don't -- don't feel compelled to speak if you don't want to. Okay.

The first person -- if you want to, you're welcome to, but you don't have to. The first person on the list --

the first four people are Linda Barr, Terri Barnato, Mark Campbell, and Dave Castellan. Dave's up here.

Linda.

MS. BARNATO: Terri.

MR. McCHESNEY: Terri. Is Linda here? Linda Barr.

MS. BARNATO: Linda had -- she had to go back to the capitol.

MR. McCHESNEY: Okay.

MS. BARNATO: She was going to speak about the legislation that's pending here in California to prohibit forced molting. But I'll speak to that.

MR. McCHESNEY: Okay. Is Mark Campbell here? Okay. Dave's here. And then Patricia Curtis, is Patricia Curtis here? But you don't want to say -- okay.

Okay, Terri. You have the floor for three minutes. I have a watch and will --

MS. BARNATO: Don't worry, I won't go over.

Terri Barnato, with the Association of Veterinarians for Animal Rights.

I have petitions in my office signed by 2,000 veterinarians from around the country that we've recently gotten, in the last two months. These veterinarians agree with us that withholding food from these birds for an extended period of time during the forced molting process is

inappropriate, especially when it isn't medically indicated for the birds.

They also agree with us that withholding food creates stress and immunosuppression in these birds, and that they are lacking in nutrition, and that this is a significant factor in the creation of Salmonella enteritidis in these birds.

And your suggestion for more research in this area just appears to me to be foot-dragging. You know, there has to be some consideration here for the wellbeing of these animals, and to date we -- we've submitted a petition to the USDA and the Food and Drug Administration more than two years ago on this issue. You've received hundreds of comments from the public, not people who have a vested interest in egg production, who want you to consider the wellbeing of these animals. And your silence is deafening.

We have a bill pending here in California to address this matter. You will see legislation in other states if the federal agencies don't want to deal with this, and the egg production industry, you can be assured of negative publicity that you deserve.

MR. McCHESNEY: Thank you.

MR. CAMPBELL: I'm Mark Campbell, Norco Ranch.

We would like to see more basic research, maybe a little money toward basic research, because there may be a

vaccine, something at the beginning of the cycle. Everything we're talking about is after this happens, and so we would like to see just a little more basic research.

MR. McCHESNEY: Thank you.

All right. Well, the next -- this is going pretty rapidly, so far.

The next person -- the next really four people -- Dave, did you have a follow-up comment, or --

MR. CASTELLAN: Just -- just a brief comment -- I don't want to take all the time, that's for sure -- to let everyone have a chance.

Just want to highlight a few key points, that the President's Food Safety Initiative promotes science-based approach to food safety. And I think we're all sitting here because we want to do that.

Number two, the American Federation of -- or, I'm sorry, the Association of Food and Drug Officials, of which I am a member, supports on-farm good agricultural practices as part of their -- their policy statement on SE in eggs. And I think that if -- if we can do that on the farm, and promote it at the retail level, as well, through our cooperative efforts with public health people and with the industry and researchers, that we can -- we can pull ahead and find answers to some of these things, given time.

The question is what do we do in the meantime.

Education is a key cornerstone, no matter if we're talking in the short term or in the long term. And I'm repeating myself, but education is so critical to changing human practices at the restaurant level, the retail level, the processing level. The SE risk assessment has stated, and I'll repeat again, that only -- human illness will only be reduced when more than one part of the food chain contributes to that reduction. We need to work together and not fragment all of these pieces that we've been talking about, in terms of research and education. We need to pull them all together and make them fit.

Thank you.

MR. McCHESNEY: Thank you.

The next four people on the list are Gregg Cutler, David Goldenberg, Hans Riemann, and Jill Snowden.

DR. CUTLER: Gregg Cutler.

Several areas that I'd like to address. One of them first is the goal of this entire process. Reduction by 50 percent and elimination in ten years. I think anybody who has read the literature on Salmonellas generally that affect more than one specie understand that a Salmonella cannot be eradicated. And I refer you to several papers, the Dillons Beach project, which is a well-recognized study about eradication of Salmonella. I think it's an unrealistic goal.

We've also indicated that at least 20 to 25 percent of cases of SE in humans come from sources other than the egg. If all we're going to address is SE in the egg, we're still going to have at least 25 percent of those cases still occurring. So we must have a multi-faceted approach that addresses all of those others if we are going to reduce them, and I think we need to look at pathogen reduction as the goal of this product.

I think that we need to look at process control. We need to look at what we're doing on farm and how we are doing it. We need to take the data that comes available from current research, from past research, from research that has been suggested here, and try to implement that as effectively and efficiently as possible.

We need to have a very strong educational component. Without education, anything we do here will just not -- not work. It just won't -- won't do anything at all. We need to educate producers, we need to educate processors, we need to educate consumers, and we need to educate regulators. There are too many of them who don't understand what's going on out in the field.

Going back to educating children. I made a note here that all I ever needed to know about food safety I learned by the third grade. And 50 years ago, when I was in the second and third grade, they had this thing called

health that they talked to you about, and you learned about safe handling of foods. That stuck with me.

I mean, I still always wash my hands before I eat anything after I use the restroom. This is something that kindergarteners need to learn, and I think we're failing to educate them at that point.

As far as research, I spoke to that some. As I said, the California Egg Commission has been extremely proactive. The other egg organizations in California have done a wonderful job of funding that, and we're making great strides in understanding. We need to understand the ecology of this organism. Without that understanding, all the rules and regulation in the world are not going to help reduce it.

Research needs to be presented to develop those rules and regulations. And again, I think we're getting way ahead of ourselves in regulating if we go before our knowledge. I think that our sampling techniques and -- and what we're doing here leave a lot to be desired in what do we do with the results of those sampling techniques. What does it mean if you get one positive sample out of a whole slew of environmental samples. What do we do with that flock? Is that flock really in a position where it may be putting eggs out?

In my experience with dealing for over 15 years with this problem, I say no. I say there's almost no risk

that that flock is putting anything out, and I think any regulations need to recognize some level of tolerance below which no action is taken, other than to review your process.

I think that, again, I need to -- to reiterate that this should be a pathogen reduction plan. We are never going to eliminate this 100 percent. Anybody who believes that just doesn't understand salmonellosis. And I defer to other people who know more about Salmonella than I do.

MR. McCHESNEY: Thank you.

Dave Goldenberg.

MR. GOLDENBERG: David Goldenberg, from the California Egg Quality Assurance Program.

It was almost three years ago to the date here, in this room, we signed a partnership agreement with the federal and state governments. The U.S. Department of Agriculture, the Food and Drug Administration, the California Department of Food and Agriculture, the California Department of Health Services, and the industry, signed an agreement here that it was going to cooperate with the California Egg Quality Assurance Program, industry and government working together to solve a problem.

About two years ago, we received a Hammer Award from Vice President Gore to show that this industry was working together to solve a problem. And this was to show that industry and government can work together to reinvent a

program, or reinvent government, so that we didn't have to have regulatory impacts here.

The California Egg Quality Assurance Program is a voluntary program, working with industry and government. And one of the differences that we see is that we can, as a industry, in a voluntary method, change -- make changes very easily and very quickly when -- when information is brought in. I think that's a big difference here. When you have a regulatory program, it takes months, if not years, to make changes.

And -- and as you can see in this whole process, you're talking about three years, whereas our industry got together, in six months it came out with a program. And when you look at the -- the data that we saw from CDC, that there's already a decrease in SE illnesses, one begins to wonder whether the government's a day late and a dollar short in putting together this program. I wonder if we just ought to leave it to these quality assurance programs to work together and to solve this problem. So I say that we need to keep it flexible.

As has been mentioned before, education is key. The California Egg Quality Assurance Plan trained producers, university, state and federal government officials, and health officials. Veterinarians, regulators, stood -- or sat side by side as we went through an educational program

that looked into egg processing, flock health management, C&D, biosecurity, pest management, and vector control. And in fact, we received a federal grant from the Animal Protection -- Food Safety FSIS, to formalize our educational program. And I submit this document, although the FSIS does have it. I submit it to you today.

We also conducted a survey of our industry to look at what they felt of the educational components of our program, and most of the results came back very positive, that they were able to make management changes in their operations based on the educational components that we put together.

We have formalized that through this grant by making some -- taking our educational component and producing two videotapes, one in English and one in Spanish, on flock health management and C&D. We have another one on rodent control that came from -- from industry, and also from government funding.

So, in essence, I think education is very important, and it needs to be expanded upon. I want to reiterate that working with industry, that the industry does not want to put out a bad product. I don't know any producer that says I'm a bad player, I like to put out dirty product. I think when you have a bacteria that's invisible, nobody knows that it's there, it's almost impossible to

regulate such a -- such a bacteria. And to come forward and to say that this regulation is going to wipe it out and -- by the year 2010, I wonder how practical that really is. It's not a -- a simple answer.

That's about it. Thank you.

MR. McCHESNEY: Thank you.

Next to Dr. Riemann. And then Dr. Snowden.

DR. RIEMANN: Thank you.

It's rather interesting that the President's Council on Food Safety has chosen to focus on eggs, since food and vector was reportedly caused ten times more frequent food-borne disease in eggs do.

Might be the feeling was that more was known about eggs to do something. But let me quote Mark Twain. He says, "The problem in this world is not what we do not know; the problem is that what you do know ain't so."

Now, in the meantime, the incidence of SE infections in humans is going down -- 5,492 reported cases in 1994, to 709 in 1998 -- and it might well disappear altogether before the plan can be implemented.

Some people are going to take credit for this decline, but I'm skeptical, because as you look back on the data from 1970 to the end of 1970's, you see there was a 50 percent reduction in the frequency of SE isolations. So what was the reason? We don't know.

I am sure that the shift in serotypes we see is caused by a new serotype being introduced in the main reservoir. We have seen that with Salmonella in fish meat. We have seen it more dramatically with Salmonella in some -- which was used as rodenticides in numerous countries for half a century. That probably was implanted solidly in the old ecosystem of rodents, where it might still be.

We have a risk assessment, an interesting one, because it's focused exclusively on the risk of eggs having SE when they leave the farm. One in 20,000, or 0.005 percent. Studies in Canada and elsewhere find that if you take sample in the supermarket you find up to two percent contaminated. So where do they come from? Apparently there are other sources which have been completely overlooked, and I think it's very important in your risk assessment to take a serious look at that.

The one to 20,000, one in 20,000 is believed to be caused by transovarian infection, and we don't know, because none of the disinfection procedures used in the laboratories who test eggs are sufficient to -- they contaminate the shell completely. So we don't know how many are sitting in the shell, how many are the interior.

It might not make much difference for the consumer, because when you break an egg you will just get the shell and the shell membrane in contact with the egg

white, but it does make a difference, because Salmonella that sits in the egg shell, they will slowly die out by 90 percent over two or three weeks -- in the interior they will multiply sooner or later if they are temperature abused.

And I could mention many other areas where they need results, and I will mention some of them that are meeting tomorrow. But I want to finish with this, that HACCP has been mentioned many times. HACCP is -- has been demonstrated to be a good food safety system. I think it should be applied very, very cautiously as a regulatory tool.

HACCP traditionally was a voluntary program, developed by the plant and the people who work in the plant. The plan became their own plan, it became part of it, they got educated in the process, and HACCP should develop and continue to develop through a sort of evolution, a continuance of evolutionary operation over years and years, so it can be improved.

I'm sure it will be improved. If it is cast in concrete, that might be much more difficult, and we don't know enough to do that. We have a tremendous lack of knowledge about the ecology of Salmonella in the farm ecosystems.

Thank you.

MR. McCHESNEY: Thank you.

I'd like to make one comment here. I've known Dr. Riemann for about a little over ten years now, and he was in the process of retiring when I first met him, and he has retired. So I -- if for no other reason, to solve this problem, we need to solve it so Dr. Riemann can actually stop working.

(Laughter.)

MR. McCHESNEY: Jill.

MS. SNOWDEN: Jill Snowden, Egg Nutrition Center. And let's see, we're down to three minutes? Well, there goes Plan A. But I have Plan B. Three comments. One -- and brief. And they'll be more -- elaborated more in the written ones.

And that is, when we talk about the benchmarks of human disease, whatever benchmarks we end up choosing have got to get related to eggs, because right now we've just got all SE, and we know some of them aren't coming from eggs. And no amount of egg-related programs are going to address the SE that come from the other sources. We also have some artifacts with the system, and that needs to be addressed in terms of the benchmarks.

We've got lots of opportunities for education and training that haven't been addressed yet. Targeted to education in food service, the vulnerable populations, and also special recipes and cultural practices. Maybe the

recipes based, or the food dishes may be based on looking at outbreak data, as to how we might want to target our educational messages so that we're talking about something other than a fried egg.

The consumer education, to make the consumer aware of options that are -- that are already available, that they're already in control of the safety of their food supply and their -- and in particular their egg supply.

That we've got pasteurized liquid product, and they're great for things like French toast and cookies. The California Egg Commission has cooked egg recipes that are available. So does the American Egg Board. So that when I made eggnog this year, I had a recipe at hand that I could use to empower myself to make -- to choose how I was going to operate in the kitchen, and what I was going to serve my guests as they came for a party.

So those things are available, but evidently are necessarily known about, that one can do those things with a little technology availability right now, to take care of yourself.

Another area for education and training is the small producers and the backyard producers, and we've discussed that earlier. I'm heartened to hear the remarks that indicated that they are going to be included as part of that, but there's certainly a training opportunity there,

because they're producing millions of eggs. And we were talking about trying to combat and get rid of thousands of illnesses. So certainly millions of eggs can make a contribution towards thousands of illnesses.

My third and final point is I need to conclude by emphasizing that the risk associated with eggs is very, very low. We're talking about an average of one in 20,000. That's .005 percent. You have to contrast this to the 10, 20, 30, 40, even 100 percent rate of contamination in other animal products.

So eggs are as safe or safer than any other raw animal product. And given that, certainly any disease associated with the product has got to be addressed. The industry has been addressing it, and the industry remains committed to continuing the decrease in human disease associated with Salmonella enteritidis, because certainly even one illness would be one illness too many.

Thank you.

MR. McCHESNEY: Thank you.

The next four people on the list here are Phyllis Geiser (phonetic), Diane Miller, Laurie Siperstein-Cook (phonetic), and Ralph Ernst (spelling).

I recognize Phyllis here, from before.

MS. GEISER: Could -- yeah. Phyllis Geiser, Hawaii Egg Producers Cooperative.

I came 2400 miles at my own expense, so if I go over a little, can you please be merciful?

MR. McCHESNEY: Well -- well, okay.

(Laughter.)

MS. GEISER: Okay.

MR. McCHESNEY: Maybe we'll just follow you all back -- we'll just move the meeting to Hawaii. How about that?

MS. GEISER: I represent the Hawaii Producers Cooperative, which is comprised of all commercial egg producers in the state of Hawaii. And we have just 580,000 layers. Our average number of layers on a farm is 65,000. Not half a million, not a million.

I wanted to share with you what makes us so different from the mainland states, what makes our costs so high. We don't have, as I said before, we don't have any breaking plants, no pasteurization facilities. We don't have any egg products produced in our state. We do not repack outdated eggs. No chicks of our egg production are hatched in our state. All chicks are air-flown from the West Coast. There are only two slaughter facilities on two of our eight islands, and only one rendering plant on Oahu. All packaging material and feed are imported through the c continental United States by ocean freight.

Despite all of this, we still are able to maintain

a majority of our market-share. And we believe it will be cost-prohibitive for us to export our eggs, so we do not export anything.

We believe that the suggested testing program in Strategy 1 will be devastating to our state because of our unique situation, and because of our small economy of scale.

We believe that the components that are listed in this national plan can be adequately addressed by our own State Egg Quality Assurance Plan. We have been working with the State Department of Health and the State Department of Agriculture effectively to regulate our egg production and marketing.

And we feel that the Hawaii regulators are acquainted with local customs, practices, and requirements, and should continue to regulate -- have regulatory oversight.

We believe that the Action Plan standards do not provide our Hawaii egg producers a level playing field with the U.S. industry.

Another thing we would like to suggest is that there has been a discussion of education, and we feel that we should also give funding assistance to our state because of our high Asian population that speak English as a second language. A lot of these immigrants are operating food establishments, and we feel that if you could assist our

state with translating the message in your educational materials, along with the graphics, in their respective language and dialect. We're concerned about getting the message to the Filipino, Korean, and Vietnamese communities.

And so, all I'd like to say in closing is that we don't want to lose the producers that we have because they can't afford to do the testing and they can't afford to do all the things that are listed in Strategy 1, and yet they are not producing positive eggs.

Thank you.

MR. McCHESNEY: Thank you.

MS. MILLER: Hi, good afternoon. My name is Diane Miller, and I'm here on behalf of Farm Sanctuary, a non-profit organization which promotes humane and healthy agricultural practices.

I appreciate the opportunity to address the connection between inhumane animal agricultural practices and human health hazards. Specifically, I will relay our concerns about battery cage-egg production and the practice of forced molting, and the human health risks associated with subjecting layer chickens to these conditions.

Forced molting is conducted in an environment that encourages Salmonella to colonize and multiply. The living conditions under which forced molting is practiced are inherently pathogenic disease-producing, and forced molting

abuses an already chronically stressed bird, leaving it greatly susceptible to SE and other pathogens.

At Farm Sanctuary, we also operate shelters for farm animals who have been discarded by the agricultural industry, or have been seized in cruelty cases. And as such, we have the perhaps very unusual experience of rehabilitating laying hens who have spent their entire lives in battery cages, and who have been subjected to the cruel and SE encouraging practice of forced molting.

The thousands of laying hens who have arrived at our facilities from these circumstances have consistently exhibited numerous conditions indicating their overtaxed systems, debilitation and overall poor health.

The birds are uniformly malnourished. One of the most common indicators of such is the appearance of their combs, which are so pale as to be nearly white, and also completely limp and flop to the side, rather than the bright red color and upright position of the comb on a healthy bird.

Forced molting undoubtedly adds to and accelerates the condition of malnourishment in laying hens. And in addition, upon release from battery cages and arrival at our shelters, the birds also must undergo treatment and rehabilitation for a myriad of other intensive confinement, food deprivation and stress induced ailments, including foot

deformities, sores, bruising, and feather loss due to continual scraping on cage wire, respiratory diseases and infection, and acute infestations of internal and external parasites.

A miraculous thing happens when formerly -- when former battery cage laying chickens arrive at our shelter and are given proper nutritious feed, outside pasture areas and sunlight, and the opportunity to nest, dust, bathe, and carry out all of their instinctual behaviors.

Typically, within just seven to fourteen days of proper care and good nutrition, their combs will fully recover their deep red color, and the birds will re-establish their optimal body weight.

You know, it's a pretty simple theory, and it was mentioned a couple of times earlier today, that good sanitation practices go hand-in-hand with a disease-free product. And it is also obvious that the more humanely an animal in production is treated, the healthier and more resistant to disease it will be.

So then if the USDA, the FDA, egg-producers and all of you in this room are truly interested in reducing or eliminating the risk of Salmonella in eggs, you will follow the lead of many other countries who have banned forced molting to protect their consumers.

Thank you.

MR. McCHESNEY: Thank you.

Is Laurie Siperstein-Cook here?

MS. SIPERSTEIN-COOK: Hello. I'm also here representing the Association of Veterinarians for Animal Rights. I, myself, am an avian veterinarian, and I also am here to comment on forced molting.

No self-respecting companion animal veterinarian would recommend to a client that they withhold food from any animal, except for medically necessary purposes. Doing so for 10 to 14 days, as is done to induce the molt, would be unconscionable in a private practice situation. The hens are -- in forced molt are forced to lose 35 percent of their body weight, and up to one-and-a-half percent of the flock dies during this process.

In my case, if I were, say, jailed and not fed for -- until I lost 35 percent of my body weight, I would lose 60 pounds in that amount of time. And I'm sorry, but I would not -- I don't think I would feel rejuvenated after that. I would probably be hospitalized.

There is nothing natural or normal about this practice. Having birds of my own, including hens, I watch them go through their normal molts and their normal behaviors, and the forced molting process has nothing natural or normal about it. The stress that the hens go -- undergo causes immunosuppression, as it would in any animal,

and has been shown by USDA's own researchers to decrease the cellular immunity in laying hens.

And as a result, the SE can spread down a line of uninfected molted hens such that within ten days 80 to 100 percent of the hens have become infected with SE, compared with only five to 35 percent of unmolted hens.

Such an infection rate increases the rate of transovarian infection, as we've been discussing, in the subsequently laid eggs. Even if the first eggs laid are diverted for pasteurization, the infection within the egg can be continued to up to 140 -- 140 days. So some infected eggs can -- can go into table-egg use, even while they're still being infected.

Furthermore, a small -- in those circumstances, a small contamination problem can rapidly become a major problem in the facility, with potential consequences to the future flocks in that facility.

In closing, forced molting is a cruel practice that causes stress and disease in chickens, SE contamination of the eggs, and illness and death in people. The USDA and the FSIS have requested that the egg industry eliminate the practice of forced molting, realizing the relationship. And I would like to -- and I would like to see this become actually a mandate in the Egg Safety Action Plan that we have been discussing today.

Also today we've been hearing a lot about what to do about eggs after they have already been contaminated, such as testing, temperature control, handling, and cooking practices. However, eliminating forced molting on the farm would help to prevent this problem before it had a chance to become -- get started.

Thank you very much.

MR. McCHESNEY: Thank you.

Okay.

MR. ERNST: Ralph Ernst, University of California.

Just a couple of quick comments. I would like to applaud the Panel for their patience and listening to all this testimony today. I think lots of good things have come out in the discussion.

I would like to make the point again that several people have made, that if you want a really effective safety program at the farm level, we need to have a program that involves these ranches, and they need to be convinced that this is going to work, that this is a program that's workable and can work.

You can't do that unless you have an educational component and you actually inform these people about what's involved. They have to know about the -- that the human safety problems are real, and they need to see the data that show that, and -- like we have seen today.

Unfortunately, a lot of small producers aren't here. In fact, there's practically no small producers here. I'd also like to point out that the smaller people, of course, have to take care of their chickens. They can't come to these meetings. So it's very difficult to communicate with that audience, and we have to make extra efforts.

We need financial support to reach those kind of producers and get the material in their hands, and the educational material they need to implement this program. I'm sure they don't want to produce eggs that would infect anybody. They -- they feel very concerned about that. They usually have upscale consumers that want a high quality product, but the -- the challenge is to find ways to implement that kind of a program and make it effective.

Thank you.

MR. McCHESNEY: Can I ask a follow-up question to that, Ralph?

What -- and this -- we'll just pick on California. What mechanism would you recommend or suggest for doing that in the state of California?

MR. ERNST: Well, at the present time, of course we've been fairly successful, but -- but we've had a lot of help. We've made a lot of efforts to contact every individual that we can identify that produces commercial

eggs, even if they're not very large. I think the smallest one that I've contacted had -- produces -- had 2,000 hens. We didn't convince him yet to join the program, but at least he knows that it exists.

We have several small packer dealers that are in the program, and a number of others that have taken all the educational program and even maintain their current status by attending educational events -- we require that every two years -- so that they are in a good position to join the program, but they haven't been stimulated by their market, apparently, to do it yet.

So we have both of those categories. But I think they have learned a lot from the program, and they probably implemented a lot of the practices on their farms, even though they didn't join the program. So the educational component can be very helpful, I think, in reducing Salmonella, even though the people may not actually join a quality assurance program.

It is a challenge, and you have also language barriers, and we have ethnic group problems. And I don't think one educational method is going to be successful in all cases. A good example would be some people -- we were talking a lot about making wonderful VCRs, but what do you do if the people don't believe in having electricity in their homes? And there are a lot of farmers that fit that

category, and some of them raise chickens.

So I would say that, you know, we've got some problems we have to address, and certainly those people aren't on the Internet, so they're not going to access all the wonderful Internet addresses I heard today. So we've got to have a multiple strategy, and we've got to use professionals in the states that know how to reach these audiences. They are out there. Cooperative extension has a huge body of people who know how to reach farmers at all levels, and if they understand what's needed, I think they'll help us. But we've got to be proactive in that way, and get their help.

MR. McCHESNEY: Great. Thank you.

The next four people on the list are Jean Houve (phonetic), Carl Lofgren (phonetic), Armando Mirande (phonetic), and Pam Rundquist (phonetic).

Jean.

DR. HOUVE: Dr. Jean Houve, Animal Protection Institute.

I'm pleased to report that today I have learned which came first, and it was the chicken. So I would like to emphasize that in this program you have to look at the chicken. And I was also happy to see that FDA is addressing the welfare and the husbandry practices on the farm as they affect the chicken in their research sub-objective 7.1.

I know a lot of you would like forced molting as an issue to go away. It will not go away. If you really -- excuse me -- if you really -- really earnestly intend and desire to eliminate SE in eggs, I think you have to address forced molting, and if you don't do it now, you're going to have to do it between now and 2010, because it's shown to contribute -- USDA's own figures show that in one study, molted flocks produced SE positive eggs twice as frequently as non-molted flocks for a period of up to 140 days following molt.

That's three and a half months. That's far past the period in which it was stated earlier that they're not producing eggs, so a lot of these eggs are coming from forced molted birds, and I think it's a component that will have to be addressed, and I am glad to see that FDA is recognizing that.

Thank you.

MR. McCHESNEY: Thank you.

Carl.

MR. LOFGREN: Yes. This will be easy because I reduced my comments to print. I will submit them for the record, and I've also included a conceptual framework for the streamlined national comprehensive grading and inspection quality assurance in food safety for shell-eggs, from the UEP, United Egg Producers.

A couple of comments. First, I want to thank this forum for the opportunity to communicate in it, and to learn some of the things that I've learned this day. I would encourage the regulators to continue to look at the practice of centrifuge that is not sanitizable. I would urge that real small operations be encouraged to meet some of the same goals that the large producers are to meet, and hope that some of the eggs that they provide don't cause a problem.

The testing component in itself accomplishes very little. I would hope that it's based upon judging the performance of the program that it had at hand. It's important to have some form of a national supervision program so that all states end up with kind of an equal approach that is effective in their state.

Food-handling and preparation certainly is the final line of defense, and education in that area is very important, and I would say educate, educate, educate.

I believe that this group of regulators has done a very outstanding job in stimulating the producers in the western part of the country, and particularly in California, to react and become aware of the problems that we can eliminate, and I would especially like to thank the California Egg Commission, who has been a very active part in that and has supplied the producer a lot of information and a lot of help and support.

The California Department of Food and Agriculture has done an outstanding job in coordinating and assisting the producers in coming together and accomplishing what has been accomplished. And we really appreciate the forum that has been given here.

Thank you.

MR. McCHESNEY: Thank you.

Armando.

MR. MIRANDE: Yes. I have spoken what I wanted to talk about. But I think it's an egg producer who asked about research maybe of vaccine. The vaccines are there. They're not perfect. They're the best that current technology can produce, and if there was a better possibility the NIH would have a thousand times the amount of money that we have to develop it, and it would've been developed 15 years ago for humans. It does not exist for humans at whatever price you want. If you consider those limitations, the vaccines we have today for chickens, at four cents a dose, are pretty good.

They can be better, but before asking about maybe some research to develop vaccines, they should be willing to try what is out there available. I'm not suggesting everybody should try it, just -- just the people that need it, the producers that need it.

I just want to mention that I understand there

were three egg producers in the last week's meeting in Columbus, I understand there's like 14 or 18 producers here. I think that speaks a lot about the California egg producers, just from the standpoint of their presence here in this meeting.

Thank you.

MR. McCHESNEY: Thank you.

Pam Rundquist. Is Pam here?

All right. The next four are John Davidson, Ken Klippen -- the next three, really -- and Steve Gemperle. And we have two after that.

MR. DAVIDSON: I, too, wish to congratulate all of you for a sincere and sustained effort in trying to resolve the -- this big problem.

I think what we see here today are short-term goals as a need, and long-term goals as a need. My understanding is that some 800 to 3,000 people each day become ill to one degree or another. A short-term goal may well be vaccine, may well be husbandry, may well be any of the things in combination that we have been talking about today.

I submit that a support of both the economics of the egg producer, the economics of the public, the public health will be better served by just putting it out there and letting the public decide what it is they want to do.

If they know all the facts and they want to continue to eat eggs that are soft cooked, that are raw, eggs that are hard cooked, or eggs that are pasteurized in liquid form or in-shell form, at a greater expense or at a greater risk, that'll be their business. But I think your job might be to inform them of what you're doing, what you're doing on a temporary basis, what your goals are for a long-term basis, and to give everybody their chance to rise to the challenge and make a free choice.

I think that's really all that I would recommend today. Thank you.

MR. McCHESNEY: Thank you.

Ken.

MR. KLIPPEN: I'm Ken Klippen (phonetic), with United Egg Producers.

And I, too, would like to thank FDA, USDA, and CDC for this forum. This is a most excellent opportunity for the industry, consumer groups, and government to work together on a problem. And we have good news, really. The incidence of Salmonella enteritidis is declining, as we've already seen today. From 1996 to 1999, it's fallen 48 percent.

Now, egg producers, as you've heard today, and there's a great many in this room, have been very proactive in -- in trying to address the issue of food safety. The

group that I represent, United Egg Producers, developed a five star quality assurance program, and of course you have the -- the California Quality Assurance Program here.

But also, the egg producers, through the American Egg Board, was a founding member of the President's Fight BAC partnership for food safety education. United Egg Producers has worked closely with private firms to encourage effective and affordable Salmonella enteritidis vaccines. We feel that's an area that holds great promise.

Producers have been supportive to -- of the requirements to refrigerate eggs in storage and transportation, to designate eggs as potentially hazardous foods out of the model Food Code, and to provide better training for food service personnel and others who handle food.

Now, in the Egg Safety Action Plan, it's a good idea. There are some very positive features of the plan. But egg producers, as represented by United Egg Producers, supports a uniform nationwide quality assurance system that will assure consumers an even safer product. Producers believe that the rules must be the same for everyone, and that's some of the points we brought out in some of the comments that you heard today.

Additional steps to guarantee food safety are appropriate, even though SE incidence has been falling

without a comprehensive federal program to date. Egg producers' own actions have been helping to reduce the incidence of Salmonella enteritidis, and you've heard that today. And that's why we're taking the credit for some of these reductions. But we're glad to see the administration taking a comprehensive view and supporting nationwide requirements.

So there's a few areas in the Egg Safety Action Plan that do not go far enough. For example, it says we should conduct research on the practice of repackaging and reselling eggs that have been returned unsold from grocery stores. We should not study the practice. We should ban the practice. And here's the industry saying stop it, and we're all in agreement. Let's stop that, because we see the potential dangers inherent in that practice.

In addition, the administration plan should provide stronger incentives to implement promising vaccination programs where rapid progress is being made.

The plan, the Egg Safety Action Plan, places too much emphasis on testing and not enough emphasis on quick implementation of quality assurance standards. For packing facilities, the Action Plan suggests waiting more than three years before implementing these measures.

The plan would require more testing than necessary. And then we talk about diversion of eggs.

That's going to impact significantly on producers. It's not a step that we take lightly. Producers believe that diversion should be required only if SE is found in the product that is actually sold to the consumer.

That's the egg. We're not selling the environment, we're selling the egg.

The Egg Safety Action Plan calls for state agencies to implement many of its requirements. Now, producers fear that the -- that using 50 different enforcement agencies will lead to inconsistent enforcement that will be both unfair to the producers and potentially detrimental to the public health. If egg safety is a national concern, administration and enforcement should be on the federal level. Moreover, USDA agencies such as the Agricultural Marketing Service and the Animal and Plant Health Inspection Service already have personnel in the states. AMS inspects every egg packer quarterly, and in many operations full-time for grading, and have offered to provide third-party compliance services for quality assurance programs.

Now, part of the Action Plan is extremely -- has an extremely alarmist warning label that discourages egg consumption, reducing egg prices at a time when producers are already losing money, like most of the rest of U.S. agriculture.

The Los Angeles Times called this proposed label a "cigarette-style label". It should be changed. Now egg producers cannot afford to have their own government effectively telling people not to buy their product.

So how do we make the plan better? Provide funding for testing and provide better focus on testing requirements. This is taxpayer dollars. Move toward a uniform national inspection program, encourage development and improvement of quality assurance programs, provide guidance to the administration as it moves forward with the Action Plan, and to continue to provide comments in forums such as this.

Thank you.

MR. McCHESNEY: Thank you, Ken.

Stephen.

MR. GEMPERLE: This is Stephen Gemperle (phonetic).

I might sound like a broken record when I'm done, I'm not sure.

My first issue, if you were to prohibit molting a bird in a negative SE environment, I believe it would not effectively reduce SE. Given there's probably no challenge, molting actually improves egg quality and reduces cracked eggs. During the feed restriction period, eggs are not laid. The alternative is to kill the hens early, of

course, unless there's a sanctuary that could receive 25 million hens a year in California. The alternative to molting is to kill the hens early, which kills 100 percent of them.

Education is probably one of the most critical areas. There should be education of poultry farmers, and especially education of food service workers. My understanding is that a vast majority of actual illnesses in humans happen because of food service problems.

And I do have a question that I really don't know the answer to, and somehow maybe someone could answer it one day. Why is it that Salmonella is more prevalent in certain areas? Certain farms have higher prevalences in the percentage of farms, perhaps in regions, and then on specific farms there is higher percentages of samples that are positive. And why is that?

The next point I want to make a comment on is the pasteurization of shell eggs. It's an extremely expensive process. My understanding is it costs over a million dollars to have a facility put in, and it's also a patented process. You'd have a significant increase in the cost of eggs because they become specialty eggs, and specialty eggs have a very limited demand. Most consumers want the cheapest eggs available. This would put smaller producers out of business, most likely.

And what I understand -- oh, I said that.

Whatever program is developed should be tiered to effectively deal with farms or regions that have the highest prevalence. And, for instance, if you were to have vaccination or something like that to protect certain flocks.

Thank you.

MR. McCHESNEY: Thank you.

The final three people on the list are Laurie Girand, Mary Jo Brooks, and Richard Mattheis.

So, Laurie.

MS. GIRAND: Thank you. Laurie Girand, STOP, Safe Tables Our Priority.

I've had a couple of questions about what we do. We're a victim's organization. Basically, we -- our members consist of victims of food-borne illness. They're parents, they're children, and other consumers concerned about food safety. I don't think that was clear before.

Consumers are pleased with FDA's taking steps on farm with regards to eggs. We support programs such as that of FACT and the Pennsylvania Quality Assurance Program, specifically with multiple point testing and diversion of eggs. We want warning labels on eggs at grocery stores and restaurants. We also want incentive labeling for Salmonella negative farms. We want large and small producers to be

treated equally.

We are skeptical that the model Food Code, coupled with state enforcement, will be sufficient at retail. We are concerned that eggs are not overseen from farm-to-table by a single egg agency.

While we support education to help protect consumers from hazards coming into our homes, we would point out that if FDA and the industry are truly successful, our children won't need to be educated about egg safety, just as we weren't, because eggs will be no more hazardous than spinach.

As a consumer whose child almost died from food poisoning, I feel it necessary to point out, especially after all the discussion about consumer education, that 79 consumers didn't kill themselves. SE-contaminated eggs killed 79 people. As a consumer whose child almost died from food poisoning, I find it revolting that industry would work against warning labels which would help save lives and prevent illnesses.

We remind you that 150 million consumers who want to eat their eggs the way they ate them 20 years ago can't be wrong. Please give consumers what they want, SE-free eggs.

MR. McCHESNEY: Thank you.

Mary Jo Brooks.

MS. BROOKS: Hi. My name is Mary Jo Brooks, and I'm just an ordinary private citizen. I'm not a Ph.D., and I'm not with the Egg Board. But I'm here to represent a growing number of people like myself that are just members of the public who are increasingly concerned about the quality of food supply, and also about the growing amount of cruelty in much of the factory farming industry.

So there are two points I'd like to make. First, it seems that a lot of the resources have been devoted to talking about how to treat some of the diseases after the fact. And it seems that given that some of the practices that are engaged in could be alleviated and thereby reduce the amount of stress and suffering on the part of the animals themselves, this would lead to healthier animals.

The public doesn't want more hormones and antibiotics and drugs in the food they buy. Many of them aren't here to speak because they have to take off work to be here during the week, and it's hard for them to do. But I can tell you I talked to a lot of these people. This is not what they want.

They're also very concerned about cruelty in the industry. So practices such as forced molting, which seems to be scientifically proven that this sort of practice, if it were alleviated, would up front cut down on the amount of Salmonella and a lot of the other diseases that the birds,

and therefore the eggs, develop. Seems like you have a win/win situation in cutting back on that type of practice, and at the same time reducing the amount of treatment after the fact.

So on behalf of the public, we'd like to see less drugs, less treatment, and maybe more humane treatment of the animals.

Thank you.

MR. McCHESNEY: Thank you.

Richard.

MR. MATTHEIS: I'm Rich Mattheis (phonetic), Pacific Egg and Poultry Association.

I know it's been a long day, and I do want to thank the Panel for all your time, and the transparency of this process, and, of course, we would encourage that that be continued.

I mentioned earlier the proactivity of the industry, and I want to talk about it some more here, as we conclude. But I do want to start by saying the industry, of course, supports food safety, supports egg safety. The industry knows that it is not good for the industry to have incidences and outbreaks, and that's why we're doing all that we can to prevent that.

What I can tell you, I'm not a producer myself, but I do represent producers, many of which are here today

and you've heard from. And I can tell you what they are saying. They're saying they're concerned that a plan that might be implemented would have significant economic impacts on their operations and their ability to compete effectively in the marketplace, and continue in business.

There is concern that a testing and diversion program would not be workable for us out here in the West, because we don't have breaking plants of a sufficient quantity to deal with that kind of issue. There's a feeling out here that we've done a lot, from a practice standpoint, to provide a safe product.

The California Egg Quality Assurance Program was outlined earlier by Mr. Goldenberg. It is a program that has been bought into by the industry. Over 95 percent of the eggs produced in this state are under that plan, and we'll get to that near hundred percent level fairly soon.

You heard earlier that there should be a uniform standard. But you also heard earlier from some speakers there should be some flexibility. There is more than one way to achieve an objective. There's precedent in government for recognizing regional differences. And that's particularly true in the federal government.

You know, in the air pollution laws we don't have attainment areas follow the same rules as those areas that are non-attainment areas for air quality standards. Even

under Federal OSHA, states don't have to have a word-for-word, regulation for regulation answer for the federal government in implementing those state standards. All they need to have is an effective program overall.

So that's why we would like the agencies to look at it in that fashion. Are there other things that can be done, other than what's been proposed. Can we get outside the box for a minute and look at alternatives to reducing Salmonella.

We think an egg-quality assurance program goes a long ways towards doing that. And we heard earlier about difficulties with enforcement, and that's something that wasn't talked about much here today. There was reference to contracting with the states, having those participate, there was reference to AMS and APHIS in performing enforcement. But are the dollars really there?

When you have an egg quality-assurance plan-type of program, you have a voluntary compliance situation where the industry has bought in, they've made a commitment to it, and are willing to do what that plan takes to improve their operations. With an enforcement program, you don't necessarily have that buy-in.

I think in recognizing regional differences, you also need to look at difficulties. Our friends from Hawaii commented about their problems with testing and diversion,

and recycling materials and those kinds of things. And we think the plan must respect those differences and unusual circumstances.

We think you should be -- in recognizing regional differences, you need to look at the body of law that's in those states. And I mentioned those pieces of legislation earlier, which -- most of which we drafted and put on the books in the last four years with our support for additional funding for enforcement, and recognize that those, coupled with a quality assurance plan, can significantly reduce Salmonella.

I think it's interesting that reductions in Salmonella over the last four years have coincided with the advent and implementation of those plans. And I think that's something that needs to be considered.

We would recommend that as an alternative, the Agency consider having a voluntary compliance program under which producers, by entering into and under a egg quality-assurance plan, would be relieved of some of the other requirements you might have for producers where such a plan is not in place.

That's all I'd like to say here today. I thank you for your time, and we'll be submitting some written comments, as well.

MR. McCHESNEY: Thank you.

I'd like to thank -- is there anyone who was not on that -- we have a couple of minutes. Is there anyone who was not on this list that would like to make a short statement?

Seeing none, I'd like to thank you especially for making my job as the Moderator easy this afternoon. And especially during this comment period, where in the past people have always -- at other meetings, have droned on and on. I thank you for your conscientious watching of time, and your respectfulness to everyone's comments. It made it very easy for me. Thank you.

Now I'll turn it back over to Lou and Judy.

MR. CARSON: Just a few brief closing remarks.

We, the federal government agencies here at the table, FDA, FSIS, APHIS, AMS, CDC, want to thank you all for your constructive and cooperative comments and questions today. They certainly are informing us on how we need to proceed. We had a public meeting last week in Columbus, and this is our final public meeting as we try to craft our proposed nationwide consistent standards.

I think many of the comments that you've raised, both respecting flexibility but having an even playing field, are something that we will have to grapple with and it is our challenge to come up with something that is practical -- practical, doable, but also protecting the

public health.

We especially want to thank you for your information that you've shared with us. As we came to these two public meetings -- Bob did not really reflect on it much, but it has been very difficult for us to come up with specific cost information from the industry as to what practices have already been put into place. And I think in both meetings we've gotten a large amount of that kind of information, and we would ask you to continue to do that and funneling in your written comments.

Remember, we have until April 20th so that we can also meet our deadline. So we would really encourage you to submit written comments to the docket so that we can consider those.

I also want to comment that it seems to me that many of the comments you've made here were also made by your colleagues in Ohio, Pennsylvania, Indiana, at our previous public meeting. Many of them asked for an even playing field so that they can present a product to the consumer that's as safe as possible, but also cost-effective for them to produce. And hopefully, we will be trying to craft such nationwide consistent standards.

Again, the President's goal, and what our goal should be here today, regardless of what level of illness is out there, it's too much. And what we're all here today is

to try and reduce that to the extent possible and practical. And as many of you have pointed out, we need to have science-based approaches to doing that.

We believe we do have enough information to proceed. We will have to justify that in our proposed regulations. You will have an opportunity to comment about the soundness of those regulations.

But suffice it to say I think as evidenced by PQEP and CQEP, and other state programs, you do have enough information for you to proceed forward, and what we are trying to do is to use that same information in making nationwide consistent standards.

I want to thank you all for your participation. It's been really great for us to hear from you, and we would ask you to continue to keep in contact with us as we proceed in proposing those regulations.

Thank you very much.

(Thereupon, the Public Meeting was concluded at 4:40 p.m.)

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CERTIFICATE OF REPORTER

I, VALORIE PHILLIPS, an Electronic Reporter, do hereby certify:

That I am a disinterested person herein; that the foregoing United States Department of Agriculture Hearing was reported by me and thereafter transcribed into typewriting.

I further certify that I am not of counsel or attorney for any of the parties in this matter, nor in any way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 17th day of April, 2000.

_____

Valorie Phillips
Official Reporter