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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

PROPOSED RULE FOR PREVENTION OF  
*SALMONELLA ENTERITIDIS* IN SHELL EGGS  
DURING PRODUCTION

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P R O C E E D I N G S**Welcome and Introduction**

DR. BRACKETT: Good morning, everybody, and I would like to thank you for coming to the first of three public meetings that we are going to have on this subject, and that is FDA's Proposed Rule for Prevention of *Salmonella Enteritidis* in Shell Eggs During Production.

We believe that the implementation of on-farm prevention measures is an important step that can really help reduce the number of cases of egg-borne *Salmonella enteritidis*, and that these programs have shown that they have been worthwhile in many of the states which have adopted quality assurance programs that employed some of these, and they have worked well there but we thought it is in the best interest of the country as a whole to have these practices applied uniformly across the country so that those states that do have those good programs in place are not at a disadvantage, and so that the public that obtains eggs from eggs that do not come from those states are not at

higher risk.

We believe that the further actions to improve egg safety, that is, building upon the Safe Consumer Handling, Labeling and Egg Refrigeration Rule that we had in 2000, are the most effective way that we can achieve our public health goals of 50 percent reduction in overall salmonellosis and also, in particular, 50 percent reduction in *Salmonella enteritidis* outbreaks by 2010.

One of the people that we have had that has also been a champion for this particular issue has been our Acting Commissioner, Dr. Lester Crawford, who is also here to open this up. He has been a leader in many areas in food safety. He has been a person in the commissioner's office who has really put a spotlight on food safety. We really do appreciate that as well. As Acting Commissioner of the FDA, which is the nation's principal consumer protection agency, Dr. Crawford assures that many of the practices that we have for food safety are implemented; that they get the recognition at the agency level that they deserve,

and he has done that. And, he has had a history of food safety so he has been experienced at this from the past.

Many of you know that he has a long and very distinguished career both in academia and in government. He was the chair of the Department of Physiology and Pharmacology at the University of Georgia, and administrator of the Food Safety and Inspection Service at USDA, as well as served in the Center for Veterinary Medicine as the director of the center at that center as well.

All of these have connections with food safety and so, consequently, it should not be surprising that he has food safety close to his heart. He has played major roles in mandatory nutrition labeling; formation of the World Trade Organization; and control of chemical and microbiological contamination in foods, both in meats and poultry, as well as FDA-regulated products; and has been an advisory to the World Health Organization and United Nations for much of his career.

Dr. Crawford received his doctoral of veterinary medicine from Auburn University and his Ph.D. in pharmacology from the University of Georgia, and he also holds an honorary doctorate from Budapest University. So, I would like to introduce and bring up Dr. Crawford for his comments to open up this meeting.

#### **Opening Remarks**

DR. CRAWFORD: Thank you very much, Bob. It is a pleasure for me to be here. I am happy that all of you are here as we kick off these sessions that deal with the so-called "Egg Rule."

My first association with it was when I was Acting Assistant Secretary for Marketing and Inspection Services at the U.S. Department of Agriculture in early 1989. I knew that I had to do something important in my first day on the job because I knew it was going to be my last day on that job.

[Laughter]

So, when the CDC report, long awaited and much anticipated and actually a brilliant report,

came forward on *Salmonella enteritides* in eggs, the numbers of people who were being infected and numbers of people who were dying and being made very ill was just startling. So, there was a big news story on that particular day in 1989 and we recognized, with my great experience as assistant secretary of a few hours, that we needed to get something moving on this and needed to get it moving fast. So, I remember asking the staff there that I assumed USDA would be doing this and they said, well, you'll have to go a little further than that. You'll need to find out which agency will be doing it.

So, I asked General Council, Alan Roll, who is a good friend of mine, who he thought and he said, "well, I think it'd probably be APHIS." So, I called up the Animal, Plant Health Inspection Service, the now famous phone call, and it turned out that the administrator of APHIS only had one day left too, primarily because of the phone call. He said, "oh, no, we don't do eggs. We don't do eggs. We've never done eggs; never will do eggs."

Eggs scare me to death."

[Laughter]

Then I asked Alan Roll, "who else do you think might do eggs?" He said, "well, you can try the Egg Marketing Service." They were about ten yards away from me and reported to me for that day. They would not return the phone call and the administrator of AMS got ill when I was trying to get to him about the eggs because it was a front-page story in the "Washington Post"--I believe the banner headline.

So, then somebody said, well, you need to try FDA and I said, well, what part of FDA? So, I called CFSAN and they said, "you know, we really don't do eggs." So, it was quite a calamity and now we do know who does eggs. I remember calling up the Center for Veterinary Medicine that I headed up until a few years before then and told them that they did eggs, and they said, "well, you no longer work here so we're not going to do eggs for you either."

[Laughter]

But we do know now, and thanks to Dr. Brackett and his group at CFSAN for being absolutely stalwart in seeing this Rule to completion. It is not completely completed at this point and that is why we are having these meetings, but I want to publicly commend Bob for his leadership in this particular area. There is every reason not to do an important public health rule like this and Bob wouldn't listen to any of them and that is why we are here today. Also, a lot of ground-breaking parts of this Rule, like FDA being on the farm; like us holding a standard that is fairly strong, indeed; and there is much that is precedential about this particular rule but let me just talk to you about a few things.

It is estimated that there are 118,000 foodborne illnesses per year caused by consumption of *Salmonella enteritides*-contaminated eggs, and you will hear more about this as this meeting goes on and I am pleased to see so many of you that are truly expert, both in the field and in the advocacy of public health and food safety, and that gives me

a great deal of heart.

If you were to eat an SE-contaminated egg that wasn't fully cooked you could suffer symptoms ranging from mild to severe gastrointestinal illness, short-term or chronic arthritis or even death. We believe that this rule on the prevention of SE in shell eggs during production, when implemented in egg production facilities, will significantly reduce the number of illnesses caused by SE-contaminated eggs.

In fact, according to our estimates, the implementation of the provisions of this rule would be a major step forward. There are a number of *Salmonella enteritides* illnesses, 33,500. We believe there will be a 50 percent reduction in all salmonellosis and a 50 percent reduction in SE outbreaks by 2010 as this rule goes forward.

The proposed rule that we are seeking your input on today builds on our earlier Safe Consumer Handling, Labeling and Egg Refrigeration and Retail Rule published in 2000. Our motivation in proposing this new rule is based on a farm-to-table

assessment of SE in eggs that have identified implementation of on-farm prevention measures as a very important step that could reduce the occurrence of SE infections from eggs.

We realize that voluntary quality assurance programs in the egg production industry have led to meaningful reductions in SE illnesses, but these programs are not always uniformly administered and they are not uniformly comprehensive in their prevention measures. I want to emphasize that this rule would apply to all egg producers with 3,000 or more laying hens that produce shell eggs for retail sale and do not process their eggs with a treatment such as pasteurization to ensure their safety. This rule would not apply to producers who sell all of their eggs directly to consumers or producers with fewer than 3,000 laying hens.

Also, if a producer has 3,000 or more laying hens and all eggs at the farm are given a treatment that will achieve a 5-log destruction of SE or are processed into egg products, then only

the proposed refrigeration requirements would apply.

Some of the major production areas that we addressed in this proposed rule, and which you will hear about in detail from our CFSAN representatives and colleagues, include procurement of chicks and pullets; biosecurity; pest and rodent control; cleaning and disinfection of poultry houses; and refrigerated storage of eggs on the farm.

We know that there will be a substantial cost to producers due to SE annually. We estimate that implementation of this rule will cost \$82 million per year for the more than 4,100 farms that have 3,000 or more hens. But it will prevent 33,450 illnesses due to SE, and the illnesses are estimated here by Dr. Brackett and company at \$2,450 per illness. This would be a total annual benefit of \$580 million resulting in \$500 million in net benefit annually.

I appreciate the fact that the requirements call for us to do this cost analysis, but I don't believe that anyone in their right mind

and in good conscience could rate this illness as being \$2,450 if they have ever had the disease. I have had the disease, and this is a gross underestimate because it is a horribly inconvenient disease. I was one of the first victims of the disease, and it happened in the year 1986, and it happened not in the United States but in Belgium. I was there for a meeting. It was another time when I was acting assistant secretary for a day, and I got off the plane in Brussels and the U.S. embassy in Belgium that was picking me up said, "we need to take you out to Antwerp because there is a building being dedicated out there and you are the highest ranking person today from the United States in the country. It's a small country and although it's on the other side, we can take you out there before you speak tonight." And I said, "well that would be great; I'd love to go out there." So, I got into the car and we went out and dedicated for Jansen Pharmaceutica, a company that did business in the U.S. as well as in Belgium and I guess was U.S. controlled by then. They were dedicating

something that I am really good at dedicating, which was a sewage treatment plant.

[Laughter]

But it was a nice sewage treatment plant!

[Laughter]

It looked a lot better than their headquarters, to tell you the truth, which was an old dairy barn. But as I went in they were serving champaign prior to my presentation which had just been given to me; standing in the corner of the tent, trying to figure out how to say what I was going to say because the presentation was in French, which doesn't come easy. I do French but I have, as you may have noted, a west Alabama accent so I wasn't sure quite who was going to understand what the heck I was saying. But as I was standing there, these Flemish girls in period costumes with wooden sandals came up with a tray of champaign in one hand and in the other hand they had what they call quail eggs on toast. The quail eggs were not staying on the toast very well. They were slopping around and slipping, if you get my meaning. I

don't believe they were quail eggs; I think they were probably pullet eggs from England at the time. I said, "no, I don't want any of those eggs, for sure," but I took the champaign. The next time they came around with the eggs I took the eggs as well as the champaign and I was sick off and on for six months and the last time I ever lost any weight was that particular time, and it was not worth it and it would cost me a whole lot more than \$2,450.

I don't mean to cheapen or trivialize what we are doing here today but it is a very important illness. This is an extremely important public health step. I wish you the best in your deliberations today. As you know, this is an open and public process so we, at FDA, want to hear what you have to say. I will be watching this very carefully because this is something, as you have just learned, that I have been working on for about 18 years. I have said to Dr. Brackett, who has suggested that I retire from time to time when we have gotten into usually budget disputes--I told him that I am not going to do it until we get the

shell egg rule out. So, at some point in the future I will be able to go fishing in South Carolina but thank you very much, indeed.

[Applause]

#### **Overview of Public Meeting**

MR. CARSON: Thank you, Dr. Crawford and Dr. Brackett. My name is Lou Carson. I am Deputy Director of Food Safety staff here, at CFSAN, and I will be your moderator for today.

I would like to tell you a little bit about the day's proceedings and then what you have in your package. Each one of you should have received a packet as you came in today. On the right-hand side is the agenda and behind the agenda are the slide presentations that will be given, one by Dr. Braden and one by Nancy Bufano. On the left-hand side you will have the press release, a fact sheet and a detection of salmonella paper in poultry houses.

The purpose of today's meeting, as has already been mentioned by Dr. Brackett and Dr. Crawford, is to start a public comment period that

was initiated actually on September 22 and will conclude on December 21. Our purpose today is to further describe and explain the Proposed Rule on *Salmonella Enteritides* in Shell Eggs During Production. We are also appreciative of having Dr. Christopher Braden, from the Centers for Disease Control and Prevention, here to discuss CDC's current data and information on SE human illness and outbreaks.

As has already been mentioned, this is the first of three public meetings, today here in College Park; on November 9, in Chicago; and on November 16, in Los Angeles, California. Today's meeting is laid out as follows: We will have two presentations, first Dr. Braden and then Nancy Bufano. Then we will set up a panel here to answer questions that you may have based on those presentations. We will be joined on the panel by Dr. Bradley Brown, who is an economist here at CFSAN.

I want to mention that today's comment period and what questions we can actually answer

are only on clarifying questions. We do have a comment period set up but if, during the clarifying question period for the panel, you do ask or mention a comment we will simply acknowledge that comment and the transcription will contain that comment and it will be submitted to the dockets as if you had written it to the dockets.

I just also want to mention a few administrative details. If you haven't already recognized, if you need the restrooms, they are up the stairs, down the hallway on the right as you proceed. And, we will have one 15-minute break that will follow the panel session just before the public comment period.

To date, we have two groups who have asked to make public comment so we will simply introduce them first but anyone here in the audience is free to make public comments and we will simply ask you to raise your hand after those two comments are made and we will offer you an opportunity to make those comments. We do try to keep comments to about five minutes per person so that we can allow

everyone to make comment who chooses.

With that, I would like to introduce Dr. Christopher Braden from the Centers for Disease Control. He is a medical epidemiologist and he will be talking to you about CDC's current data on SE illnesses and outbreaks.

**CDC SE Human Illness/Outbreak Presentation**

DR. BRADEN: Thank you. It is my pleasure to travel here from Atlanta to present to you today. As has been said, I would be happy to entertain any questions on clarifying the data that I am going to show you today during the panel that we will convene later on in this meeting.

But let's go ahead and start with my presentation. I am in the Foodborne and Diarrheal Diseases Branch in the Division of Bacterial and Mycotic Diseases at the National Center for Infectious Diseases at CDC--the usual mouthful of acronyms and so forth that you find from the government, you can find there too.

I am just going to clarify a couple of terms that I will use over and over again during my

presentation. One is *Salmonella enteritides*, and what we mean by that is that it is the bacterium salmonella, species *enterica* and the serotype is enteritidis and it is referred to as SE often in these slides.

A serotype is a subcategory of salmonella based on the reaction with specific antibodies. Salmonellosis, of course, is the disease that is caused by infection with *Salmonella enterica*, and I will be talking about isolates quite a bit because that is what our surveillance is based on, and an isolate is just a salmonella bacterium obtained from a single laboratory culture from a patient.

Now, I am going to talk about two types of surveillance today. One is a surveillance of individual patients. Salmonellosis, as many of you know, is a nationally notifiable disease and states have laws which require case reports to local or state health departments. But then the states voluntarily report those cases to the Centers for Disease Control.

The second type of surveillance is a

surveillance for foodborne outbreaks. A foodborne outbreak is a situation in which two or more people are ill due to a common food exposure. They may be reported to health departments by people involved in an outbreak, especially if they know or are suspicious that a common food has been the source of their illness. But they also may be recognized by health departments through their surveillance efforts. Outbreak reports are then reported to the CDC by health departments basically after they are investigated or identified and investigated in aggregate. It is not a patient-based system so that a report will come of the aggregate summary of an outbreak having so many cases and due to this type of vehicle and due to that type of pathogen.

I am going to start with our case surveillance, the National Salmonella Surveillance System, established in 1962 when serotyping was just really being implemented widely in the United States, and at first it was a paper-based aggregate collection of data prior to the 1980s, at which time the Public Health Laboratory Information

System was implemented. That system is an electronic system that collects isolate data by serotype, and it is based on the number of salmonella isolates at public health laboratories.

Now, salmonella is not fully serotyped by clinical laboratories. For the most part they need to send them to the public health laboratories for them to be serotyped, and that is a fairly routine thing for many clinical laboratories to do. So, we think that this is a fairly complete measurement of salmonella isolates in the United States.

Let me go right to some data now. For the four top salmonella serotypes in the United States, starting from 1970 up through 2002--and 2002 is our last published data we are trying to get the 2003 data out now--but kind of dominant here is this upper line which indicates *Salmonella typhimurium*, and in 1985 there was this huge outbreak due to contaminated milk. That kind of compresses the axis over here of isolates in thousands. So, what I am going to do, I am going to take that outbreak out and kind of expand that axis a little bit to be

able to see what the trends are a little bit more closely.

What you will see is that *Salmonella typhimurium* has been historically the predominant serotype of salmonella in the United States until the rise of others, in blue here, *enteritides*, and in yellow here, serotype *heidelberg* in the late 1980s. *Heidelberg* then started to drop off but *enteritides* continued its climb in the number of isolates reported to the CDC and became the number one serotype in the mid-1990s. On the bottom there, in green, you will see *Salmonella newport* and *Salmonella newport* is making a little bit of headway in illnesses, if we can call it that, more lately.

A little more detail about *Salmonella enteritides*, here, starting in 1989 to 2002--you remember, this is where you are seeing this increase before here so we are just looking at the top of the curve here and then more recently. So, 1995 actually was the peak of *Salmonella enteritides* cases that were reported to CDC at

10,201. In about 2002 it is just about half and 5,116 was the number of isolates reported to CDC in 2002. But most of that decrease was made in the late 1990s and you can see that basically since about 1999 to 2000 we haven't made a lot of progress, although from 2000 to 2002 we have had a bit of a decrease.

Many of you also know that *Salmonella enteritides* is not homogeneous by region and this graph shows that. The green line is New England states. The pink line is the Mid-Atlantic states. Here, in black, are the Pacific states and then, in yellow, the mountain states. The light blue line here is the total cases as we have seen in the previous slides.

So, you can see that this is actually the rate, the number of illnesses per 100,000 population, and the rate historically has been around 1/100,000 back before the 1970s or so but it climbs to over 10 in a couple of regions in the United States during what we call the *Salmonella enteritides* epidemic in the United States. It

seemed to spread from the east to the west as time went on. But basically most regions of the country have seen some fairly dramatic decreases since the late 1980s.

I am going to go ahead and talk about another surveillance system that we have for case surveillance in the United States that is managed by the CDC but has full participation of both the FDA and FSIS in the USDA. This is called FoodNet. FoodNet is a network of selected state public health departments in the United States which participate in conducting active surveillance, surveys and epidemiologic studies. I have listed here the bacterial pathogens for which they do active surveillance.

What I mean by active surveillance is that they don't depend on the clinical laboratories for forwarding isolates to the state public health laboratory and the state public health laboratory then reporting them to CDC. These state health departments routinely audit the records for clinical laboratories throughout their catchment

area for isolates of these pathogens. So, that is what we mean by active surveillance.

These are the FoodNet sites currently but the number of FoodNet sites has grown in the United States starting in 1996 when FoodNet started, and the population that was covered at that time was 14.3 million, by 2002 36 million people were in the catchment areas of FoodNet sites, representing about 13 percent of the U.S. population.

FoodNet actually has not shown a significant decrease in *Salmonella enteritides* between 1996 and 2002. Remember, FoodNet is not necessarily representative of the country as a whole but in those FoodNet sites, in this graph, what you have here is the baseline. This is the reference point of 1. Anything below 1 would be a decrease; above 1 is an increase in a relative rate compared to 1996. So, you can see that year by year, in this analytic model, they first had a decrease but then it has come back up a little bit in 2002 where we had basically no significant decrease in *Salmonella enteritides* in FoodNet sites

given their surveillance.

I am going to describe another thing that FoodNet does. What it does is it studies what we call a surveillance pyramid. The surveillance pyramid is the fact that what we get reported to CDC is basically a small proportion of what actually is happening out in the community. You have a population that is exposed to some risk. In this context it would be *Salmonella enteritides*. Some of those people who are exposed become ill. A fairly minor proportion of those who become ill actually seek care. If they seek care, the doctor may treat empirically without obtaining a specimen but some specimens are obtained and, of course, you have to obtain a specimen before you can test a specimen and isolate organism. Then, finally at the top is whether that organism is reported to the health department and CDC.

So, what FoodNet does is it tries to fill in those steps in some quantitative way to measure what proportion of those cases are actually measured in the end. In order to do that they

conduct surveys. For instance, they conduct a population survey to see how many people were ill with an illness consistent with salmonellosis in a given period of time, and then how many of those people actually went to seek care for that illness, and they do that through telephone surveys, very large ones. They do a physician survey to see, if they go and seek care, what is the physician's usual practice about obtaining specimens and a laboratory survey to say, well, do you do the correct test to actually isolate salmonellosis or *Salmonella enteritides*, and then to determine, of those tests in clinical laboratories, how many are then forwarded on either by reports or by sending isolates to a public health laboratory for surveillance purposes.

This is the result of the combination of those intermediate steps. In 2002 we had 5,116 cases reported and those are, remember, isolates that were identified or received in state public health laboratories. For every case of salmonella infection reported 38 go unreported due to the

laboratory insensitivity, lack of culture or not seeking care. If you multiply that out, why, then we get 194,408 cases.

We have done some analysis of the sensitivity of that particular estimate and about 90 percent of the time you will find that this multiplier falls between 23-65. That gives you some range there. We did this by Monte Carlo simulation for 90 percent inclusion.

I am going to go on now to talk about *Salmonella enteritides* outbreak surveillance. Outbreak surveillance for this disease started in 1973 with the collection of paper reports. Reporting forms and the system was enhanced in 1998, and I will show you the results of that in a minute. In addition, we implemented what is called the Electronic Foodborne Outbreak Reporting System, or EFORS, in 2001.

Here you can see, historically back before 1998, that we would get anywhere from 400-800 reports of outbreaks, total outbreaks due to anything in the United States. This is not

*Salmonella enteritides*; this is all outbreaks of foodborne origin, all pathogens, chemicals, viruses. Then, when we did what we call CDC-initiation improved reporting in 1998 we basically doubled the number of reports that we got to us. What we mean by that is we basically went back and we started verifying outbreaks with the states that report them and then they say, "oh, we got these others that we didn't report," and sent us cleaner data, more complete data, and that increase we don't believe is real. We believe that is a surveillance artifact due to the fact that we were more active in collecting those reports.

So, what do we have as far as outbreaks due to *Salmonella enteritides*? In 1990 to 2002 we have a decrease over time. Now, this is just the numbers of outbreaks. You can see them going from 1990 to over 80 outbreaks a year to 2002 where there are 29 outbreaks. But, as I said, you know, there is some surveillance artifact that is mixed in there. Okay?

This next slide looks at percentage of all

outbreaks that were outbreaks due to SE. We see, of course, that when you get past 1998 the percentage is smaller and you see this decrease occurring over time. This is all good news.

This is the number of cases in outbreaks from 1985 to 2000. I don't know how many of you remember the Swan's ice cream outbreak that kind of dominates the graph there, but the number of cases in outbreaks actually hasn't decreased all that much in the last number of years.

I am going to talk a little bit more about some of the characteristics of *Salmonella enteritides* outbreaks. When we collect this information we try to determine the venue in which the outbreak occurred, and for the most part outbreaks occur in commercial venues. They also occur in health institutions, homes and others in about equal amounts but more than half occur in commercial venues.

This is an analysis of 960 outbreaks between 1985 and 2002. The commercial venues include restaurants, delis, bakeries, cafeterias,

vending trucks and catered events.

Then, I am going to spend a little bit of time on this in a few minutes but here is what we have as far as we know about egg-associated SE outbreaks. As I told you before, in 1985 to 2002 we were analyzing 960 outbreaks. You will see that for just under half we actually determined the vehicle, the food that was responsible for a foodborne outbreak. When you look at outbreaks where the food was determined and where you could determine whether an egg was part of that food--that is why this denominator is a little bit different than that one where 326 over 413, or 79 percent of outbreaks had egg or a primarily egg-containing food as the vehicle. These are the associated number of cases for those numbers.

Over time that proportion has actually been very consistent. Although the number of outbreaks due to SE has decreased, the proportion of those outbreaks due to eggs has been consistent. That is determined in yellow, here; the blue is the non-egg containing outbreaks; in the grey there is

a food but we can't determine whether or not an egg was a component.

These are the types of foods that were implicated. In red is the largest proportion of eggs and egg batter dishes, at 32 percent; deserts, 25 percent; sauces and dressings that contain egg, 13 percent; and then a smattering of other types of foods, pastas, drinks and purees and stuffings in a catch-all category called "multiple," responsible for 9 percent.

I am going to go back and talk about foodborne outbreaks for a second. When you have a foodborne outbreak, often at the beginning--I am not talking about the text on the slide; I am just explaining this a little bit right now. At the beginning we don't know what it is due to. We don't know the pathogen. Sometimes we do because it is picked up from surveillance but sometimes it is not picked up from surveillance and people just call in or it is recognized in some other way, saying, we are all ill. We will respond to that, mostly health departments, local health

departments, and you have to generate hypotheses.

If you know it is *Salmonella enteritides* you would be remiss to not include eggs as a hypothesis, but each outbreak is different and you have to generate multiple hypotheses and then test them statistically by doing specific epidemiologic studies, like either a case control study or a cohort study.

Now to the slide, foodborne outbreak investigations are conducted by generating multiple hypotheses and statistically testing them. We are not just looking for egg vehicles; SE has been associated with many other food vehicles so in order to be successful in an outbreak you have to consider a wide variety.

Now, given that as a little bit of background, also when SE outbreaks are determined to be due to eggs and there is a trace-back that is conclusive, SE of the same subtype is often identified on the farms of origin. I am telling you this because this is the type of information that gives us a little bit of confidence that this

proportion of 90 percent of outbreaks is probably a reasonable proportion to base some estimates on.

But there is uncertainty in that. When you attribute egg association to all cases there are two types of uncertainties that we are dealing with. One is that only half of the outbreaks are actually identified with the food vehicle so there is uncertainty in attributing the proportion of egg-associated outbreaks to outbreaks of unknown vehicle. If we say 80 percent overall, that means that we are attributing the same proportion of outbreaks where the food is not determined. We are saying that same proportion is actually due to eggs, which is uncertain.

The next uncertainty is that we are taking outbreaks, cases and outbreaks, and attributing that proportion to all cases, and most cases of *Salmonella enteritides* are not associated with outbreaks. So, there is uncertainty in making that transition.

So, for this rule what we did was we tried to come up with some bounds in that estimate of 80

percent of SE illness due to the eggs. So, we took what we think, you know, is a high range. The last calculation we had was 79 percent. We said that is the high range of what we are going to call SE due to eggs. Now let's look at what is the other bound of the range. We can say, well, let's just assume that when we don't identify a vehicle in an outbreak, none of those are due to eggs. Okay? So, if you look at those 900-and something--I forget--outbreaks, the total number of cases in those outbreaks, 32,338, those where the vehicle was determined was 23,077. If we divide that out by all outbreaks, we get 53 percent and we are going to take a mid-range estimate of 66 percent. Okay? That is how we are dealing with the uncertainty that I outlined here.

Now, for the rule this is how we came up with the estimated number that you have heard already mentioned once here today, 118,000. That is based on these numbers, reported SE cases in 2001, 5,614--that multiplier that I talked about in FoodNet, 38. Also, FoodNet, when they contacted

patients with SE, they said did you travel in the time period when you were probably exposed and 16 percent said yes. So, we are going to throw those out because they are not due to eggs--even if they were due to eggs, they were not due to eggs here, in the United States. Then, we are going to take the proportion due to eggs, 66 percent as the mid-range estimate.

So, here is the math, 5,614 times 38, 213,000. Subtract out the 16 percent in travel, 179,200. Then say actually only 66 percent of those are due to eggs, 118,270 or, to round it off, 118,000. Pretty straight math there but you know where they are coming from. This is the number that was used in the FDA SE proposed rule and this is what the procedure is and the number that will be used to follow the impact of regulations for a goal of 50 percent reduction by 2010.

I am going to show you one other graph. This is from a paper that was just published in this month's Journal of Emerging Infectious Diseases. This is a journal that is available to

everybody. It is on the CDC website. If you go to the CDC website you will see the Emerging Infectious Disease journal for October. You can get this article on the analysis of annualized change in incidence of SE in relation to the adoption of egg quality assurance programs.

What we are going to do here is we are going to look at the percentage change on the Y axis. This is the percentage change in annual incidence for states that have adopted EQAP programs. On the X axis would be the number of years before adoption and the number of years after adoption, and they are all normalized to time zero. Even though they adopted at different times, we anchored it to time zero.

There were 4 states in which there were 5 years of data after adoption of an EQAP. Before adoption we see each year an increase of 10 or more percent of *Salmonella enteritides* time zero starting one year after, which is a little bit surprising to us but this is what the numbers say. They are looking at an average annualized incidence

decrease of about 8 percent. If you go over 5 years, that is a 40 percent decrease in *Salmonella enteritides*.

Now, there are 6 states in which we have at least 3 years of data to look at and we see a similar decrease in incidence immediately after adoption of EQAP. There are 7 states with at least 2 years of data after adoption--same thing. Then, there are 11 states--these are all states that adopted either state- or industry-sponsored EQAP programs. One other caveat, they had to have an incidence of *Salmonella enteritides* of greater than 1/100,000 because if you don't have a problem with it you can't show a difference.

So, what we showed in this type of analysis is that, regardless of where and regardless of when, states have shown a significant reduction in the incidence of *Salmonella enteritides* after the adoption of egg quality assurance programs. Now, we couldn't take into account the fact that there are other mitigation activities going out there. There is

refrigeration; there is consumer education, etc. But those took place at different points in time and when you normalize on this I think you can fairly say that this looks like a significant intervention.

All right, so conclusions--there has been a nationwide decline in SE cases since 1996 but less so in recent years. There is no significant change in the rates of SE illness in FoodNet states however. Important declines in outbreaks--although significant numbers of outbreaks continue to occur, 29 in 2002, and control programs are making progress but need to be widely adopted. Thank you very much.

MR. CARSON: As I mentioned, I would like you to hold your questions or your comments until we have the next presentation and then we will have a panel to address those comments. Next, I would like to introduce Ms. Nancy Bufano, Consumer Safety Officer here, in the Center for Food Safety and Applied Nutrition in our Office of Plant Dairy Foods and Beverages. Nancy?

### **Presentation of FDA's Proposed Rule**

MS. BUFANO: Good morning. I am going to provide a very brief overview and background of the rule; a more detailed discussion of the specific provisions of the rule. I will point out where we are seeking specific comments and then I will just briefly cover the economic analysis which, of course, is the costs and benefits.

As both Dr. Brackett and Dr. Crawford stated, this proposed rule is just one step in a broader farm-to-table egg safety effort that includes our requirements for safe handling statements on egg cartons and refrigerated storage of eggs at retail and those have been in place now for about three years, and our egg safety education for both consumers and retail establishments which is ongoing.

As I think probably all the speakers have pointed out, eggs have been in the past several years a major cause of foodborne illness. In seven years, starting in 1993, there was an average of 80 percent of the source confirmed outbreaks that were

egg associated, and eggs cause approximately 118,000 SE illnesses per year. FDA believes the best way to prevent SE illnesses is to prevent them on the farm.

Our approach was developed with support and input from both the industry and consumer groups. Many of you were at public meetings we held several years ago where we requested input and comments, and we have used that input and those comments in developing this rule and we will look forward to your continued comments on this rule as we move into the final rule and implementation.

Our proposed requirements have already been tested at the state level in egg quality assurance programs, the different provisions that I will talk about, and we know that they work. The benefits from the proposed rule are \$580 million and 33,000 illnesses avoided annually, at a cost of approximately \$90 million annually, and the health outcomes can be clearly measured.

From the onset in developing this rule we used a risk assessment, risk management approach.

The 1998 USDA/FDA joint risk assessment on SE in eggs analyzed each step in the shell egg farm-to-table continuum to determine the relative risk that each step contributed to SE contamination of eggs, and it revealed that preventive measures should be taken at each step of the continuum to maximize human health benefits. But the most effective preventive measures that can be taken to prevent illness from SE in eggs is to prevent eggs from becoming contaminated initially on the farm. While some infection we know is unavoidable, that is why refrigeration is necessary throughout the food chain to stop the bacteria from multiplying if it is present. That is why the proposed rule requires pasteurization or treatment of eggs from SE-positive flocks. We know that thorough cooking also kills the bacteria, which is why our consumer and retail education is ongoing.

I am going to talk now about specific provisions of the rule and what does the regulation say. Who is covered by the proposed rule? You are covered by the proposed rule, you are covered by

all the requirements--and this should say if you have 3,000 or more layers. So, it is not more than 3,000, it is 3,000 or more layers. If you do not sell all of your eggs directly to consumers; and if any of your eggs are not treated. I will talk in just a little bit about what we mean by treated.

You are covered by only the refrigeration requirements in the proposed rule if you have 3,000 or more layers, you do not sell all your eggs directly to consumers and all of your eggs are treated.

So, who is not covered? If you have less than 3,000 layers you are not covered. If you sell all your eggs directly to consumers you are not covered by any of the requirements.

What is treated? Treatment is a technology or process--the way we have defined it in the proposed rule, it is a technology or process that achieves at least a 5-log destruction of SE for shell eggs, or the processing of egg products in accordance with the Egg Products Inspection Act.

I will go through the five SE prevention

measures that are provisions of the proposed rule. These are measures that are taken during production at the farm that can reduce the risk of SE contamination. They include SE-free chicks, a biosecurity program; rodent and pest control; poultry house cleaning and disinfection; and refrigeration of eggs on the farm.

Chicks and pullets--your chicks and pullets must come from SE-monitored breeder flocks that meet the National Poultry Improvement Plan's standards for United States *Salmonella enteritides* monitored status or equivalent standards. The National Poultry Improvement Plan is a cooperative program among the Feds, states and industry to control certain pathogens and poultry diseases, including SE.

Biosecurity program--biosecurity applies to the grounds and all the facilities and seeks to reduce SE from environmental, personal and animal contact. The proposed rule requires that you limit visitors to your farm and in houses. You restrict movement of equipment between the houses so it is

not a source of SE. You restrict persons moving between houses so they are not a source of cross-contamination. Prevent stray poultry and other animals from entering the grounds and that you do not allow your employees to keep poultry at home.

Rodent and pest control program--we know that mice, rats and flies are primary carriers of SE so they must be controlled. The presence of SE in rodent populations has been highly correlated with the presence of SE in poultry houses and in eggs. So, for these reasons, the proposed rule requires that you assess populations of rodents and pests using an appropriate monitoring method and, if necessary, use an appropriate method to decrease these populations. Also, that you remove debris within houses and debris of vegetation around houses that may harbor pests.

Cleaning and disinfection of houses would, according to the proposed rule, only be required at depopulation when either the house or the eggs from that house have tested positive for SE. The

cleaning and disinfection provisions call for removal of visible manure, a dry cleaning followed by a wet cleaning, and then finally disinfection using appropriate disinfectants.

The final provision is refrigeration of eggs on the farm. Since refrigeration has been shown to minimize the growth of any SE that might be present in the eggs, the rule proposes that eggs that are held at the farm for more than 36 hours after laying be refrigerated at an ambient temperature of 45 degrees Fahrenheit or less. This provision will apply to all eggs, regardless of whether or not they will receive a treatment. It is important even if eggs are treated that if there is SE there we keep the numbers low enough so the treatment will be effective in destroying that SE.

We will talk now about verification of the SE prevention measures. In environmental testing for SE, according to the proposed rule, we require once per laying cycle when any group of hens in a house is 40-45 weeks of age. If that environmental test is positive, you are required to review and

make adjustments to your SE prevention measures and either being egg testing within 24 hours or divert all the eggs from the positive house to treatment for the life of the flock.

Environmental testing after an induced molting period--if you do induce molting an environmental test is required at approximately 20 weeks after each molt. Again, that is for each group of hens within a house. If that is positive, the same requirements apply. You are required to review and make adjustments to your SE prevention measures and either begin egg testing within 24 hours or divert all eggs from that house to treatment for the life of the flock.

I am going to talk now about egg testing. Egg testing is only required when an environmental test is positive. I have a flow chart on the next slide which is a little bit easier to follow but I will go through the steps in egg testing and then we will look at the flow chart.

Each test is 1,000 randomly collected eggs from one day's production. You are required to

conduct 4 tests at 2-week intervals. If all of those 4 tests are negative, then you are not required to do any more testing. If any of those tests are positive, all of your eggs have to be diverted and you have to start over again with the 4 tests at 2-week intervals. Once you achieve 4 tests that are negative, because you did have a positive at one point, you are required to conduct one test per month for the life of the flock. If any of those one tests per month are positive, you have to divert your eggs and, again, you have to start again with the 4 tests at 2-week intervals.

I think it is a little clearer on the flow chart. So, you start with the 1,000 egg test. If it is positive you have to divert and start over again. If it is negative at the second 1,000 egg test--positive, divert; start over again. If it is negative at another 2 weeks, the third 1,000 eggs test positive, divert; start over again. If it negative another 2 weeks, another 1,000 eggs test. Again, if it is positive you divert and start over again. If it is negative and none of these have

been positive, then there is no further testing. If it negative but you did have a positive in here before, in other words at your second or third time through, then you are required to conduct one test per month for the life of the flock and if any of those tests are positive you divert and start over again with the 4 tests.

The methodology for environmental sampling--for environmental sampling you must use a scientifically valid sampling procedure. The proposed rule discusses two environmental drag-swig sampling methods but we also request comments and data on drag swabbing methods and possible alternative methods for sampling the environment that might be more uniform, such as air sampling. We will consider the comments that we receive and determine what methods should be required in the final rule.

The testing methodology for the environmental samples is the paper you have in your packet, "Detection of Salmonella in Environmental Samples from Poultry Houses," published in 2001.

It is also available on CFSAN's website. The testing methodology for egg samples is a pre-enrichment method described in the Journal of Food Protection or an equivalent method. This method, here, was actually developed by CFSAN researchers and that is available from our office. I don't believe it is on the website yet.

Administration of the SE prevention measures--you are required to have one individual at each farm who is responsible for administration of the SE prevention measures. That individual must have completed training and I will talk in just a little bit about training, or have job experience that is equivalent to training. Their responsibilities include developing and implementing the SE prevention measures; reassessing and modifying the measures as necessary; and reviewing records.

I will talk about recordkeeping requirements. The proposed rule is the following records, records of environmental and egg sampling and results of SE testing; those records indicating

compliance with diversion requirements, obviously if required; and those records indicating that all eggs will undergo treatment, if that is applicable.

I will talk a little bit about guidance and training. We do plan to publish guidance on the standards for each provision and, per our Good Guidance Principles, each guidance will be published for comment prior to implementation. We anticipate publishing draft guidance at the same time as we publish the final rule. The final rule, obviously, will have an implementation period so during that time we can receive comments on the guidance and then have final guidance published by the time the rule is to be implemented. With regard to training, we anticipate training both industry and government using an alliance similar to what we have done which has been very successful.

The small business provision in the rule exempts small farms--and this should say with less than 3,000 layers; not 3,000 layers or less. They are exempted from all the provisions. This

provision reduces the cost of the rule by \$40 million but it only allows for fewer than 200 additional illnesses. We know that on-farm preventive measures work from specific states' experiences and from the regional shifts in illnesses once controls were put in place.

This is kind of an older graph but the pink line here shows the decrease in SE outbreaks in the northeast after 1992 when Pennsylvania implemented their egg quality assurance program.

The goal of our egg safety program is outcome-based. Our current goal is to achieve a 50 percent reduction in egg-associated SE illnesses by 2010. We are incorporating it into Healthy People 2010 initiative.

I am going to briefly touch now on the economic analysis. The major benefits of the rule are realized from preventing severe acute cases of SE illness and death, and from preventing reactive arthritis as a chronic complication of acute illness. The major costs come from the pest control biosecurity; refrigeration; the testing and

diversion; and the recordkeeping. And, small business effects exempt farms with less than 3,000 layers. Most layer farms are small businesses so most will be exempt.

The economic benefits--the benefits from averting 33,000 illnesses annually range from \$250 million to \$1 billion dollars. This includes healthcare costs, pain and suffering and lost productivity. The cost savings to Medicare and Medicaid services for reduced medical costs is \$4 million.

The annual cost to industry is estimated to be \$82 million. We estimate that 4,100 farms will be affected based on the following, 2,350 farms that have 3,000 to less than 20,000 layers; 950 farms that have 20,000 to less than 50,000 layers; 350 farms with 50,000 to less than 100,000 layers; and 450 farms which have more than 100,000 layers.

The cost to government is based on the 4,100 farm figure or, to us, 4,100 inspection sites. FDA will inspect and enforce with state and

other federal agency partnerships. The requirements will be phased in over a two- to three-year period. The expected annual cost to the government is \$8 million and this includes the cost for state contracts, for audits, lab testing and training, outreach for industry and FDA.

The summary of the economic analysis--the benefits are exceptionally high because the present value of future reactive arthritis costs are prevented, and the uncertainty analysis showed that even low-level benefits are still much higher than estimated costs.

Our request for comments--as you read through the preamble of the proposed rule you will notice that we actually request comments in several areas but here are the main three areas, measures for at-risk populations; registration; and recordkeeping.

Measures for at-risk populations--the current 2001 Food Code contains several provisions that are specific to institutions that serve highly susceptible populations. Here we are talking about

hospitals, nursing homes, day-care centers, senior centers. We are asking if the current FDA Food Code system, which is state adoption and implementation, is adequate to achieve our desired public health outcome for high risk individuals, or can that outcome only be achieved through mandatory federal standards. If so, how would those standards be implemented? Specifically, which of the specific egg-related provisions in the 2001 Food Code for retail establishments that serve at-risk populations--which of those should be mandated? So, we are requesting comment on that.

With regard to registration, we are asking if FDA should require egg producers to register the name and location of their business with us. Most of you probably know that all food production facilities, with some exceptions, are required to register with FDA under the Bioterrorism Act but farms are exempted. So, most egg producers are exempted under the BT Act from registering.

With regard to recordkeeping, we are asking if you believe we should expand the

recordkeeping provisions to include any of the following, establishment and maintenance of an actual written SE prevention plan; and maintenance of records indicating performance and compliance in implementing the specific measures, for example, monitoring records and activity logs.

The participatory process we have used in developing this proposed rule was to set a public health goal; to consult with industry, states, federal partners and consumers; and to use the lessons learned and steps from existing egg quality assurance programs.

With regard to enforcement, the rule, once finalized and implemented, will be enforced by FDA but we are considering contracts with states and federal partners to assist us in our inspection efforts. In enforcing the rule, we will determine if on-farm measures are in place and if they are administered; if eggs have been tested and what the results of those tests are, obviously, if that is necessary; and if SE-positive eggs have been diverted.

As I am sure you are well aware, in addition to this meeting today, we have a meeting on November 8 in Chicago and one the following week, November 16, in Los Angeles, all to procure comments from the public in addition to written comments that we look forward to receiving. The comment period is 90 days. It ends December 21.

I will just conclude by saying that we expect that this proposed rule, when finalized and implemented, will significantly decrease the number of SE-contaminated eggs produced on the farms and, ultimately, decrease the number of SE egg-associated illness and death caused by consumption of shell eggs.

**FDA and CDC Panel:**

**Stakeholder Questions and Answers**

MR. CARSON: We are going to now form our panel and be taking questions from the audience. Are there any questions to start with? There will be a microphone coming down, Howard, to your left, if you would go to the microphone. When you ask your question, would you please give your name and

your affiliation and then make your question?

MR. MAGUIRE: Thank you, Lou. Howard Maguire. I am Director of Government Relations for the United Egg Producers. I want to note that the presentations this morning have already answered or helped to answer several questions we had.

We still have one that is not quite clear, and there are a few that aren't quite clear in the rule. The first one is what laboratories are going to be used to conduct these tests, both the environmental tests and the surveillance tests? Under some of the egg quality assurance programs both private and state laboratories have been used, and will there be a laboratory certification program? In fact, some of the producers even have their own laboratories and then use other public laboratories outside of state labs.

MR. CARSON: Do you want to answer it?

MS. BUFANO: I don't think we have anticipated having a laboratory certification program. I don't think we have anticipated certifying certain laboratories or, certainly, we

would have stated it in the rule. So, as we envision now, there wouldn't be any limitation on what laboratory you could use but, you know, certainly if you have comments and think a certification program is a good idea or not a good idea, we would certainly welcome those comments.

MR. CARSON: The normal practice for FDA is to specify the methodology and for labs to show that they can meet performance measures with that particular methodology, but not to specify laboratories themselves. You may use any laboratory that can meet those specifications.

MR. MAGUIRE: Thank you. That answers the question. I have other questions. Are you going to go around the room?

MR. CARSON: Well, since you have the mike you might as well go on.

MR. MAGUIRE: Okay. This is one that you would probably anticipate I would ask. The rule exempts flocks of less than 3,000 birds, as Ms. Bufano noted. I understand there are literally tens of thousands of flocks in that size range and

it becomes somewhat of a chore to develop an inspection program. But have you looked at any science that would indicate those flocks are going to have an SE incident rate--the incident rate being that you would see a positive egg at the same level as flocks larger than 3,000? Or, is it less? Is it more? And with that question, I don't know but do we know if those flocks of less than 3,000 birds employ any control practice, the food safety practices that are used in several state egg quality assurance programs now?

MR. CARSON: Let me first start and then I will turn it over to Dr. Brown and Nancy Bufano to answer you. We have tried to lay out our rationale for exempting farms with less than 3,000 layers, and I think both in the economic section and in the proposed rule we have tried to address that. By and large, farms with less than 3,000 layers contribute perhaps less than one percent of eggs to the commercial market. Based on that and looking at SE illnesses and outbreaks, we see no association that we could directly link with such

small production facilities. But, having said that, let me ask Dr. Brown if he would like to talk about that from an economic standpoint.

DR. BROWN: Well, you hit the nail on the head with the fact that farms with less than 3,000 layers--although there are about 35,000 of them in the United States, they produce less than one percent of the commercial egg market. So, any one of these provisions implemented on those farms with less than 3,000 layers, the costs outweigh the benefits for that size of a farm. I believe some of those farms do practice already some of the things in the proposed rule. The details are all in here. I can't recall them exactly, all the numbers on those.

MR. CARSON: Again, this is a proposed rule and we are accepting all comments so, if your comment is that you believe all farms, regardless of the number of layers, should be covered by this rule then we advise you to make that comment to the docket.

MR. MAGUIRE: Thank you. I would like to

ask another question for clarification. Ms. Bufano again helped to answer some other questions about the number of environmental samples that might be required. We have been getting a lot of producer inquiries about "in my situation, how many samples do I have to take and how many analyses do I have to perform on the environment?" It is clear on the egg testing but will there be some additional guidance as to--and we, ourselves, are asking--is it one; is it 12? I think in the preamble an average of 12.1 samples per house was used. In other words, what should we tell our producers about the number of samples they would be expected to take?

MS. BUFANO: Is that not in the testing methodology?

MR. MAGUIRE: There is a discussion in the preamble of samples that could be taken, examples based on some of the state quality assurance programs that are out there.

MR. CARSON: Correct.

MR. MAGUIRE: And that is really like one

sample per row, one analysis per row.

MR. CARSON: Correct. Right now, just as you have stated, in our rule we have put forward two types of drag swabs that are taken or their alternatives. We really are soliciting comments on the sampling regime that should be applied on the environmental testing. So, we have not specified what we will recommend in our final rule. We understand that there are many different types and styles of poultry houses and we may need to stipulate, based on the type of house, how you would randomly do those kinds of environmental tests.

But we are open to comments as to what you think is a reasonable number of those. We want it to be statistically significant. We do want that to represent the poultry house. So, we have laid out two possibilities, one from the California program and one from another program as two examples, but we are simply soliciting comment on that and we haven't specified right now.

MR. MAGUIRE: Thank you. Louis, as you

can imagine, we have several other questions but we will either get to them later in our comments here today or in the written comments.

MR. CARSON: I believe Nancy mentioned in her presentation, and let me reiterate it, that our intention is to publish guidance at the time of the final rule that will lay out the specifics of environmental testing, and the like. That guidance will be put out under our Good Guidance Practices for public comment again. So, you will have an opportunity to comment on those and, obviously, those comments can refine what we put out in the proposed guidance recommendations.

MS. SMITH-DOWAAL: Good morning. Caroline Smith-Dowaal, from the Center for Science in the Public Interest. First of all, I just want to thank you for your excellent presentations this morning, but also overall for a rule at long-last that I think is responsive to the requests by both consumer organizations and the egg industry itself for a level playing field when it comes to these egg quality assurance programs, and making sure

that everyone was playing.

I have a number of questions, like my colleague from the egg industry, but I think it would be helpful for me if you would start out and just tell me what happens if an egg test is positive, and how do farms get back into the table egg market once they have had a positive test.

MS. BUFANO: And you are talking about a positive egg test?

MS. SMITH-DOWAAL: Yes.

MS. BUFANO: Right, if an egg test is positive you are required--let me get my little flow chart just to make sure that I am speaking correctly--if an egg test is positive you are required to divert the eggs from that house to a treatment that achieves at least a 5-log reduction. Then, you have to start over again. If you want to get back into table production--you can just continue to divert and not do any more testing--if you want to get back into table production you have to start over again with the 4 tests at 2-week intervals and you have to get 4 of those negative

and then you can go back into table egg production. But you still have to, for the life of that flock, conduct one egg test per month, and that has to be negative. If it is positive you have to go back to diversion and have to start again with the 4 tests if you want to resume table egg production.

MS. SMITH-DOWAAL: So, once you have had one positive egg in a flock, that flock will be under constant monitoring if you wanted to do any table egg production from that flock.

MS. BUFANO: Right. You have that one egg test per month, exactly.

MS. SMITH-DOWAAL: Thank you for that. Now, I think that you proposed something quite interesting in the proposed rule, which is the idea of just using the testing program and not mandating the preventive controls. I think that is kind of interesting from, you know, kind of a philosophy of food safety. What if you just had the monitoring and didn't tell the industry how to do it? I do think that might be something the agency might consider with the flocks of less than 3,000 birds.

That is an interesting concept, but I think the industry understands the need for these kind of preventive controls. They have certainly been tested through the Pennsylvania Egg Quality Assurance Program and many others. So, I think for the industry overall the model you have is the correct one. But I thought that was an interesting concept that you may want to use for smaller producers.

I also want to ask about your thinking regarding registration of the facilities. Are these farms covered under the bioterrorism registration provisions?

MR. CARSON: Again, on the slide that Nancy presented--as you know, the 2002 Bioterrorism Act does have the registration of food facilities. However, farms are explicitly exempt from that requirement. So, no farms, therefore no farms doing egg production are covered and are registered with FDA currently. So, what we are asking here, for purposes of FDA knowing where and who is producing eggs, we are simply asking the question

is it appropriate for us to require registration or some version thereof so that we know where egg producers are located throughout the country?

MS. SMITH DOWAAL: I think that is a very important question, one we will certainly weigh in on, but the issue of FDA knowing where the farms are I think is important to ensure that, in fact, we do have a level playing field when it comes to the industry.

Forced molting and its effect on food safety--you had a lengthy discussion of that in the proposed rule but it wasn't really clear where you came out from a public health standpoint. You seemed to indicate that some of the science indicated forced molting was an important consideration here but others indicated it wasn't. Why am I unclear on that?

MS. BUFANO: I think what we are saying is that the science is not clear, that there are studies showing one thing--there are studies showing a link and then there are other studies that do not show a link. So, we feel that the

scientific evidence is not clear because you have the studies that don't show a link. So, we are saying that the science is not clear so that is why you are not clear.

MR. CARSON: Generally speaking, we try to look at forced molting or molting as a risk factor and I believe the scientific data is not clear as to whether it is a risk factor, an increased shed for SE either up to the molt or just after the molt. So, we simply have described the evidence and the data that we know to date but we do not make any conclusion based on that because we cannot see a clear path as to whether it is or is not.

MS. SMITH-DOWAAL: But I thought a lot of the data did show that the shedding of *Salmonella enteritides* actually came from ARS, one of your sister organizations. So, have you evaluated the quality or perhaps the conflicts of interest that may be present in these studies so you have full consideration of the quality of the science with respect to these studies?

MR. CARSON: I don't know that we have

done exactly as you asked but we have certainly consulted the experts at the Southeast Regional Poultry Laboratory, Dr. Gast and others, and we will continue to seek their advice as we proceed. But I believe this rule, being reviewed by them, does meet where they consider the science to be today.

MS. SMITH-DOWAAL: Well, then I would recommend that in the final rule you discuss if there is any conflict of interest with respect to these various studies and, if they are funded by industry, that that be clearly indicated in your discussion.

One final point, you discuss the need for uniform recordkeeping--or a comment that had been made during your preliminary discussions on this proposed rule for the need for uniform recordkeeping to facilitate recall and trace-back. But I notice that the discussion you have is on recordkeeping for HASOP[?] and HASOP recordkeeping is really not the same thing. I am probably not telling you anything you don't know, Lou, but HASOP

recordkeeping has to do with preventive controls at the time of production. The records needed to accommodate effective recall and trace-back are different. Those are records that actually may go all the way to the consumer, certainly to the retailer. So, I think you haven't adequately answered that question and that concern of ours as we proceed in looking at the final rule. I would like you to reconsider that because issues, as you know, of trace-back of these contaminated egg products have been challenging for the agency, and in consumer recalls generally we are finding that the information going to the public is not adequate.

I would like to make one final note on the issue of 118,000 estimate of illness. I know it is about four times or five times lower than the estimate from the 1998 risk assessment. The most recent risk assessment that has come out of USDA is about 350,000 estimate. So, it is always challenging to us when the government comes out with more than one estimate, especially within a

period of several weeks. I know there will probably be other commenters who bring this up later but I do think--I really appreciated the discussion of how that number was derived, but I do think the agency should work more closely together to at least come to an agreement on what is the right number. It looked to me, frankly, like you were low-balling it. You were giving us the low-ball estimate. It was enough to get through OMB. But it may not reflect the real burden of illness on the public. So, we wish you would come to a better agreement with the risk assessors in making your estimates. Thank you.

MR. CARSON: Thank you for that comment.  
Yes, sir?

DR. PATTERSON: I am Paul Patterson, from Penn State University, and I just had a question about the pests and flies and the risks associated with that. I am somewhat familiar with rodent testing and egg quality assurance programs and the risk associated there, but less so with the flies and I wondered if you could share with us what that

risk is and maybe the data that suggests that is a risk for food safety in eggs.

MR. CARSON: I think the data for the flies and other pests really comes from our trace-back and looking at those kinds of indicators of SE prevalence in the poultry house. Certainly, as you do rodent test control if you are having lots of flies--I mean, we are talking about some controls that are obviously not in place and your poultry house seems to be wide open to all manner of rodents and pests. When we see flies, and stuff, we also see a lot of other animals getting in and out of these poultry houses and it is usually where there are very poor controls in place in total. So, flies are sort of an indicator. Also, as you know, flies are from manure. If manure management is poor you will have an increase in flies around there. So, it generally leads to an indicator of other practices that are not in place and that is why we put it in there as part of rodent and pest control, that you are having a systematic set of controls in place to maintain

that poultry house in the best practice possible.

DR. BROWN: Just a note, there is a study by Hensler that says that poultry houses with a large rodent populations are 4.2 times more likely to test positive, and for benefits for pest control there is a paper by Davison and Rand.

MR. CARSON: Right. I think the gentleman's question though had to do with the specific types of pests, not pests in general. Is that correct?

DR. PATTERSON: Not in general; specifically the flies. I am aware of the Hensler data and the Davison publication but we were trying to put our finger on what you were looking to in the flies that had a direct relationship to food safety.

MR. CARSON: Again, we appreciate that comment to the docket and we will try and respond to it, but it generally is with our trace-back investigations.

DR. PATTERSON: Another question regarded the training. I am a little unclear. We mentioned

4,100 poultry farms and that the sign-off on the keeping of records would be an individual responsible for the program. Does the training only apply to that one individual, or what level of training and outreach are you looking to do? Clear to the farmer level? I am just curious.

MR. CARSON: Thank you for that question. The training program that we are looking to do would be a collaborative one with industry. So, we are looking to train those people who manage poultry farms and who have people in place who are supposed to do it on a day-to-day basis. I think you first have to train people to make sure they are aware of what the requirements are and then you need to get down to the details to make sure those requirements are being put into place in a practical manner.

So, the training is going to be done--is intended to be done for us to enforce the rules but also for industry to know how to implement the rules so that we have a transparent process so when FDA or states, or whoever, comes onto the farm to

do an inspection you are aware of what we are going to be looking for; you know what you should be doing; and the training is there so that we can have successful implementation of these proposed measures.

DR. PATTERSON: Okay. Just one more quick one related to the Food Code and outreach. You had indicated that, you know, states are implementing things related to the Food Code, but it seems like that is a real opportunity and I was wondering if you could--you know, you have gone through the exercise of documenting the potential impact on economics and food safety but if you have considered the potential there by training food service workers and those in institutional settings, retail and those sites. I wonder if you played out those scenarios, as CDC is so good at doing, in FDA.

MR. CARSON: Well, there is an ongoing federal/state effort with the Conference for Food Protection where there is an extensive training program or model program for individual companies

or at the state level. We do conduct training around the country. FDA has regional retail food specialists that work with the states and audit their programs, and at the state level there are a number of training programs to get to that. But, as you know, at the retail setting the major difficulty in training is the turnover. In retail you train someone today and they are gone tomorrow so it is sort of a very difficult cycle to make sure that you have well trained staff at the retail level. It is such a transient occupation, it is a very difficult thing, but there are efforts under way to do that overall, not just on eggs.

DR. SCHROEDER: This is Carl Schroeder, from the Food Safety Inspection Service. I just wanted to follow-up on the point that Miss Smith-Dowaal made, and this is what I tried to make clear at our public meeting when the question came up last Friday. The predicted number of illnesses from our risk assessment, the 350,000 value versus the 118,000 value that is cited in the proposed rule--it is very important for us all to understand

that those were arrived at in two completely different ways. It isn't like we both took the same data set and came up with these different values. That then would be concerning.

The purpose of a risk assessment is not to look back retrospectively to determine the number of illnesses for any given year. The approach that was outlined by Dr. Braden today and the 118,000 value that is cited in the proposed rule is perfectly logical. It makes all the sense in the world to us and, in fact, when we do that very same process we come up with essentially the same numbers. So, again, I would just like to reiterate that the number predicted in the risk assessment and the number presented here are two very different things. Thank you.

MR. CARSON: Yes, I was afraid of that.

MS. SMITH-DOWAAL: I appreciate those comments from Dr. Schroeder. As we discussed last week on this same topic, the issue has to do with government statements and also with the use of risk assessment. We were told that risk assessments

would be used to ground the regulatory proposals. And, I don't mind--well, I do actually mind waiting years and years for these risk assessments to come out, but when I find that we are waiting years and years for risk assessments and years and years for proposals and the proposals aren't grounded in the risk assessments it makes me wonder why are we going through these exercises.

In addition, as Dr. Braden, as Dr. Schroeder, and as I know that 38 multiplier could be many things. It could be 64; it could be 28. The bottom line here is there is probably a range of annual illnesses that is not reflected in the proposed regulation and is not reflected in your risk assessment. So, maybe we need to go back to looking at those ranges of illnesses and grounding it a little more in reality because we know that there is year to year variability. We know that multiplier may not be spot-on. Thank you.

MR. CARSON: Thank you. Other questions concerning the presentations? If you have just a comment, I would ask you to hold it to the comment

period but if you do have a question, please.

MR. PIERCE: I am Chris Pierce. I am with the Penn Poultry Council, and we are the administrative body of the Pennsylvania Egg Quality Assurance Program. My question this morning pertains to the sister organization, the National Organic Program, and their mandatory requirement that organic laying flocks would have access to the outdoors. My question would be in regards to the proposed ruling that we have in effect that identifies the concerns with the rodent and pest control and the data identifying the increased risk of those eggs being contaminated, in addition to the biosecurity requirements. I didn't know if this body had any feedback that they can share with us on how these two entities will interact with one another in regards to one part of the USDA saying you must put your birds outside with cutouts in your layer houses so your birds can come and go at free will and meanwhile, they are walking by where the mice come in. Then we also have this part of the program saying, please, seal your facilities so

pests and rodents don't have access, migratory fly-aways and things such as that. Thank you.

MR. CARSON: We haven't actually reconciled those two things, as you might imagine. That comment has also been made by UEP in the past to us. We will take that comment under consideration but we have not addressed it in our proposed rule. Yes, sir?

MR. ROACH: Hello. I am Steve Roach, with Food Animal Concerns Trust. I just have a couple of questions. We will make comments later but my questions are related to the presentation. I was just wondering, in several places in the proposed rule it talks about how you can use alternative methods and I was wondering do you have any guidance on validation of the alternative methods? I think we addressed it a little bit with the sampling but it would be, you know, alternative methods for sampling or also for the testing of the samples.

MR. CARSON: Let me ask Nancy if she wants to respond.

MS. BUFANO: Well, we don't have guidance but, as we said, we will be publishing guidance.

MR. ROACH: And will there be some type of process for validation of the alternative methods?

MS. BUFANO: The alternative method would just have to meet the same requirements. We are not going to validate methods.

MR. CARSON: We are not going to validate methods per se. We will put out a method for environmental testing, a method for egg testing and we will say you can use this method or an equivalent one. As you know, in microbiological testing there are so many ways to skin a cat so if you can meet that same standard with another test, perhaps with another piece of equipment that you would use that is not specified in this method but is basically equivalent to what we have proposed, then you simply need to validate your performance that you can recover SE in your 1,000-egg sample at the same rate that you would in our method and that is the validation. So, it is commonplace in chemistry and microbiology to allow alternative

methods based on other manufacturers' equipment, and the like. You just need to meet the same standard.

MR. ROACH: Yes, I think the sampling may be a harder challenge and I realize that that will be difficult because, you know, when you go from farm to farm, or, you know, our houses and flocks that we work with the sampling methods need to be different.

MR. CARSON: Again, we will await comments but one proposal might be for us to provide several templates, that if your poultry house is of this construction and style, then you can apply this, and if it is this you can apply that, and if it is somewhere in the middle then you try to approximate that. As we know, there are many different poultry houses and styles and we probably can't come up with one for every one, but we will try to show you what we believe is an adequate sampling regime and we will ask you to apply that.

MR. ROACH: Okay. I guess an individual inspector to some extent would have to make some

judgment on that.

MR. CARSON: Absolutely.

MR. ROACH: I hate to go back to the registration question but I just want to have a clarification. So, the exclusion is for farms, but if you are a packer that is processing eggs do you need to register? Because if the packer is on a farm, are they excluded? I am just not sure.

MR. CARSON: In the Bioterrorism Act we do define each term. So, if you are simply a farm and only doing the traditional farming activities you are exempt. But on the farm, if you do additional activities such as packing and processing or storing and holding, then you are covered by the rule by those definitions. So, it depends on what activities you have under way on your farm.

MR. ROACH: Okay, so have you all figured out what percentage of the 4,100 would be registered under that because of their in-line processing?

MR. CARSON: Well, for those that do in-line processing the farm itself is not

registered, only the in-line processing component. Obviously, for in-line it is virtually in the same location but the point I am trying to make is that the farm component is not registered even in an in-line process.

MR. ROACH: I was just wondering could you make a quick comment? I notice that you might consider other federal partners for enforcing and I was just wondering what you are thinking about with that.

MR. CARSON: Well, during our public meetings that we held back in 2000--we certainly know that the Agriculture Marketing Service that administers the egg quality voluntary program is already on the farms. We know that many states have people on the farms already. So, we are going to try and leverage resources where we can but, obviously, it will be FDA enforcing these rules and it will be FDA's rules. We are going to simply look at what is the most cost effective way to implement them and enforce them.

MR. ROACH: I have a couple more. One of

the goals is a 50 percent reduction in terms of SE and I was just wondering what is the baseline. Are you starting at when the rule is finalized?

MR. CARSON: The baseline is 118,000 that has either been championed or not.

MR. ROACH: So, it has to be 2002 numbers basically.

DR. BRADEN: It is based on 2001 data.

MR. ROACH: On 2001? Okay. I think that is all the questions I have.

MR. CARSON: Another question here?

MR. ADAMS: Jim Adams from Weiner's Feed Mill in Pennsylvania. I just have a question, if you assumed a certain number of positive environmentals in eggs for coming up with your laboratory costs?

MR. CARSON: Let me ask Dr. Brown if he can respond to that.

DR. BROWN: Can you repeat the question, please?

MR. CARSON: He asked whether in coming up with the laboratory costs for either

environmental--well, I think it is environmental testing, did we assume a certain number of positives?

DR. BROWN: Yes, and I am not sure exactly where that data came from but it is in the rule here.

MR. CARSON: Perhaps we could search in the rule and get back to you on that specific question. I don't think we have it right at our fingertips. Obviously, in coming up with costs you have to come up with non-zero numbers. We will try and get back to you during the break of just before the comment period. Randy?

MR. GREEN: My name is Randy Green and, like Howard, I represent United Egg Producers. This is a follow-up question to the last one but a more general one. The \$82 million cost that is attributed to this proposed rule, does that in general represent total costs, including what people are spending already in existing programs and testing that may be required by customers, or is it the incremental effect of this rule, the new

stuff people will need to do?

DR. BROWN: It is the incremental effect of the new stuff.

MR. GREEN: Thank you.

DR. BROWN: Excluding farms that are already doing the proper things.

MR. CARSON: I don't know if everyone heard that. It is the incremental cost of the new things, and we did take into account that some farms or poultry houses already have some of these measures in place. Yes, Howard?

MR. MAGUIRE: The rule talks about, and we talked this morning some about the SE farm administrator that is going to be trained and be responsible to make sure that the control program works right on the farm. One question we have is that, you know, some farms only have 10,000 birds but they may be part of a bigger part. Their house may have 10,000 birds. Do you envision that this SE farm administrator can be responsible for several houses?

MR. CARSON: The answer is yes. Our

intent here is to identify the responsible individual. When FDA conducts an inspection of any of our regulated food products, we meet generally after that inspection with the responsible--either the facility manager or someone that is responsible for the overall conduct of that facility. We wanted someone similar to that being identified for the poultry farms. But that person need not be physically there each and every day. He may have responsibilities for multiple farm locations, but someone needs to be identified so that as we conduct our inspection we have someone that we can refer our comments and our inspectional report to, and to talk over things that we wanted to point out.

MR. MAGUIRE: Thank you. One last question, if I might, along the same lines of the farm administrator, we have already had a lot of discussions with our producers and with scientists, etc., but one question that has come up on the farm administrators is it seems like they are taking on quite a responsibility to make sure the program

works right. The rule doesn't address it specifically but if they don't carry out their responsibility to the fullest, are there similar criminal penalties involved? Obviously, FDA can seize product and that kind of thing, but I am asking this more from a personal standpoint of the employees that would actually be doing this work. If I knew the Public Health Act better I could probably answer that myself.

MR. CARSON: We haven't addressed that in this proposed rule. Obviously, if there is an egregious practice under way FDA will take all the appropriate actions necessary but our intent here is to remove contaminated eggs from the marketplace. The ultimate responsible individual at that farm is the owner of that farm, and if FDA were to take action the owner of that farm would be the person identified and any individuals responsible for the implementation of these rules.

MR. MAGUIRE: Thank you.

MR. CARSON: Rich?

MR. WOOD: I am Rich Wood, with Food

Animal Concerns Trust as well. Just a couple of follow-up questions. Is the SE trace-back program at FDA still going to continue with this proposed rule in place?

MR. CARSON: Yes, there is no reason to not. I mean, as we continue to have an outbreak response program within CFSAN relating to all of our food commodities, the SE trace-back would continue.

MR. WOOD: So, this would not be seen as a substitute for that then?

MR. CARSON: No, we would hope that we would reduce the travel time--

[Laughter]

MR. WOOD: In terms of reducing travel times and knowing where to travel, again, with no registration the whole premise of this program is based on self-selection. An egg producer of whatever size will determine where they fall within the parameters of the rule, is that correct?

MR. CARSON: That is correct. I mean, the way that we get to remedy that is to conduct

inspections. We are not totally in the dark as to where all egg producers are but it would be cleaner and neater if we did have the registration but, nonetheless, we are simply asking for comment.

MR. WOOD: And the anticipated inspection rate, and it probably is in the rule, are you expecting to be on every farm once a year for those 4,100 farms, or what is the inspection hope for outcome?

MR. CARSON: It is an annual inspection for each of the 4,100 farms.

MR. WOOD: Thank you. And just a final question in terms of the egg testing protocol, is there an expected outcome in terms of having eliminated the SE count through that series? The slide that showed the series of tests, you know, if it is positive you go for another test; positive, another test; positive, another test--have there been studies that have shown the predictability in terms of the number of tests that a farm usually has to go through before coming up with a negative test? The reason I am asking is that on our farms,

the 14 farms that we work with, we didn't use that protocol, which we do support, but we simply diverted all the eggs immediately when we have a positive environmental. In terms of a public health perspective and concern, I am wondering what is the risk in this protocol.

MR. CARSON: I don't know that we have fully analyzed that but we do offer both options. You can simply divert or you can go through the testing regime. We will certainly look into that. In the back, is there a question?

MR. HERR: Yes, good morning. Chris Herr, with the PennAg Poultry Council. Three quick questions. On page 11 of Nancy's slides you mentioned the \$8 million annual costs for state contracts, audits, lab testing. Can you explain that for a minute? Does that mean potential state contracts with laboratories? Elaborate, please.

MS. BUFANO: I am trying to find it.

MR. HERR: You talked about state contracts. I was just curious about what that meant.

MS. BUFANO: The annual cost being \$8 million?

MR. HERR: Right.

MR. CARSON: The 8 million covers the annual enforcement of the rule--training, our lab testing if we were to collect any samples, and being prepared to deal with any response to that. So, the 8 million is covering all that. We just made a general estimate. If we do employ states through state contracts as we do currently in other food safety inspections, such as seafood and others, then that has a certain cost associated with it and we are simply just counting that as part of those costs. If FDA were to conduct the inspections, then the cost would either be new inspectors or taking time away from other programs, or whatever, but that amount of money is our estimate.

MR. HERR: Thank you. Does FDA envision putting their Good Housekeeping seal of approval on eggs that happen to be produced under this system, an FDA approved label?

MR. CARSON: The answer is no. We have not put an FDA seal of approval or Good Housekeeping seal of approval on anything, to my knowledge. Again, FDA is there to simply assure that industry is producing safe foods and we are not there to promote those safe foods, and a seal generally is a promotion.

MR. HERR: Okay. One last quick question, within the rules will you consider state established programs that are already in existence that, quite frankly, may go beyond what you are currently asking for, and accept them as they are?

MR. CARSON: Well, again, any program that meets our standards certainly complies with those standards. Therefore, if farms in Pennsylvania are complying with a standard that is even more stringent than ours, then it would obviously meet those standards. So, upon inspection they would have no problem with an inspection to show that they are meeting those standards. That is simply what we are trying to do. We are trying to get all 4,100 farms to comply to these standards of

practice.

MR. GREEN: Randy Green, with UEP. I have a question for Dr. Braden on his excellent presentation, and I would like to refer to page 6 of the hard copy, if I could. As I understand it, we use a multiplier of 38 to go from isolates to total cases. I may not have all this terminology right but, again if I am not mistaken, that 38 multiplier is the same one that was used in the 1998 risk assessment that was published. So, it was obtained several years ago. On those charts you did a good job of explaining why the numbers for total outbreak reports increased substantially in the 1990s, and I would infer probably if we had the same data earlier it would be sort of a flat line maybe or, anyway, it is not the kind of big increase it looks like.

In the next chart we have a pretty clear downtrend in the total number of outbreaks due to SE. So, the endpoint is 29. It is a lot lower than it started out.

You tried to illustrate in the bottom

chart that the percentage of outbreaks due to SE has been going down also pretty sharply.

Because of the change in the data, that would lead me to think that the middle chart might look even steeper than it does if you sort of normalized everything. So, the downtrend in the number of outbreaks maybe is even a little sharper than it looks like here.

So then my question is does any of this cause us to wonder whether that 38 multiplier is still valid, or has something changed where, you know, maybe that number is no longer the right one to use?

DR. BRADEN: That is a good question. Thank you. That number of 38 was derived, like you said, quite a while ago now. It was not specific to *Salmonella enteritides*. It was derived for salmonella in general. Salmonella in general actually has had some decline over time but certainly not what we have seen with *Salmonella enteritides*. It is based upon a survey of the syndrome of salmonellosis. If somebody is not

diagnosed you can't determine that the illness they had, that they didn't go see the doctor for, was *Salmonella enteritides*.

So, I think that in general we would need to use the same number. Like I said, the change in the syndrome of total salmonellosis hasn't changed over time so we don't feel a need to re-study the whole question. Parts of those surveys have been redone and they have been consistent over time so we have some confidence but, nonetheless, you bring out some uncertainty around that number, and we all understand that there is some uncertainty around that number. I tried to address that a little bit and that is something that, unfortunately, we have to live with.

MR. CARSON: At this time we are going to take a break, about 15 minutes, so return around 11:35. If you go out into the cafeteria, please take your badge so you can get back in, whether it is a visitor badge or whatever.

[Brief recess]

MR. CARSON: Before we start with the

comments, there were two questions that I don't think we quite adequately responded to during that session. One had to do with flies and the other had to do with the rate of environmental positives that we used in assessing the cost. So, I would like to address those two first before we proceed to the comments. First, Dr. Brown, will you talk about the cost?

DR. BROWN: Yes, we actually used data from Pennsylvania and Maine as well, and we used the layer study. We actually developed a distribution, and the distribution has a mean of 12.3 percent, and we used Pennsylvania's rate of 7 to 9 percent as a mode for that.

PARTICIPANT: Percent of what?

DR. BROWN: It is the percentage of houses that tested positive for environmental in an environmental test.

MR. CARSON: Are you following? We used several published studies and came up with a distribution curve, and we took--did we take the median of that?