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EGG SAFETY: ARE THERE CRACKS IN THE FEDERAL FOOD SAFETY SYSTEM?

HEARING

BEFORE THE

OVERSIGHT OF GOVERNMENT MANAGEMENT, RESTRUCTURING AND THE DISTRICT OF COLUMBIA SUBCOMMITTEE

OF THE

COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

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EGG SAFETY: ARE THERE CRACKS IN THE FEDERAL FOOD SAFETY SYSTEM?

THURSDAY, JULY 1, 1999

U.S. SENATE,
OVERSIGHT OF GOVERNMENT MANAGEMENT, RESTRUCTURING,
AND THE DISTRICT OF COLUMBIA SUBCOMMITTEE,
OF THE COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:08 a.m., in room SD–342, Dirksen Senate Office Building, Hon. George V. Voinovich, Chairman of the Subcommittee, presiding.

Present: Senators Voinovich and Durbin.

OPENING STATEMENT OF SENATOR VOINOVICH

Senator VOINOVICH. Good morning. Unfortunately, Senator Durbin and I—and anybody else who is here—are going to have to excuse ourselves around 10:45. We have to go down and cast a vote, and we will adjourn the hearing at that time and rush back so we can continue with the hearing.

We call this morning's hearing "Egg Safety: Are There Cracks in the Federal Food Safety System?" The Subcommittee on Oversight of Government Management, Restructuring, and the District of Columbia is going to focus on the Nation's egg supply and the extent to which the Federal food safety infrastructure is adequate or inadequate to ensure that the eggs we eat do not pose a health risk.

I would first like to address the health risk posed by eggs which has prompted greater scrutiny of egg inspection practices. That risk is *Salmonella enteritidis* which, for the sake of ease, I propose we refer to as "SE" for this hearing. This bacteria is a relatively new threat, and it was only identified as a public health problem in 1988. Apparently, there has been a mutation in the *Salmonella* bacteria, and SE can now be passed directly from hens to their otherwise healthy-looking eggs.

According to the Center for Disease Control, not all hens infected with SE pass it on to their eggs, and the number of eggs thought to be infected is one in every 20,000, or 3.4 million out of 67 billion eggs produced in this country every year. I am sure that there may be some other statistics, but those are the ones that we are using.

This has created a health risk in eating undercooked or raw eggs that simply did not exist before. Eating an infected egg does not always result in illness. Proper refrigeration limits bacterial growth, and cooking eggs at 160 degrees Fahrenheit destroys SE. For illness to occur, eggs must be contaminated at the farm or dur-

ing processing and then handled improperly, inadequately refrigerated, undercooked, or consumed raw.

Since the late 1980's, the number of SE cases grew until it peaked in the mid-1990's and has declined somewhat since then. The Center for Disease Control estimates that in 1997, the last year from which accurate figures are available, over 100 deaths and 300,000 illnesses were attributable to SE contracted through infected eggs. My wife contracted *Salmonella* when she was overseas, and you get very, very sick with it. And so if you talk around 300,000, that is 300,000 pretty sick people, and we were worried about her.

The segments of the population most at risk from SE are, of course, the very young, senior citizens, and individuals with deficient immune systems. Between 1985 and 1998, approximately 68 percent of deaths attributable to SE occurred among nursing home residents. They are the most vulnerable.

A cursory glance at the current oversight system for egg safety would seem to indicate that it is indeed fragmented. The question for the Subcommittee is to determine whether the fragmentation is affecting the safety of our Nation's egg supply. Four agencies within two separate Federal Departments have jurisdiction at different times over eggs during the production and distribution cycle. There are many specific examples of this that will be discussed by witnesses from the General Accounting Office and others here today.

In addition, most of the 50 States split responsibility for egg safety between their health and agricultural services, and, finally, private industry polices itself. My understanding is that the egg industry has taken the threat of SE seriously, and has implemented some measures to mitigate the risk. So often we think that the only way that we can have good health and safety is that it has to be regulated, but I think conscientious people that are in the business are doing what they can internally to do the job.

Therefore, it seems to me that there are three important questions which we have to answer today. One, from a good government point of view, how can the current egg safety system in this country be better organized and managed; i.e., can you do a better job with all the agencies that are out there? Are they doing the job that ought to be done? We will start with that.

Second, do the health risks of SE warrant going in and saying that the current system, even if it was improved substantially, is inadequate to get the job done, and that we should reorganize and combine and so on?

And last, but not least, are there some short-term things that need to be done? In other words, is there, within the current framework, something that can be really zeroed in on that can deal with this problem and substantially reduce the threat of SE?

Hopefully, we are going to get some answers from the witnesses here today. I am sure they have a little different point of view, and that is why we have you here.

I would now like to yield to the distinguished Ranking Member of this Subcommittee, Senator Durbin, for an opening statement, and I must tell you that if it wasn't for Senator Durbin, we wouldn't be here today. He has spoken to me often about the importance of this reorganization, and he has been here a lot longer

than I have and it has been a passion with him. Senator Durbin, I am sure you have an opening statement that will underscore why you are so concerned about this situation.

OPENING STATEMENT OF SENATOR DURBIN

Senator DURBIN. Thank you, Chairman Voinovich, for doing this, and I believe that your cooperation demonstrates that this is truly a bipartisan issue. We are all interested in food safety, Democrats, Republicans, Independents alike. And the fact that this hearing is taking place clearly indicates your level of interest.

What really precipitated it was this GAO study, and we will hear a lot about it today. If you stacked all the GAO studies produced each year, it probably would reach the height of the Washington Monument. They are important, requested by Members of Congress in most instances to look into various problems. But, unfortunately, most of them go unread and unheeded.

This is an exception. It is an exception because we learned as late as yesterday, just a few days after this report came out, that the administration has announced that it got the message, that it is going to start making some dramatic changes when it comes to the question of food safety involving eggs.

I am glad to see that, and I am happy that the Clinton administration has been responsive on the food safety issue, and I hope that they will stick with us. There is more to be done, and I hope that we can continue on a bipartisan basis to achieve it.

Let me say at the outset, before we say anything else, eggs are a wholesome, nourishing, and economical food. Let me add this: Everyone I have spoken to in the government levels, from the agencies as well as the General Accounting Office, has said that the people in the egg industry have been cooperative throughout this whole effort. That is an encouraging thing, and I hope that that spirit of cooperation will continue today not only through the hearing but as we talk about ways to improve the safety of this important food product.

Eggs are perishable. They need to be handled with care. And perishable products always have a degree of risk, but the risk is manageable.

This issue of foodborne illness when it comes to eggs was really dramatized last year by a program on television, ''Dateline,'' which focused on some things that were being done by egg handlers and packagers which, frankly, are unacceptable. And I think that this report and this debate and this Subcommittee hearing will move us forward, and I want to commend the folks at ''Dateline'' for bringing this matter to national attention, at least to a higher level of national attention.

Now, make no mistake, America has been blessed with one of the safest food supplies in the world. But we can do better. Foodborne illness is a significant problem, as the Chairman has said. GAO estimates 81 million people will suffer food poisoning each year and 9,000 will die. Children and the elderly are especially vulnerable. There is a threat from emerging pathogens such as *Salmonella enteritidis*—and I hope one of us has pronounced it right, I am not sure; I will call it ''SE,'' too, so it gets us both off the hook—which was virtually unheard of before the mid-1980's.

How big a problem is this? Let me show you some headlines from the Richmond, Virginia, newspaper. And this is not an old story. Unfortunately, it is a new story, June 12, 1999: ''*Salmonella*-tainted eggs at a popular restaurant in Richmond, Virginia, were determined to be the cause of a recent outbreak of foodborne illness that left 7 people hospitalized, 92 with documented *Salmonella* infection, and nearly 200 people claiming illness late May,'' according to the Richmond *Times-Dispatch.* The restaurant chain involved here learned their lesson and announced when they were reopening that they were going to be extremely careful in using pasteurized and processed eggs that would avoid *Salmonella* contamination.

But that is why this is a real problem. Statistics can be pushed back and forth by both sides, but I think everybody understands that we want to increase consumer confidence in our entire food supply, and certainly when it comes to eggs.

In terms of medical costs and productivity losses, foodborne illness costs the Nation $37 billion a year. The Department of Health and Human Services predicts foodborne illnesses and deaths will increase 10 to 15 percent over the next decade. American consumers spend about $617 billion a year on food, $511 billion spent on foods grown here in the United States and the rest imported. Our ability to assure that the safety of our food and to react rapidly to potential threats to food safety are in the forefront of our consideration are critical not only for public health but also for the vitality of both domestic and rural economies and international trade.

I would like to address for a moment the issue of consumer confidence, and I would like folks to put it in the context of what is going on in Europe today. Many of you followed the dioxin crisis in Belgium which literally closed down their food industry. Days before the national election, eggs, poultry, beef, pork, and dairy products were pulled from the shelves in Belgium. Countries worldwide have restricted imports of eggs, chickens, and pork from the European Union. Part of the controversy in Europe is the failure of government to win the confidence of consumers. People lose confidence and panic unnecessarily when their government doesn't step up to meet its responsibilities. From mad cow disease to dioxin, we cannot afford to ignore these lessons regarding government's role in effectively and efficiently managing food safety.

A credible Federal food safety system assures consumers and makes our products more acceptable here and abroad. Everyone shares that responsibility in ensuring food safety—Federal, State, Local Government, industry, and us as well, the consuming public.

The administration stepped forward on the issue of food safety, and I commend President Clinton and Secretaries Glickman and Shalala for their leadership. I want to acknowledge as well the list of accomplishments by agencies represented by Dr. Potter and Ms. Glavin today. Although in today's hearing we will examine egg safety, where much work remains to be done, I want to commend the dedication of the professionals in both departments and our Federal agencies who are committed to improving the safety of the food supply.

Industry and State Governments also have a record of which we can be proud. It is clear the egg industry has stepped forward itself

and taken the lead in developing such things as quality assurance programs. I want to work with the United Egg Producers to solve the challenges we face, and I ask for their input in developing legislation. How well is our government managing the safety of food from farm to table? Currently, the Federal food safety system is fragmented with at least 12 different Federal agencies and 35 different laws governing food safety, 28 different House and Senate subcommittees with food safety jurisdiction. It is no surprise with this overlapping jurisdiction that there is lack of accountability. An example of this, of course, is the FDA and USDA regulating eggs, which is the focus of today's Subcommittee hearing.

Last summer, I asked the General Accounting Office to evaluate how well the Federal Government was doing. GAO has completed the report which I mentioned earlier. It shows gaps, inconsistencies, and inefficiencies. What is even more disturbing is to discover, in the absence of uniform Federal regulation, that States have established their own, creating a patchwork of varying regulations. This was a difficult undertaking for our staff, but we tried to map each State's different egg safety regulations. We couldn't put it all on one map. They are so different and so diverse. Marianne, if you will show the two different maps, we can get into this later, but the State laws are all over the place. And I think it argues for a consistent national standard based on good science and consumer food safety.

Later this month, the Subcommittee will have a hearing on creating a single independent food safety agency, an idea which my colleagues and I have introduced in legislation, the Safe Food Act of 1999. But GAO has been unequivocal in its recommendation for consolidating Federal safety programs, and those recommendations go back perhaps to 1977 or before. This has been an issue even before this Subcommittee which goes back 2 or 3 decades. The fragmented Federal regulatory structure remains an obstacle to a comprehensive, consistent, and effective food safety and egg safety strategy.

I welcome the witnesses and their insights. The GAO report is excellent, and I thank you for the good work that you put into it. In the coming weeks, we will try to develop legislation that takes some of your recommendations.

Thank you, Mr. Chairman.

Senator VOINOVICH. Thank you, Senator Durbin.

I think that the public should understand that this Subcommittee's title is the Subcommittee on Oversight of Government Management, Restructuring, and the District of Columbia. Senator Durbin and I have talked about it, and we are going to really try and follow up on the responsibilities of this Subcommittee and pay particular attention to the GAO studies that have been done so that we can get at some of these things that for a long time have been just laying on the shelf. This Subcommittee's Chairman had several hearings with the Department of Energy. The thing that really was striking to me is every single year they came back with a report saying there is a problem, there is a problem, there is a problem, and nothing was done about it. And now we are back at it again. Hopefully, that will be taken care of.

So I think, Senator, that you have raised a real issue, something that has been around for a while, and I think we ought to attack it and make a decision.

We are lucky to have such good witnesses here today. First of all, I would like to introduce our first panel of witnesses: Larry Dyckman is the Director of Food and Agriculture Issues at the U.S. General Accounting Office. Good to have you here. Ms. Margaret Glavin is the Associate Administrator, Food Safety and Inspection Service of the U.S. Department of Agriculture. Dr. Morris Potter is the Director of Food Safety, Food and Drug Administration, Department of Health and Human Services. Both are here, Dr. Potter and Ms. Glavin, on behalf of the administration. We thank you for coming, and we look forward to your testimony.

I would like to start out with Mr. Dyckman.

TESTIMONY OF LAWRENCE J. DYCKMAN,[1] DIRECTOR, FOOD AND AGRICULTURE ISSUES, U.S. GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY STEVE SECRIST, SAN FRANCISCO REGIONAL OFFICE

Mr. DYCKMAN. Good morning, Mr. Chairman, Senator Durbin. With me today is Steve Secrist from our San Francisco regional office. He is a senior evaluator who has been responsible for much of the work that I will be talking about today.

We want to thank you again for the opportunity to discuss our work on the safety of eggs and egg products. My testimony, as you know, is based on a report we are issuing today to Senator Durbin. Eggs are an important part of most American diets. I might tell you that my wife eats several eggs a day. She watches her cholesterol and she eats the egg whites, but she enjoys them very much. On average, each American consumes about 245 eggs annually. But over the last decade, eggs contaminated with *Salmonella enteritidis* bacteria, which we will all refer to as "SE," have increasingly been implicated as the cause of foodborne illnesses in the United States. SE may have caused about 300,000 illnesses in 1997, according to the CDC, resulting in up to 230 deaths. Most SE outbreaks with identified causes are linked to eggs.

The Senator spoke about the case in Richmond. We have been in touch with the Virginia State officials, and they have 121 confirmed cases of illnesses connected to SE infection. And they believe eggs are the likely cause of those infections.

It is important to note at the onset that responsibility for ensuring that eggs are safe to eat is shared among four Federal agencies and two departments, and often two agencies in each State. As the blue exhibit shows, the process begins under the authority of USDA's Animal and Plant Health Inspection Service, which ensures that egg-laying hens are bred free of SE, and continues under the authority of FDA, which is responsible for egg safety on farms where eggs are produced. That chart is on page 5 of the written testimony. It is also in our blue book report if it's difficult to follow for people in the room.

At the processing stage, either FDA or USDA's Food Safety and Inspection Service may have authority, depending on whether the

[1] The prepared statement of Mr. Dyckman appears in the Appendix on page 41.

eggs are sold whole in the shell or broken to create an egg product. Shell eggs may also be graded for quality by another USDA agency. Once transported to the retail level, both shell eggs and egg products are under FDA's authority, but the millions of restaurants, institutions, and other retail food operations throughout the United States are generally inspected by either a State agriculture or health department.

The number of agencies involved is a key factor in the problems documented by our review. Clearly, the egg situation is a case study of the cross-cutting and duplicative problems that we have reported to this Subcommittee and to many other committees in our series on major management problems and challenges facing government agencies. It was also reported as a major management problem concerning food safety in general in our report concerning the Department of Agriculture.

Our work in this particular review found that neither FDA nor USDA requires the egg farms and processing plants under their authority to use a prevention-based approach that would identify control and monitor known safety risks. Over the last few years, the Federal Government has introduced such programs referred to as Hazard Analysis and Critical Control Point systems in meat, poultry, and seafood processing.

At the State level, 13 States responsible for about two-fifths of the Nation's egg production have established voluntary prevention-based programs for egg farms. However, these programs differ in critical areas such as when and how to test for the presence of SE.

Although refrigeration retards the growth of SE, our work found that the first national requirement to refrigerate eggs at 45 degrees or colder from the time they are packed until they reach the consumer may not, for a variety of reasons, effectively reduce safety risks. The responsibility for implementing and enforcing the requirements will be split between USDA and FDA. USDA has issued regulations which will take effect later in August requiring that eggs be refrigerated during storage and transportation. We found out today, actually, that FDA is in the process of proposing regulations for retail locations, restaurants, and grocery stores, and we are encouraged by that. We haven't seen them yet, but it is good to hear that they are on their way.

In addition, many experts believe that safety risks could be better reduced by controlling eggs' internal temperature. The regulations will focus on air temperature rather than on the internal temperature. Yet eggs are often in the 70- to 80-degree range when they are processed and packed, and it may take up to 6 days before the internal temperature is reduced to the air temperature in the cooler.

Our work also found inconsistent policies and practices in three other areas. Certain groups, including the elderly in nursing homes, are more likely to suffer severe health consequences from eating contaminated eggs. Yet only about half the States have followed FDA's recommendation that they require food service operators to use pasteurized eggs or egg products when serving vulnerable populations.

Also, Federal policies allow some eggs, as we have learned from the "Dateline" news show, to be returned from grocery stores for

processing to be repackaged, re-dated, and returned to the retail level for sale. Moreover, Federal rules on how expiration dates are used on eggs vary considerably.

Finally, we found that the involvement of the four Federal agencies enforcing a variety of laws make it difficult to direct resources to the greatest safety risk or to effectively coordinate egg safety policies. For example, USDA by law provides daily full-time inspection of plants where eggs are pasteurized to kill harmful bacteria, whereas FDA almost never inspects egg farms where eggs can be contaminated.

Mr. Chairman, in your invitation to me, you posed a question, and I would like to answer that question right now, and the answer is: Yes, the Federal food safety program for eggs is cracked, disjointed, it is duplicative, and it is not always risk-based. We are offering some recommendations that we think will address those problems.

First, to address the need for a consistent farm-to-table approach to egg safety, the report we are issuing today asks the Congress to consider consolidating responsibility for egg safety in a single Federal Department.

We are also recommending: First, that FDA develop a model prevention-based program for egg farms and processing plants which States can adopt to reduce the risk of SE contamination; second, that the USDA develop regulations that would require prevention-based programs at plants where egg products are processed; and, third, that USDA and FDA jointly study the cost and benefits of implementing rapid cooling techniques in egg processing and packaging operations.

In commenting on our draft report, USDA and FDA generally agreed with our recommendations. We would be happy to answer any questions you or Senator Durbin have.

Thank you.

Senator VOINOVICH. Thank you very much.

I would like to remind the witnesses that their entire statements are going to be entered into the record, and to the best of their ability, if they could limit their statements to 5 minutes, it would be most appreciated.

We will now call on Dr. Potter for his testimony. Dr. Potter?

TESTIMONY OF MORRIS E. POTTER, D.V.M.,[1] DIRECTOR, FOOD SAFETY INITIATIVES, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. POTTER. Thank you, Mr. Chairman, and Senator Durbin. I am Morris Potter, Director of Food Safety Initiatives at the Food and Drug Administration, and I am pleased to be here with my colleague, Maggie Glavin, from USDA to testify on the government's role in the oversight of egg safety and to describe how we have applied science to protect the public's health.

HHS, USDA, and the States have a long history of working together to understand and initiate actions along the farm-to-table continuum to reduce the risk of SE. Federal surveillance and research efforts have been critical to our better understanding of SE

[1] The prepared statement of Mr. Potter appears in the Appendix on page 55.

and efforts to develop science-based control schemes from farm to table.

In the early 1980's, routine public health surveillance identified SE as a growing public health problem, as you see in the first part of that upper figure. In 1986, outbreak investigations linked this growing problem to contaminated whole shell eggs. FDA, CDC, ARS, APHIS, and AMS immediately responded by working together and with State Governments, universities, and the egg industry to conduct research and to put into place prevention and control mechanisms as that information developed.

To control a public health problem like SE in eggs, one must first understand it. Surveillance of human illness, laboratory research at ARS, FDA, and universities, and field investigations have all been essential to that understanding. Data from CDC's *Salmonella* surveillance system show that SE infections increased more than 8-fold from 1976 to 1996, as you can see by making a composite of that top—the lines in the top figure.

Another valuable data source early in the outbreak was the surveillance of outbreaks of infections with SE. States reported 26 SE outbreaks in 1985 when that surveillance system started. By 1990, the number of reports had increased to 85. There were strong regional differences in the number of outbreaks just as the chart reflects strong regional differences in the number of infections.

Many SE outbreaks have been attributed to food served in commercial establishments, such as restaurants, hospitals, schools, nursing homes, and most were associated with food that contained undercooked eggs. Most deaths linked to reported outbreaks have occurred among the elderly in hospitals and nursing homes.

These two characteristics, the association with undercooked eggs and commercial establishments, emphasized the importance of nationwide adoption and enforcement of FDA's Food Code which first focused attention on proper egg handling in 1990. The Food Code contains special guidance for food handling in institutions to try to reduce the risk particularly for those vulnerable populations. The Federal agencies have collaborated on a number of additional efforts to improve institutional food service handling of eggs.

In addition to epidemiology, our public health response to SE in eggs has relied heavily on laboratory science and field investigations. Design of on-farm control programs required understanding the organism and its mechanism of action as well as comprehending the natural history of SE's introduction, spread, and persistence in the environmental of a laying house.

Universities, States, and industry have conducted many of the field studies. Since October 1995, FDA has traced eggs from 12 outbreaks back to flocks of origin, additionally leading to field investigations of 112 laying houses in 9 States.

Various control programs have been tried showing that combinations that include the use of uninfected replacement birds, rodent control, cleaning and disinfection between flocks, and environmental monitoring will reduce the incidence of infected flocks. Controlling SE during production is crucial in mitigating the risk of SE in eggs.

Research in this area is being conducted by both FDA and ARS to uncover all important sources of the SE problem and to develop

ways to maintain SE-free laying hens. As additional studies are completed, we will be able to determine more precisely which factors are critical and what performance standards must be met for optimal public health protection. Our ability to now move forward on a comprehensive program for improving the safety of eggs is a direct result of the investments in research during the past several years.

We can also use surveillance to track the public health progress we are making to control SE in eggs. As you see in the chart, SE infections have been dropping since 1996, especially in the Northeast where control efforts began first and have been most intense. The data also indicate a downturn in commercial establishments and the average size of outbreaks.

In 1995, FDA, CDC, FSIS, and five State health departments began a collaborative project or program called FoodNet to collect more precise information on the incidence of foodborne disease. FoodNet recently reported a 44 percent decrease in the infection rate for SE from 1996 to 1998 in the areas of the country under surveillance, and you see that in the bottom figure there on the chart.

Collectively, these systems report substantial decreases in SE during the past 3 or 4 years. We believe that these data show that the coordinated efforts of all of those involved in the farm-to-table handling of eggs contributed to this dramatic decrease in illness, including Federal agencies, State governments, the egg-producing industry, retailers and food service, and consumers. Federal and State efforts to trace back from outbreaks to infected flocks and to establish egg quality assurance programs that include microbiological testing and diversion of eggs from infected flocks to pasteurizing plants have been important factors in this reported decrease, and we will continue to work collaboratively to further reduce the prevalence of SE in laying hens.

But just as these data on the chart demonstrate progress in the control of SE, they also document a very large public health challenge that remains to be overcome. We need to finish the job we started for the public. The joint FSIS–FDA risk assessment made it clear that all of the steps from the farm to table can contribute to egg safety, and we will consider all possible measures to achieve our public health goals.

As you know, FDA has been working on a proposed rule to address refrigeration and labeling of eggs that is consistent with the requirements of the FSIS rule. FDA's proposed rule was put on public display today. It proposes requirements that all shell eggs be stored and displayed at temperatures of 45 degrees or less, and it would cover shell eggs both in interstate and intrastate commerce. It proposes safe handling statements on the labels of shell eggs.

In addition, the President's Council on Food Safety will create within 120 days a farm-to-table approach for addressing SE in eggs. This will be part of the Council's overall strategic plan for food safety that should come out early next year.

Information from recent research, the joint FDA–FSIS 1998 Salmonella Risk Assessment, and the comments we received on the joint FDA–FSIS ANPR of May 19, 1998, intended to identify farm-

to-table actions that will decrease the risk of SE in shell eggs will be used by the task force to help finalize its recommendations for a strategic plan for a comprehensive system for the safety of eggs and egg products.

Mr. Chairman, there clearly are complex lines of jurisdiction over eggs between FDA, FSIS, and AMS. Those lines, however, are not cracks in the system but seams. We have a long history of coordinated effort to address the public health challenges we face in SE in eggs. Much has been done to address those challenges but more, indeed, is needed. We are committed to provide the country with a seamless coordinated farm-to-table policy.

Thank you very much.

Senator VOINOVICH. Thank you, Dr. Potter. Ms. Glavin.

TESTIMONY OF MARGARET GLAVIN,[1] ASSOCIATE ADMINISTRATOR, FOOD SAFETY AND INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE

Ms. GLAVIN. Mr. Chairman and Senator Durbin, I am Margaret Glavin, the Associate Administrator of the Food Safety and Inspection Service. I am pleased to appear with Dr. Morris Potter, my colleague from FDA, to discuss the safety of eggs and egg products in general, and specifically to discuss the egg products inspection program of the Department of Agriculture. Because several agencies at USDA play a role in egg safety and regulation, I am joined today by Michael Holbrook of the Agricultural Marketing Service, Dr. Jane Robens of the Agricultural Research Service, and Dr. Thomas Myers of the Animal and Plant Health Inspection Service.

Let me begin by emphasizing USDA's commitment to improving the safety of the food it regulates—meat, poultry, and egg products. Over the past several years, USDA has implemented a strategy for change that emphasizes the need to prevent food safety problems before they happen and the need to address food safety hazards all along the farm-to-table chain.

FSIS has a long history of inspecting meat and poultry products, but the agency's involvement in egg products inspection is relatively new. The USDA Reorganization Act of 1994 set the stage for FSIS involvement in egg products inspection by transferring this responsibility from the Agricultural Marketing Service to the Food Safety and Inspection Service.

Under the Egg Products Inspection Act, FSIS is responsible for continuous Federal inspection in plants processing liquid, frozen, and dried egg products. During fiscal year 1998, 102 FSIS inspectors monitored operations at 73 egg product plants across the country. We also have cooperative agreements with six States to provide inspection of egg products. Additionally, FSIS oversees the importation of egg products into the United States.

I understand the concerns of the current statutory framework for egg safety presents a fragmented system of oversight. I do, however, want to make two points: First, that USDA activities regarding shell eggs and egg products go beyond FSIS—and that is what my chart indicates—and any effort to adjust the current statutory

[1] The prepared statement of Ms. Glavin appears in the Appendix on page 74.

framework for egg safety should consider the broad range of activities carried out by the Department.

The second point—and it echoes Dr. Potter's remarks—is that FSIS and FDA, which share statutory authority for egg safety, have worked closely together and are making progress in developing a coordinated approach to the problem of SE in eggs and egg products.

Let me first address the broad range of USDA activities beyond FSIS by providing a few examples. The Agricultural Marketing Service administers a voluntary grading program for shell eggs and is responsible for the shell egg surveillance program. AMS last year announced a prohibition on the repackaging of eggs packed under its voluntary grading program while it studied the issue further, and that agency is now working on a proposed rule to address this matter more fully.

The Animal and Plant Health Inspection Service conducts activities related to animal health, and several of its activities have a public health impact by reducing the risk of disease in layer flocks. For example, APHIS administers the National Poultry Improvement Plan, which certifies that poultry breeding stock and hatcheries are free from certain diseases.

The Agricultural Research Service and the Cooperative State Research, Education and Extension Service carry out needed food safety research that helps us to improve the safety of eggs and egg products. And USDA agencies play a role in educating consumers about the safe handling of eggs.

FSIS has developed numerous publications on egg safety and uses a variety of networks to get this information to the grass-roots level, including the network of the cooperative extension agents throughout the country.

Regarding the second point, that FSIS and FDA are working together to address the problem of SE in eggs and egg products, I would like to provide two examples. In May 1998, FSIS and FDA jointly issued an Advanced Notice of Proposed Rulemaking to initiate a comprehensive and coordinated process of addressing the problem of SE in shell eggs and to solicit input from the public on the strategies. And FSIS and FDA have conducted a joint quantitative farm-to-table risk assessment on SE in eggs that was released last summer. The risk assessment is helping us to better evaluate interventions in terms of their public health impact as we further develop our food safety strategy for shell eggs and processed eggs.

These joint initiatives complement and provide a framework for other initiatives taken by FSIS. For example, in August 1998, FSIS published a final rule to implement the requirement for the refrigeration and labeling of shell eggs that were mandated by the 1991 amendments to the Egg Products Inspection Act, and FSIS is now developing a proposed rule that would address HACCP for egg products.

For the future, more progress is needed, and to facilitate that progress a strategic plan for shell eggs and egg products is being developed by the strategic planning task force of the President's Food Safety Council. It will be completed within 120 days and will

parallel the broader strategic planning effort that is already underway by the Council.

We have certainly not won the war against foodborne illness by any means, and eggs remain a major source of SE illness. But the steps we have taken with HHS are making a difference, and we are committed to further progress.

This concludes my testimony, and I thank you for the opportunity to be here today with FDA to discuss the safety of shell eggs and egg products.

Senator VOINOVICH. Thank you very much. We decided, in order to move the hearing along, that Senator Durbin will go and vote, and I will ask my questions, and when he comes back, he will ask his, and hopefully they will not be the same questions.

Obviously, the General Accounting Office feels that the organizational structure leaves something to be desired, and I would like to call on Mr. Dyckman. You have heard the testimony, and I would like to have you comment on what you have heard this morning. Does that color your judgment on this matter?

Mr. DYCKMAN. I appreciate the opportunity, Mr. Chairman.

Egg safety is a microcosm of food safety. We have been on record for many years, as Senator Durbin pointed out, supporting consolidation of all food safety efforts in the U.S. Government. And if we had our druthers, that would occur and egg safety would be part of that consolidation. We recognize that there are political, social, economic, and other kinds of implications of doing that, and it may take time before that occurs, if it ever occurs.

In the interim, we have known about the problem with egg safety for 11 years. We reported in 1992 that there is a need for a much better, closely coordinated effort, a common strategic plan for egg safety. I am encouraged and heartened that either the work that we have done or maybe it is just time that the two primary agencies are coming together and seemingly working for that plan. However, look at our food chart up there; it took me quite a while to understand this chart. This review has been my first exposure to egg safety, and I kept asking my staff, now, let me get this straight: Why does FDA have responsibility on the farm? Why does Agriculture have a responsibility for the egg product plants? Who has responsibility for refrigeration at this point and at that point? Why do they have differing labeling requirements? Why aren't there HACCP-like procedures, HACCP-like systems required at different points? Why isn't the entire system risk-based?

And while I am encouraged by what I hear today, GAO still believes that there is a need to consolidate egg safety responsibilities in one Federal agency.

Senator VOINOVICH. And that is just one of the things. You are basically recommending that we have food safety consolidation, period, and that one of the reasons is the issue of egg safety, but there are many other areas that you feel could be better addressed if you had a consolidation of those agencies.

Mr. DYCKMAN. That is correct. If there was one agency that had budgetary authority over the Federal Government's food safety programs, one agency that had authority or one official that had authority over the research that is done on food safety, I think it

would be a lot more efficient. I think we would be able to accomplish more as a agency, as a country.

Now, we have among the safest food safety systems in the world. But I think we can accomplish more and it would be a much more efficient system if there was one Federal agency that had all responsibility for food safety. I understand you might be having a hearing on that later this month, and we would be happy to help you with that hearing.

Senator VOINOVICH. From your observations, what role should the States be playing in this?

Mr. DYCKMAN. In egg safety?

Senator VOINOVICH. Yes.

Mr. DYCKMAN. I think it is quite clear that at the retail level in particular, and also at the farm level, the Federal Government doesn't have the resources to police, to monitor all establishments or even a large fraction of the establishments. I think the Federal Government has to set minimum policies and then allow States to develop a more stringent or equal to Federal minimum policies, whether it is a HACCP-type program at the farm level or a HACCP-type program at the shell egg processing plants.

Obviously, many States are moving in that direction. We noted that there are 13 States that have some type of HACCP-type program. We are encouraged by that. Some of those are relatively new, so it is a little too early to evaluate their effectiveness. States want to work, I believe, as equal partners with the Federal Government, and I think that is the way it should be.

Senator VOINOVICH. In your report are you specific in terms of the responsibilities that the Federal Government would have and where the States' responsibilities would be?

Mr. DYCKMAN. Our report mentions the States' responsibilities. It doesn't go into a lot of detail in terms of how they should interplay with the Federal Government in the future. Clearly, regarding our recommendation for the Federal agencies to come up with a HACCP-like program or requirement and model for the farms and for the egg-processing plants, there will have to be a partnership on the State level to enforce that because the Federal Government will never have enough resources to enforce it.

Senator VOINOVICH. So what you are saying is that there definitely is a role for the States to be playing.

Mr. DYCKMAN. An equal role, a very strong role. And, a lot of this commerce is interstate commerce where the Federal Government has a clearly defined role. Where it is intrastate commerce, obviously the States generally have a much stronger role and the upper hand.

Senator VOINOVICH. In your report, did you note any State out there that—you referred to 13 States that have started HACCP programs. Is there a ''best practice'' State out there?

Mr. DYCKMAN. I will ask Steve to comment on that.

Senator VOINOVICH. Yes.

Mr. SECRIST. I think Pennsylvania—back in the early 1990's, Pennsylvania was part of a pilot project along with the Animal and Plant Health Inspection Service to look at SE reduction measures, and then that pilot project ended, but it became what is now the Pennsylvania Egg Quality Assurance Program, and that was one of

the first, probably the first comprehensive SE reduction program at the State level. And subsequent to that, other States have adopted similar measures. California and some of the other states that we have mentioned have taken elements of that plan and developed their own plans. Pennsylvania would be a good model to look at.

Senator VOINOVICH. Well, as a former governor and chairman of the National Governors Association, one of the things that I always felt could be improved was the relationship between the Federal Government and State Government in this whole regulatory area, and that the idea of sharing best practices, getting the directors of the Agriculture Departments together to talk about best practices, to see if you couldn't cascade them throughout the country, would be a good idea. I think that perhaps coming out of this we could be in touch with the Governors Association to see if we couldn't improve their coordination, since at least you acknowledged that they have a role to play here. And I would be interested also, Dr. Potter and Ms. Glavin, in your opinion of that.

We have heard an argument, and it has been around, on reorganization. Why not? The system that we have currently—can it get the job done?

Ms. GLAVIN. Our focus at this point is very much on identifying those actions which would include such things as regulation and research that need to be done in order to improve egg safety, and we are focused on that rather than on the organizational issue at this point. We think there is a lot to be done and a lot that can be done even under the existing structure.

Mr. POTTER. Just to amplify that, I absolutely agree with what Maggie said, but each of the Federal agencies brings to the mix its own set of skills that are garnered over the years due to its involvement in all of the things that it does in addition to its specific role in the farm-to-table pathway of eggs. And our efforts to pull together that expertise and those resources, the intellectual capital of the Federal agencies to bring to bear on a problem I think has shown itself valuable. We are committed to a single food safety framework, and I think that the collaboration among the agencies is starting to show a measure of progress in achieving our public health goals.

There is a strong role for States in food safety for a number of reasons. As GAO pointed out, there is a great resource issue for the Federal agencies to get out to individual establishments, be they producers or restaurants, but also there is a relationship, as you know, that builds up between the State agencies and the producers and businesses in the States that can help facilitate communication and speed adoption of good practices.

Senator VOINOVICH. I am going to have to excuse myself, and hopefully Senator Durbin will return to the hearing and he will bring it back into session. But when I get back, I would like to hear from both of you. We do have the Results Act, and you have performance plans that you have put together, and I would be interested to know how much coordination in this particular area has gone on between your two respective agencies. I will be back.

[Recess.]

Senator DURBIN. If we could ask everybody to resume, I am going to try to pick up where Senator Voinovich left off. Thank you very

much, and I apologize for the interruption. But we had a vote on the floor, and Senator Voinovich will be back very briefly.

I tried to ask my staff to recount briefly the Chairman's questions, and I hope I don't go over the same ground. I apologize if I do.

I would like to ask the GAO and other witnesses present if they will bear with me for a minute, or 2 minutes, maybe, to go through a primer so that we understand what we are talking about here.

It is my understanding that this contamination, this SE contamination, can be detected in chickens before the eggs are laid. Is that true?

Mr. DYCKMAN. Yes.

Senator DURBIN. All right. It is also my understanding that the incidence of this contamination in eggs depends on a variety of factors. One of them, of course, is whether it was initially contaminated, which we will assume for a moment that is a possibility. The other is the age of the egg. Is that not true?

Mr. DYCKMAN. That is correct.

Senator DURBIN. And what kind of standards have you found in your investigation in terms of the vulnerability of an egg to contamination? Can you give us any standard?

Mr. DYCKMAN. What we have found is that there is no HACCP-based system at the farm level in the production of the eggs and also at the processing plants. It is not really a risk-based system. Now, some farms obviously do follow better sanitary practices than others.

Senator DURBIN. My question wasn't clear. What I am asking for is on the age factor. How old is an old egg? When do you start getting into the time frame of an egg's age where it is more susceptible to contamination?

Mr. DYCKMAN. First, let me say at the onset I am an accountant, not a scientist, but if you will bear with me, I think it is about 21 days or so.

Senator DURBIN. That it is more susceptible to contamination. Now, I read 30 to 45 days in the report.

Mr. SECRIST. There has been some scientific research that has been done that shows that at least in that research study they may have a natural protection against SE replicating, growing in the egg for perhaps up to 21 days. That is under certain conditions, assuming that the SE is deposited in the egg white and that it is under a certain temperature.

What we have found in terms of expiration dating was that there currently are no Federal standards for expiration dating on egg cartons and that AMS under the voluntary grading program only requires a 30-day expiration date if the producer decides to use a date. They are not required to use a date, but if they do, it cannot be over 30 days. Otherwise, you can put any expiration date you want on an egg carton.

Senator DURBIN. When do you start counting? When is the first day? Is it the day that the chicken lays the egg?

Mr. SECRIST. It is the date that the eggs are packed.

Senator DURBIN. So there could be a period of time between the chicken laying the egg and their arrival at the packing house?

Mr. SECRIST. Yes, there could be.

Senator DURBIN. Do you have any idea what range of time we are talking about? Is it a matter of 24 hours or days or longer?

Mr. SECRIST. That probably varies. There are obviously in-line operations where the egg farm is co-located with the packing plant, and the eggs are coming into those plants very quickly. It is also possible that eggs might be produced and shipped to the packing plant and that could take some time.

Senator DURBIN. So the question of expiration, susceptibility to contamination, you really have to start off with some basic understandings and agreement. When are we going to start counting and how long will we count? Would there be disagreement from FDA or USDA on any of the points that have been made so far?

Mr. POTTER. I think only a point of clarification, not a point of disagreement, and that is that the eggs are contaminated before they are laid, and what we are really debating here is opportunities for growth of organisms that are already there rather than the contamination itself.

Senator DURBIN. Do you have a time frame where you think they are more likely to have this growth of contamination, age of an egg?

Mr. POTTER. The growth of the organism occurs after the yolk membrane breaks down, which is a function of both time and temperature. So as the eggs are colder and fresher, there is no growth. Where precisely—whether it is 21 days or 30 or 45 days—would be modified by the temperature the eggs are kept.

Senator DURBIN. And has either the FDA or the USDA established a standard for when we start counting, how many days, age of an egg?

Ms. GLAVIN. As Mr. Dyckman indicated, the grading service counts from the day of packing for expiration. That is for eggs that are graded by USDA.

Senator DURBIN. And what is your experience in terms of how many days between the egg being laid and it being packaged?

Ms. GLAVIN. Again, I would agree with Mr. Dyckman that varies depending on the kind of process that is used.

Senator DURBIN. So if we are going to give the consumer some peace of mind here and say, now, after 30 days you ought to think twice about cooking with that egg, we better start by understanding among ourselves, at government agencies, when we are going to start counting. If you start counting at the packing plant, there is no telling how old that egg is when it is packed. Is that not true?

Let's talk about temperature for a minute, and that is another element here. If the egg is kept at a certain temperature, the likelihood of this contamination and outgrowth is diminished. Is that true?

Mr. DYCKMAN. Yes, 45 degrees seems to be the temperature that scientists tend to agree will prevent further growth of SE.

Senator DURBIN. Well, I would like to follow up on that for a moment, if I might. The testimony of Dr. Potter is that there is some seamless—your word—relationship and coordination between the USDA and the Food and Drug Administration. Let's talk about the seam.

In 1991, by legislation, we instructed your departments to come up with standards when it comes to the temperature of eggs, how they are going to be stored and maintained in order to protect public health. I would have to say by virtually any measure that both agencies failed in meeting that statutory responsibility to the point in 1998 where Congress had to put in your appropriation bill a mandate which said you are going to lose $5 million if you don't finally come out with this rule on the temperature of eggs. And so 8 years after Congress gave the responsibility to your agencies, that rule was finally issued. Is that true?

Ms. GLAVIN. Yes, sir.

Senator DURBIN. Why did it take 8 years, a pretty wide seam by anyone's interpretation, for the rule to be issued?

Ms. GLAVIN. Well, as you said, the law was passed in 1991, and at that time the responsibility was with the Agricultural Marketing Service, and they issued a proposal to implement the rule, the 45-degree rule, in 1992. Shortly after that, there were a number of legislative proposals to change that law, to make changes in it, which somewhat complicated the issue. In 1994, the Reorganization Act was passed, and in 1995, responsibility for egg products inspection passed to the Food Safety and Inspection Service. And as you indicated, our appropriations in 1998 told us we better get this regulation finalized, and we did do so in 1998.

I think it is important to recognize that we were not sitting on our hands all that time, although I can't disagree that it was a very long period of time. We did put together a joint Advanced Notice of Proposed Rulemaking with FDA setting out a strategy for dealing with egg safety and also seeking data, mainly from the industry, on which we could make good, sound judgments about how to regulate in this area.

We also completed the first ever risk assessment on bacteria in foods, and that was the SE risk assessment, and that has served us very well as we have moved forward.

Senator DURBIN. So it took 8 years.

Ms. GLAVIN. Yes, sir.

Senator DURBIN. Eight years for the U.S. Department of Agriculture to finally conform to the requirement by Congress to establish some standard about the temperature of eggs. But the story doesn't end there because the USDA responsibility, because of this fractured jurisdiction, stops, does it not, at a certain point when it comes to the temperature of eggs? And what is that point in the process?

Ms. GLAVIN. Well, the responsibility—or the regulation based on the legislation is for the temperature of eggs during storage and transportation.

Senator DURBIN. So you are not talking about when it reaches the store or the restaurant or anything of that nature?

Ms. GLAVIN. It is until it reaches the store or the restaurant, yes.

Senator DURBIN. OK. And so at that point, we have a hand-off here to a new Federal agency, the Food and Drug Administration. Now, they are going to take over the question of the temperature of eggs after the USDA is finished. Is that correct, Dr. Potter?

Mr. POTTER. That is correct.

Senator DURBIN. Now, you have known for 8 years this was coming, and so what has the FDA done? What rule have you promulgated to talk about the temperature of eggs once it has reached this point of transportation to the end user?

Mr. POTTER. Well, that proposal is on display at the *Federal Register* now. It is out and it conforms to the temperature and labeling requirements of the eggs as they come to that pass-off.

Senator DURBIN. So you don't have an FDA final rule even after 8 years?

Mr. POTTER. That is correct.

Senator DURBIN. Now, there is another thing that I want to get to, and that is, you mentioned 45 degrees, but there is some confusion here as well. Are you familiar with your Food Code?

Mr. POTTER. Yes.

Senator DURBIN. What is it?

Mr. POTTER. The Food Code requirement is for 41 degrees——

Senator DURBIN. Just in general, what is the Food Code, for the record?

Mr. POTTER. Oh, I am sorry. The Food Code is a model code for adoption by States that sets uniform standards across the country.

Senator DURBIN. Voluntary for each State.

Mr. POTTER. Right.

Senator DURBIN. And how many States have passed it or enacted this Food Code?

Mr. POTTER. At present, 14 States have adopted it, and an additional 22 are in the adoption process.

Senator DURBIN. And so when we look at this Food Code, we keep talking about 45 degrees. We look at the act which you have sent out to the States in terms of standards, and do we find 45 degrees is the standard?

Mr. POTTER. Well, remember that the Food Code is for all foods and all pathogens. For some pathogens, like *Listeria,* that grow at slightly lower temperatures than *Salmonella,* a lower temperature is more appropriate. But restaurants and other food service establishments are unlikely to have one refrigerator for things for *Listeria* and another for *Salmonella*.

Senator DURBIN. That is right. So what is the standard in the Food Code?

Mr. POTTER. The standard for retail is 41 degrees. However——

Senator DURBIN. Forty-one degrees. Go on. Internal temperature.

Mr. POTTER. That is refrigerator temperature.

Senator DURBIN. Forty-one degrees internal temperature for the eggs is your Food Code standard, and the standard we have been discussing here is 45 degrees air temperature.

Mr. POTTER. I believe the Food Code requirement is 41 degrees ambient temperature. In other words, that would be the refrigerator temperature setting.

Senator DURBIN. We had a different reading on it, but let's assume that it is 41 degrees under any standard. Think about this for a second. Think about what we have just discovered. In 1991, Congress passed a law and said to the USDA and the FDA: We think the temperature of eggs is important to protect American consumers; please write some rules so that we can understand how

to transport eggs, how to store eggs, so that we can best protect American consumers.

Eight years pass and only when Congress says in the USDA appropriation, if you don't finally do your job, you are going to lose $5 million this year, they do it. They issue it. The Food and Drug Administration, which is supposed to pick up the baton after the transportation, then decides they have got to do it, too. Now we are waiting to see when that rule becomes final, and in the process, we find that at least there is some ambiguity, if not inconsistency, in the standard we get from these two agencies: 45 degrees, 41 degrees, voluntary, mandatory.

Is it any wonder that we have this GAO report which questions whether these agencies are conducting a "seamless coordination"? I think it is pretty clear that there are some seams and they are pretty wide.

Let me talk about some other things that I think need to be talked about. Repackaging. The U.S. Department of Agriculture, after the "Dateline" story, came out—and I am glad they did—and said for the eggs that we grade there is a prohibition against taking old eggs off the shelf, bringing them back to the plant, packaging them with new eggs, for obvious reasons: Older eggs, more susceptible to contamination.

What percentage of the eggs sold in America are graded by the U.S. Department of Agriculture?

Ms. GLAVIN. I believe it is about 30 percent.

Senator DURBIN. Thirty percent. That is the figure that I have, too. So we now have a standard from the U.S. Department of Agriculture for about a third of the shell eggs that are sold in the United States, and virtually no standard, at least no Federal standard, no national standard, when it comes to all other eggs. Is that correct?

Ms. GLAVIN. That is correct.

Senator DURBIN. Another indication of why we need to start talking about a national standard. If it is dangerous to a consumer not to know that they are buying a dozen eggs that might have a variety of different ages, dangerous enough for the USDA to issue a standard, then certainly it raises a question about why this danger shouldn't be a matter of concern nationwide in terms of what we accomplish.

Let me also, if I can, visit for a second this question of APHIS, the Animal and Plant Health Inspection Service. They are involved in the inspection, if you will, of the actual farms where the eggs are being produced. Is that correct?

Ms. GLAVIN. They are responsible for something called the National Poultry Improvement Plan which has to do with the health of the laying flock, yes.

Senator DURBIN. OK.

Ms. GLAVIN. The breeding flock, I am sorry.

Senator DURBIN. The breeding flock. And you can test these chickens to determine whether or not they are contaminated with *Salmonella*. Is that correct? But there is no requirement that you test them under the law, is there?

Ms. GLAVIN. No.

Senator DURBIN. So this is all voluntary.

Ms. GLAVIN. Well, for——

Mr. MYERS. It is voluntary, but for interstate movement or international movement, that is required.

Senator DURBIN. So, again, eggs that are moving between States or that are going to be sold overseas, then we test the flocks; but if they are sold in the good old U.S. of A. within a State, no standard. Is that correct?

Ms. GLAVIN. Yes.

Senator DURBIN. How can that give the consumers any confidence? Do you think it does?

Ms. GLAVIN. I think that, as we have said this morning, it is necessary to look at a range of ways of addressing this problem, which is a very serious problem and which is not solved.

Senator DURBIN. Well, it is clear that it is not solved, and I think, frankly, that there are some things that we need to do.

How many people at the Food and Drug Administration work on egg safety?

Mr. POTTER. We can get you a firmer number. I don't know that. It is a little hard to calculate because there—because of the way we operate, it is not 100 percent of very many people's time, but it is a portion——

Senator DURBIN. How many people devote part of their day to the issue of egg safety in America at the Food and Drug Administration?

Mr. POTTER. I will have to get back to you with that because it involves our field staff, and I just don't know what those numbers are.

Senator DURBIN. What did the General Accounting Office find when it looked into how many people at the various agencies—U.S. Department of Agriculture and the Food and Drug Administration—were involved?

Mr. DYCKMAN. Well, we know that there are about 102 inspectors at FSIS.

Senator DURBIN. The U.S. Department of Agriculture?

Mr. DYCKMAN. The U.S. Department of Agriculture. When I asked our staff how many people at FDA, I believe they could remember one person that has an egg responsibility on a full-time basis.

Mr. SECRIST. Yes.

Mr. DYCKMAN. There were other people involved, but that is all we could identify.

Senator DURBIN. And this agency, the Food and Drug Administration, which you found one person to be working on a full-time basis, has a responsibility for so-called shell eggs, those eggs that have not been broken. What is the volume of shell eggs in the United States each year?

Mr. DYCKMAN. It is 70 percent of 67 billion.

Senator DURBIN. So it is in the 40 billion range?

Mr. DYCKMAN. It is up there.

Senator DURBIN. I think in our conversation you also indicated that most of the FDA response you found to be after the fact. If there had been evidence of some foodborne illness, there was an attempt by the FDA to trace its source?

Mr. DYCKMAN. Right. Their primary responsibility seems to be a trace-back responsibility, not a preventative type responsibility.

Senator DURBIN. That is a point which I think is very important here, and, Dr. Potter, I would like to give you a chance to respond to that as well. But every indication I have—first, let me say this: The Food and Drug Administration is one of my favorites. It is one of the most important agencies in the Federal Government. Dollar for dollar, we get more out of the FDA than virtually any agency, $1 billion a year we spend there, and we rely on them every time we turn around, for medical devices, pharmaceuticals, and a wide range of things. Such an important agency that we should pay more attention to it and devote more resources.

Having said all that, after I read this GAO report, I have to conclude that the FDA view of its responsibility on egg safety issues is almost non-existent. It comes in after the fact, after someone is sick, to try to figure out what happened. The incidence of inspection by the FDA once every 10 years suggests that this is an example that cries out for you to give it up, get out of the egg business. Let's give this to the FSIS and tell them we want it to be based on good public health science and try to put it under one roof. I just don't think the FDA has devoted the resources or attention to this issue that it should, and please respond.

Mr. POTTER. Thank you for your kind remarks about FDA. Regarding your criticisms, the first thing I would like to respond to is the one person working on eggs. Obviously, we have, as I said in my response, some portion of the work day of a large number of people who deal with eggs. We don't have the inspection force that USDA agencies have, and as the Chairman pointed out, very often we depend on collaborative arrangements with our partners in State agencies to do much of our inspection and field work.

We trace back eggs from outbreaks to laying houses for a number of reasons. One, obviously, is a reaction to the outbreak to remove dangerous eggs from the marketplace, but more importantly, perhaps, is on a prospective basis, those investigations, 112 laying houses, 6.7 million hens during the last couple of years, teach us about those critical factors that introduce and maintain *Salmonella* in those laying houses so that we can come up with the performance standards for critical control points and establish proactive prevention programs.

Senator DURBIN. I will ask one last question and turn it back over to the Chairman. We have not mentioned pasteurization of eggs, which I had to have people explain to me. I thought if you have to heat an egg, doesn't it cook the egg, and it is my understanding that there is a process that can pasteurize an egg and, therefore, reduce if not eliminate the possibility of SE contamination even for shell eggs. Is that correct, Doctor?

Mr. POTTER. That is correct.

Senator DURBIN. And let me ask you this: Has the Food and Drug Administration developed any performance standards for shell egg pasteurization to suggest this is the answer to protect American consumers and give them peace of mind?

Mr. POTTER. The Food and Drug Administration as early as 1990 recommended the use of pasteurized egg products, the broken-egg pasteurized products, in nursing homes and hospitals and for egg

dishes that would be made from pooled eggs. So we are very strong proponents of pasteurizing technologies, and we are in our approach to food safety attempting to make our guidance and regulations technology driving so that we encourage new technologies that will produce things like in-shell pasteurization.

One of the comments we got back early in this SE problem from nursing home food service managers was that people in nursing homes really look forward to their sunny-side up egg and we were taking that away from them by requiring them to use pasteurized egg products. And we think that it is a tremendous advance to be able to pasteurize eggs in the shell so that we are not taking that one sunny spot out of the day of people in nursing homes.

Senator DURBIN. Let me try again. I understand what you have said. I understand that pasteurizing the processed eggs and broken eggs is a good consumer safety move. But your responsibility at the FDA is for shell eggs, too, and now we have the technology to pasteurize shell eggs. The question I asked you was: Have you developed at the FDA a performance standard for shell egg pasteurization? The same question.

Mr. POTTER. OK.

Senator DURBIN. Yes or no?

Mr. POTTER. Let me ask Dr. Troxell to give you a direct answer.

Mr. TROXELL. Thank you. We have advised AMS on the appropriate performance standard for in-shell pasteurization, a five-log reduction to use in their seal program they are developing. Also, this technology, while it is very promising, is still being pilot-tested, and the feasibility on implementing this technology on a national basis is still a question that we are very interested in pursuing.

Senator DURBIN. How many years have you been field testing?

Mr. TROXELL. We have not been field testing this technology. Several companies have been field testing the technology. Some of the systems have been rather crude in form. Others are now developing specific engineered systems to run this kind of in-shell pasteurization.

As you pointed out, it is very easy to cook the egg, so one has to be very careful on the appropriate temperature.

Senator DURBIN. I am going to leave this area——

Senator VOINOVICH. For the record, would you please give me your name and the title you have?

Mr. TROXELL. I am Dr. Terry Troxell, the Director of the Office of Plant and Dairy Foods and Beverages at the FDA.

Senator VOINOVICH. Senator Durbin, we better——

Senator DURBIN. I am going to conclude. The last thing I will tell you is that in 1994, 5 years ago, the FDA set a standard for pasteurization of shell eggs, having learned that a commercial-scale pasteurization technology had been developed which inexpensively processed eggs without noticeably altering aesthetics or functionality.

This is something consumers would like to know about, and they would like to have the protection of pasteurization. I don't know what the FDA is waiting for here. I really think that this is another example where, for some reason, much like the temperature question, things have gone on for years and years and years, and

people have become sick, some have died, waiting for the Federal Government to meet its responsibility.

Thank you, Mr. Chairman.

Senator VOINOVICH. Thank you.

I would like to finish up with one question for all of you. We have seen a reduction in the number of SE cases, so obviously something is being done.

For the record, where is most of the problem in terms of this? Is it on the farm? Is it in the processing and shipping? Or is it mostly generated in the institutions that use the eggs? For example, how many of these cases come up when we use eggs in a family? Is most of the problem in institutions?

Mr. POTTER. About half of outbreaks are related to institution—excuse me, to commercial food service, which would include restaurants, schools, and hospitals.

Senator VOINOVICH. So half the problem is in the place where the eggs end up?

Mr. POTTER. Well, what the joint risk assessment showed us is that there are critical factors at each step in the chain, and there are opportunities for intervention at every step in the chain. I think that most of our early attempts have been focused on the laying house during egg production and at the kitchen because those are the two areas that we felt we could address first.

Senator VOINOVICH. And you think that those two areas are where you have made the most inroads rather than the people that are at the institutions?

Mr. POTTER. Well, again, institutional food service, the kitchens there have been a major focus. The agency has collaborated on training videos for nursing home food service directors and medical directors who are getting ready to go out to nursing directors and food service directors with additional advisories for about 12,000 nursing homes, 80,000 day-care centers, 60,000 elementary schools, to get this information in the hands of not only those institutions, but in the hands of parents of young children, too, to hit at both ends of the age spectrum.

Senator VOINOVICH. Thank you. We will now move on to our next panel.

Senator VOINOVICH. I would like to ask the second panel to come forward. It is composed of experts on the issue of egg safety and representatives of the egg industry.

Michael Jacobson, a Ph.D., is the Executive Director of the Center for Science in the Public Interest.

Ms. Jill Snowdon, Ph.D., is the Director of Food Safety Programs at the Egg Nutrition Center.

Keith Mussman, co-owner of Mussman's Back Acres, is from Illinois, and is appearing on behalf of the United Egg Producers.

And Harold "Butch" DeVries, Executive Vice President and General Manager of Mallquist Butter and Egg Company, is also from Illinois.

We would like to thank all of the witnesses for coming this morning.

I again want to reiterate that your statements will be entered into the record. We would appreciate your limiting your testimony to no more than 5 minutes, and because we are running out of

time, I am going to be pretty fastidious about sticking to that 5-minute rule.

Senator Durbin, would you like an opportunity to introduce the witnesses from your State?

Senator DURBIN. Just very briefly, I am happy to have two witnesses with Illinois connections.

Harold DeVries of Rockford, Illinois, married with two children and three grandchildren. His business started in 1930, and he came to work at Mallquist in his senior year in high school in 1955, 44 years ago. The business has nearly half a million chickens, produces and processes 11,000 cases of eggs a week for the Chicagoland area.

Keith Mussman, from Back Acres, Inc., a family farm corporation with 1,200 grain farm and 240,000 laying hens. They produce, process, and distribute eggs in Illinois and Indiana. He was born and raised in Grant Park, which is in northeast Kankakee County, and lives there with his wife Barbara and three kids.

Thanks for being here. Thank you all.

Mr. JACOBSON. I have to confess I am also from your great State of Illinois.

Senator DURBIN. We are everywhere.

Senator VOINOVICH. Now I know why he wanted to have this hearing. [Laughter.]

We have heard from the Federal agencies. This is interesting. Now we are going to be hearing from the people that are actually producing the eggs and also the public interests who are interested in protecting the citizens. We really appreciate your being here.

We are going to start off with Dr. Jacobson, who is the Executive Director of the Center for Science in the Public Interest. Dr. Jacobson, we would like to hear from you.

TESTIMONY OF MICHAEL F. JACOBSON, PH.D.,[1] EXECUTIVE DIRECTOR, CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Mr. JACOBSON. Thank you very much, Senator.

CSPI is a non-profit consumer-advocacy organization that focuses on nutrition, food safety, and alcohol issues, and is supported by our 1 million members, including thousands in both Illinois and Ohio. Accompanying me today is Caroline Smith DeWaal, our Director of Food Safety, sitting behind me.

Most consumers think that government watchdogs are ensuring that their food is safe. But any watchdogs that there were, were asleep while eggs contaminated with *Salmonella* grew into a national public health epidemic. Twenty or so years ago, a strain of *Salmonella* called *enteritidis* developed the ability to infect a chicken's ovaries and enter an egg before it is laid. The advent of that enterprising strain of bacterium means that it is no longer safe to eat runny eggs, taste cookie dough, or enjoy raw eggs in desserts and salads.

Today, infected chickens lay an estimated 2.3 million contaminated eggs each year, any one of which could cause an illness or an outbreak of food poisoning. Since 1990, eggs have been directly

[1] The prepared statement of Mr. Jacobson with an attachment entitled "Scrambled Eggs," appears in the Appendix on page 80.

linked to at least 123 separate outbreaks of food poisoning, mostly from SE. CDC has reported that since 1985 there have been nearly 800 SE outbreaks largely associated with eggs and egg dishes.

A recent risk assessment on eggs conducted by USDA said that SE-contaminated eggs have caused an average of 660,000 illnesses and 330 deaths annually. While the CDC data from a few areas around the country suggest that the number of illnesses has declined, many more illnesses could be prevented with mandatory national programs.

Some people say that the consumer should be the only critical control point. We say that consumers should be able to expect that eggs are safe.

In 1986, CDC first identified SE in eggs as a public health problem when there was a food poisoning outbreak that sickened more than 3,000 people. Since then, unfortunately, no government agency has mounted an intelligent, comprehensive counter-attack on SE. There is no government-mandated SE testing program for eggs or laying flocks, no mandatory expiration date for shell eggs, no ban on repacking and re-dating old eggs, no mandatory refrigeration of eggs throughout the distribution chain, and no label on egg cartons to alert consumers. The government has simply failed to take the necessary steps. Instead, the production of safe eggs has been stymied by overlapping responsibilities between FDA and USDA, irrational assignment of inspectors, and two agencies developing duplicative and competing SE control programs.

Eggs provide one of the best illustrations of the need for a centralized Federal framework for food safety as proposed by Senator Durbin last week in the Safe Food Act.

In 1997, in an effort to jump-start government efforts, CSPI petitioned the FDA to develop a mandatory on-farm control program for eggs modeled after an effective State program. CSPI also petitioned FDA to require a label on egg cartons alerting consumers to the risks and advising them to cook eggs thoroughly. There has been little visible action since CSPI petitioned the FDA, but we hope that this *Federal Register* announcement—that we haven't seen yet—will pave the way for action in the foreseeable future.

The actions that the agency has mentioned today are important but not sufficient. In a critical omission, FDA and USDA have failed to utilize the single most effective public health measure, and that is on-farm SE monitoring and control. Though temperature controls and labeling help prevent illnesses from contaminated eggs, on-farm programs like HACCP would help prevent eggs from being contaminated in the first place.

Under an on-farm program, manure and eggs would be tested for SE, and eggs from flocks that test positive would be diverted to pasteurization plants where they would be rendered harmless.

Programs like that appear to be working in some States. We need such programs mandated as soon as possible throughout the country.

Thank you very much for your attention to this important public health problem.

Senator VOINOVICH. Thank you very much, Dr. Jacobson.

We will now call on Jill Snowdon, Director of Food Safety Programs, Egg Nutrition Center.

TESTIMONY OF JILL A. SNOWDON, PH.D.,[1] DIRECTOR OF FOOD SAFETY PROGRAMS, EGG NUTRITION CENTER

Ms. SNOWDON. Thank you very much. I serve as the Director of Food Safety Programs at the Egg Nutrition Center, which is a scientific and technical resource on nutrition and food safety of eggs and is a joint effort between the American Egg Board and the United Egg Producers.

The pursuit of egg safety should be considered a success story. The disease incidence of salmonellosis caused by *Salmonella enteritidis*, which we know as SE, has been on the decline in the United States. Multiple lines of evidence—taken from data collected over the last 3 to 8 years, from both national and regional levels, including both sporadic cases and outbreaks—show the same downward trend.

SE outbreaks from both egg and non-egg sources have decreased from a high of 82 outbreaks in 1990 to 45 in 1998. Both the number of outbreaks and the number of people ill in the outbreak have decreased.

The incidence of this disease is also recorded in CDC's *Salmonella* surveillance system and records a decline in salmonellosis caused by SE on a regional basis. This is also reflected in data from States such as California and Pennsylvania. They, on their recording basis, are also showing a decline.

But perhaps the most compelling line of evidence for the decline is from CDC's FoodNet program which reports a 44 percent decline in salmonellosis caused by SE over the last 3 years. FoodNet data indicate 1.4 million cases of salmonellosis in the United States in 1997. Fifteen percent of the reported cases were caused by SE. One could estimate on these numbers than that there were 210,000 cases of salmonellosis caused by SE in the United States in 1997.

These cases can result from a number of food and non-food sources, including eggs. There are a few other indicators of this decline, and they are included in my written testimony.

It should be pointed out that illness from SE is only a fraction of all cases of salmonellosis and that eggs account for only a portion of all of those reported cases.

There are a number of characteristics which make eggs unique, and the unique qualities of eggs should be—the biological and physical unique qualities of eggs need to be taken into consideration if we are developing effective intervention strategies. SE is associated with the infection of an internal organ. This is in contrast to all other foodborne microorganisms which are typically associated with feces and dust. This may dictate the type of control mechanisms that then become most effective.

The egg, intended to be new life, has multiple properties that deter or destroy microorganisms. These properties are listed in the written testimony. I am going to concentrate on just one—that of the yolk membrane. If the yolk membrane is intact, SE will not grow because of an absence of nutrients. So the integrity of the yolk membrane is determined by time and temperature.

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[1] The prepared statement of Ms. Snowdon with attachments appears in the Appendix on page 122.

Data from the United Kingdom indicate that SE will not grow in eggs for about 28 days if they have been stored at 60 degrees Fahrenheit or less.

However, the security of the intact egg vanishes once that egg is broken and its contents are mixed together. Once the natural antimicrobial properties are destroyed, the liquid egg has to be pasteurized, cooked thoroughly, or held chilled to ensure that microorganisms do not grow. Proper care of pooled eggs may be the most critical control point in the spectrum of egg safety.

Senator Durbin, if I can make a small but important addition to your observation about the outbreak in Virginia, when I spoke with the investigator in charge of that outbreak investigation, he indicated that they closed the restaurant down as soon as they walked in because the food preparation practices were so abysmal. In that conversation with him, he indicated that they were using bare hands to handle sausage and bacon, and then those same bare hands were dipping toast into the egg batter mix. So the production of safe food needs to be accompanied by the safe preparation of food.

The industry supports food service education. As an example, I would like to include this book, which is the American Egg Board's food service recommendations for eggs, as part of the record, please.[1]

To move food safety from production to preparation is part of the goal of protecting the food supply.

The egg industry became aware of this problem, identified ways to combat it, and implemented actions. Now disease rates are dropping, and the egg industry is continuing to look for additional techniques to combat SE.

I have appended a list of industry activities to the testimony and will only mention participation and quality assurance programs in my verbal testimony.

Participation in industry-generated quality assurance programs continues to increase. All quality assurance programs in the egg industry have been based on the principles of Hazard Analysis Critical Control Points, which is the best technique to protect the food supply. In a survey of large producers in the United States, 93 percent were producing eggs under the guidelines of a quality assurance program. In a survey of the top six egg-producing States, it was estimated that between 85 to 95 percent of the eggs in those States were produced under a quality assurance program. Microbiological analysis of manure samples from laying houses detects *Salmonella enteritidis* about 3 percent of the time or less, further evidence that the presence of SE in laying houses is the exception, not the norm.

In addition to diverting eggs as part of quality assurance programs, the organism is controlled by a variety of means and mechanisms dictated by a HACCP program.

In summary, I would say that the pursuit of egg safety should be considered a success story. The public health community discovered the problem and placed much of the responsibility upon egg

[1] "The Incredible Edible Egg, A Natural For Any Foodservice Operation," appears in the Appendix on page 151.

producers. After years of effort—including extensive scientific research, debate, controversy, education, and changes in production and food preparation practices—the trend in disease incidence is downward.

The egg industry has contributed substantively to this success. The recent decline in both outbreaks and sporadic cases has occurred in geographic areas where control measures have been most intense.

But even though the fruit of man labors are beginning to ripen, there is still more work that needs to be done. The egg industry remains committed to continuing to take the steps that continue to make the rates drop.

Thank you for inviting us to be part of this hearing and to be part of the process to ensure a safe food supply. Eggs are a nourishing, appealing, economical food that can continue to be enjoyed with assurance.

Senator VOINOVICH. Thank you, Dr. Snowdon.

Our next witness is Keith Mussman, co-owner, Mussman's Back Acres, representing the United Egg Producers.

TESTIMONY OF KEITH MUSSMAN,[1] CO-OWNER, MUSSMAN'S BACK ACRES, ON BEHALF OF THE UNITED EGG PRODUCERS

Mr. MUSSMAN. Mr. Chairman, and Senator Durbin, thank you for this opportunity to be here today. I believe it is an opportunity of a lifetime. And if I may add an aside, Senator Durbin, as a resident of Illinois, I am proud to be one of your constituents.

Senator DURBIN. Thank you.

Mr. MUSSMAN. Good morning. My name is Keith Mussman, and I am a farmer producing eggs in Illinois. I have been in this business all of my life, having followed in the footsteps of my father who produced eggs and sold them in the Chicago area almost 50 years ago. I am testifying today on behalf of my industry organization, United Egg Producers, a national cooperative representing the interests of nearly 80 percent of all egg production nationwide.

The egg industry considers food safety of paramount importance and is committed to enhancing the safety of shell eggs and egg products as is evidenced by the number of voluntary programs it has undertaken. For example, the egg industry through UEP has developed a national five-star quality assurance program. UEP has sponsored HACCP training workshops, published egg handling and preparation guidelines for food service employees and consumers, and supported FDA in determining that eggs, like other protein-rich foods, should be classified "potentially hazardous."

Data were collected in a recent survey from 41 egg producers with 1 million or more laying hens and representing a total 125 million layers, which is approximately 50 percent of the Nation's total. Of those responding, 93 percent reported to be participating in one of the industry's egg quality assurance programs.

The egg industry has initiated and implemented voluntary programs in response to every concern raised about food safety, while providing a wholesome food at a price comparable to or now even

[1] The prepared statement of Mr. Mussman appears in the Appendix on page 169.

less than it was at the time my father was marketing eggs in Chicago 50 years ago.

In 1998, FoodNet reported a 44 percent decline in Salmonellosis attributed to SE during the past 3 years. Likewise, the record on outbreaks—where two or more people became ill—shows a decline in illness that began in 1990.

The Egg Products Inspection Act of 1970 provides uniform standards of quality, grade, condition, weight, and labeling for shell eggs in interstate commerce.

Eggs which fail to meet grading standards are either diverted to the breaking market for pasteurization or deemed inedible for humans and processed for other uses such as pet foods.

Shell eggs are cleaned in wash water of approximately 110 degrees Fahrenheit, or 20 degrees higher than the egg temperature. A sanitizing solution is used in the washing process to enhance cleaning.

Soon after processing, eggs are packaged and stored at 45 degrees Fahrenheit.

Most of the SE outbreaks associated with food have been a result of improper food handling and preparation. Holding raw egg batters at room temperature for extended times, using containers that go unwashed between uses, inadequate cooking, and inadequate cooling of leftovers have all contributed to foodborne outbreaks.

It is a fact that a zero-risk or a sterile food supply is impossible.

It is important that accurate information is communicated about risk and that sound food service educational information is provided to consumers, and particularly to the food service sector, so that everyone is well educated in safe food handling and understands their responsibilities for ensuring food safety.

Just as there is no single control method that will eliminate all pathogens and toxins from the food chain, there is no single method for providing a 100 percent guarantee that foods will be free of pathogens.

For the most part, the different agencies the producers and processors must deal with are doing a difficult job well. We as producers do not always agree with the actions taken by these agencies, of course, and when we disagree with them, we have not been shy about saying so.

We have not had the GAO report long enough to study it in great detail. However, we are not convinced that the structure of our food safety agencies is the problem. They have different roles and different areas of expertise. To us, the real issue is what our public policy should be, not who implements them.

Under the present system, we have already witnessed a significant decline in the number of cases of Salmonellosis since 1996. Coordination among agencies currently provides checks and balances.

Congress, of course, should insist that this coordination be cooperative rather than competitive. Everyone's goal must be protecting food, not turf.

I want to finish up with a few brief comments about the GAO report. I just got it yesterday, so I haven't had time to study it thoroughly. But I have looked at the recommendations GAO makes to the agencies.

First, GAO recommends that FDA develop a model HACCP-based program for egg operations that could be adopted by the States. Our industry is implementing HACCP-type programs and is receptive to this recommendation. However, we would want to review any FDA proposals.

Second, GAO recommends HACCP for egg-breaking plants. Generally, our processor members are supportive of HACCP regulation, and many have HACCP plans in place already. FSIS has said it intends to propose exactly this kind of system.

Third, GAO recommends study of the costs and benefits of implementing rapid cooling techniques in egg processing and packing operations. We agree that research is a good idea, and, in fact, quite a bit has been done. However, commercial applications are still a ways off. The increased cost would be a concern, and as I understand it, the consumer would not benefit from a health standpoint.

I do wish GAO had given the agencies a little more credit for working together in recent years, and I wish the positive steps our industry has taken had been highlighted more. We have not been followers. We have been leaders. I am proud of my business and of my industry for promoting a safe food supply. Thank you.

Senator VOINOVICH. Thank you, Mr. Mussman.

Our next witness is Harold "Butch" DeVries, Executive Vice President and General Manager of Mallquist Butter and Egg Company. Mr. DeVries.

TESTIMONY OF HAROLD "BUTCH" DEVRIES, JR.,[1] VICE PRESIDENT AND GENERAL MANAGER, MALLQUIST BUTTER AND EGG COMPANY

Mr. DEVRIES. Thank you, Mr. Chairman, Senator Durbin. Good morning. My name is Harold DeVries, and I am Vice President and principal stockholder at Mallquist Butter and Egg Company in Rockford. My company is a small agricultural business packaging about 4 million eggs per week from its one-half million laying chickens. We also distribute liquid and frozen eggs. I am here today at the request of Senator Durbin's office.

Food safety is very important to me personally, to my company, and to my industry. The reputation of my company is dependent upon quality, and we operate quality assurance programs to ensure a safe food supply. Mallquist Butter and Egg Company has instituted procedures to identify those critical control points from the farm through distribution for monitoring quality assurance, including cleaning and disinfecting the poultry house, rodent and pest control, proper egg washing, biosecurity, and refrigeration.

Today I want to share some information about food safety action in the State of Illinois, discuss a task force that was established by the Department of Agriculture and Public Health to analyze food safety issues, and to recommend actions to resolve public concerns. As a producer, I had the honor of serving on that task force.

During 1998, local health departments in Illinois investigated almost 1,200 complaints about food and illness. Microorganisms that caused the foodborne outbreaks could only be determined in one-

[1] The prepared statement of Mr. DeVries appears in the Appendix on page 180.

third of the incidents; two-thirds of the outbreaks occurred because of unknown causes.

While the causes and effects of foodborne diseases are better understood today, emerging risks need to be monitored. For example, consumers are changing; increasing numbers of elderly and others are at higher risk of severe illness; consumers spend less time cooking than ever before and may have received less instruction on food handling at home or school.

Where the rubber meets the road is at the local level. More than 90 Illinois local health departments and 135 municipalities provide food safety functions at the community level through inspections of restaurants, schools, caterers, and food stores for adherence to food safety requirements. They promote safe food-handling behaviors through educational efforts with school children, the general public, and the retail food industry.

The HACCP system is widely accepted by the scientific community as the best known approach to enhancing the safety of foods. If HACCP systems are fully implemented, the effectiveness of the food safety system can be enhanced significantly, but absolute safety of potentially hazardous foods cannot be assured.

The first recommendation from the task force is to broaden coordination and cooperation between the Illinois agencies with the respective Federal and local counterparts so that food safety programs are consistent and uniform.

The second recommendation is for the development of a mechanism to ensure that regulated industries, government agencies, and the general public have a formal venue to advise the Departments of Agriculture and Public Health on issues of mutual concern relative to the food supply.

The task force also recognizes the value of the Federal Government's FoodNet. In the last 3 years, as reported by FoodNet, the incidence of Salmonellosis associated with SE has decreased 44 percent. This is great news for the egg industry and the public. It suggests that efforts by the industry are having an effect.

The egg industry has demonstrated responsiveness and cooperation with Federal, State, and local agencies in addressing the safety of shell eggs and egg products. A large number of agencies are involved in food safety. However, the expertise from these agencies addresses the issue of food safety from different and complementary perspectives. The egg industry has developed numerous programs and activities designed to enhance food safety and to educate the channel from farm to table in the proper production, transportation, processing, handling, and preparation of its products.

Education and training can be one of the least costly yet most effective means to protect consumers from foodborne illness. Increasing individual awareness of food safety matters all through the food chain and motivating customers to adopt simple, yet important sanitation and food-handling behaviors is effective in improving food safety. Thank you.

Senator VOINOVICH. Thank you, Mr. DeVries.

I am pleased to hear that the industry is doing what it can to improve food safety, and I think it is logical that you would do that. You are in the business and you want people to buy your product, and if everyone thinks it is not safe, they are not going

to buy eggs. So I am sure that you are trying to do your very best in your own operation to make sure it is as clean as possible because if it is not, it affects your business.

I also would like to compliment the State of Illinois for looking at the local contribution to improve the situation. We were talking earlier when you were gone, Senator Durbin, that the States do have a role, the Federal people said that there is a definite role for States, and that they couldn't handle it without State involvement. I think that more activity in the area of best practices should be shared throughout the country to guarantee that things are going well on the farm and also that better food safety and preparation is being practiced.

From your perspective, is the real problem in the food handling and preparation rather than on the farm? And we have talked about a reduction of some 40 percent. Where did the reduction take place, as a result of what? Does anyone want to comment on that?

Mr. MUSSMAN. I will jump in on that one. I think the reduction has come because of a better awareness both on the farm and in food handling on how to better handle eggs to make them safer. One statistic that has leapt out at me continually is science has pretty much stated that perhaps one out of 20,000 eggs is contaminated with SE. If you extrapolate that for the number of eggs a person eats, 240 or 250 eggs a year, your chances of being exposed to a *Salmonella*-infected egg would be once in 84 years.

Now, I realize if your wife is the one that got it, that is very important to you. But just keeping those statistics in mind, the risk is really minute.

In answer to your original question, because those numbers are so minute, it is believed that most of the problems are at the food-handling end of the situation, as Dr. Snowdon mentioned on that other outbreak. Just plain mishandling of food.

Ms. SNOWDON. The industry recognizes it has a responsibility to produce the best and safest product it can, and it has been taking the kinds of steps to do that. So I think that certainly is one of the reasons that we have seen the decline, the concerted effort at the production level to ensure that the organism doesn't move into the hens to begin with, if it moves into the hen that it doesn't make it into the egg, if it makes it into the egg that it doesn't make it into the marketplace. So that is definitely a part of it, and industry is aware of that responsibility and fulfills that responsibility.

I think the contrast that Mr. Mussman just pointed out is one that has also struck me from the viewpoint, and my point that once that shell is broken, that you have a phenomenal opportunity for growth and spread both. And so that no matter how clean the product an industry produces, it has got to be accompanied by appropriate food-handling practices.

I think that we are seeing an increase in that, the FightBac campaign that we have at the national level, other national level educational programs the industry has put together in terms of appropriate food-handling practices. So I think that we are starting to work the entire spectrum, and I think that the benefits that now we are getting in the last couple of years are a result of working that entire spectrum.

Senator VOINOVICH. Dr. Jacobson.

Mr. JACOBSON. I think the egg industry does deserve praise for the actions that it has been taking. It is great to hear of these individual reports from particular operations. But it has been a long time coming. And as Senator Durbin emphasized, government regulation has been a long time coming. Taking 8 years to get out a rule on temperature is too long.

Despite the regulations, the voluntary industry practices, I don't see handling labels on eggs warning somebody of a problem, saying cook it thoroughly. I haven't heard the egg industry voluntarily banning the practice of repacking. And I don't think the egg industry can do it because it is a diverse industry, not every company is part of the United Egg Producers. It is simply voluntary.

The GAO report says the States have a patchwork of programs, presumably some better than others. But if the industry is doing as good a job as it is presenting, I don't see why it wouldn't mind having a mandatory Federal floor, a mandatory HACCP program dictated with parameters set by the FDA and USDA, so that would be the floor, and if some companies want to do better, fine. But at least have that mandatory floor so we are not waiting for voluntary industry action. And as we see in so many areas, voluntary action can be temporary action. It can be crisis-driven. We see it today, but if the pressure is off, things can go back to the old ways.

That is why we would like to see some mandatory rules for mandatory Federal rules so that flocks are inspected for SE, and if a contaminated flock is discovered, eggs would be diverted to that pasteurization stream—not thrown out.

I don't see why the egg industry would object to having a sensible program. This current system, as described by the GAO, is crazy. It goes from, at the upper left of the chart, USDA to FDA, then down to USDA, then back to FDA, then to either one of them, depending where it is. That is a crazy system. It needs to be rationalized. And it is especially dramatic when you have those 102 USDA inspectors inspecting pasteurized eggs that are the safest ones you can get. And FDA every 10 years inspecting fresh shell eggs. That doesn't make sense. And, of course, that is driven partly by the budgetary process where FDA money is FDA's, and USDA money is USDA's, and they can't mix. If you had a single food safety agency, as Senator Durbin and several other Senators and the GAO have recommended, I think we could have a more sensible and possibly even a more economical approach, and certainly we could get a timelier response to food safety problems.

Senator VOINOVICH. Thank you. I pointed out earlier that each of the Federal agencies, under the Results Act, are supposed to be putting together performance standards and goals for their respective agencies. One of them requires coordination, and I would be interested to find out from the Department of Agriculture and from Health and Human Services just how much they have sat down with each other to talk about how they coordinate their activities and to identify holes that are there and how to respond to them, as you just pointed out in your testimony.

Mr. JACOBSON. I think for the country, though, it doesn't make sense to be stuck with a jerry-rigged system, not just for eggs but food safety in general, where the Commerce Department does fish, and the Treasury Department cares about alcoholic-beverage safe-

ty. It doesn't know anything about health. It doesn't make sense, and there shouldn't have to be this complicated web of probably temporary jerry-rigged collaborative efforts when you could have one sensible and really seamless system for helping ensure the public safety.

Senator VOINOVICH. Would anyone like to comment on that?

Mr. DEVRIES. I would just like to make a comment and clear up a few things that you talked about earlier about the age of eggs before they were packaged and dating and those types of things. We are an off-line operation, so the eggs don't go into the egg washer and grader immediately, but within 2 days they are always packaged. And from that point on, there is a 30-day expiration date put on the eggs. In the State of Illinois, we have been doing that now for, I think, over 25 years.

You talked about refrigeration. We have been refrigerating eggs in Illinois since I became employed there at 60 degrees, and when this was brought up in 1991 about the 45-degree temperature, we then instituted that also, and we have been carrying that out.

So, from our standpoint, the State of Illinois has a great egg inspection program that followed through with the Department of Agriculture and the Health Department.

Senator VOINOVICH. Mr. Mussman.

Mr. MUSSMAN. I concur.

Senator VOINOVICH. Do any of you think that we need to have improved regulation on the Federal level in terms of your industry? You start smiling at that question. But have you, as an organization, made recommendations to any of the Federal agencies involved on how they could improve their operations?

Mr. MUSSMAN. I think one of our concerns has been the cooperation between the agencies, but we sincerely feel that that is a management problem. It is not a problem having it in the different organizations. It is just there are organizations themselves sorting out who is going to be in control.

United Egg Producers has taken a position for 21-day expiration dates. Even though there is no law prohibiting repacking of eggs, UEP's position for years has been to not do it. Obviously, there are some renegades out there that will. I think not just the egg industry, but other industries are the same way. You have got some guys that don't play by the rules.

We feel sincerely that we have been leaders in the food safety issue, and we have had tremendous cooperation with FDA, USDA, and FSIS on the issue. Speaking from—I am going to take off my egg producer hat and put on my taxpayer hat right now. I told my father I was coming out here and explained the reason, and he said, "They are just going to add another layer of bureaucracy." From the grass-roots issue, that is a tremendous concern. Government never gets smaller. You can take all these things away from the other departments and create—I don't care what you call it. It is going to add costs to the government, and we sincerely believe that it is not going to make food safer.

Senator VOINOVICH. Well, I appreciate your comments. I know that has been one of the things that you hear from folks about a new agency, that it becomes kind of a large burgeoning agency that makes it more difficult for people to get answers. But you don't

have any complaints that you have FDA, then you have USDA, and then you have the State agencies all visiting your places? No complaints from your people about the multiplicity of agencies that are regulating your operations? This makes sense?

Mr. DEVRIES. From my standpoint, we are inspected on a quarterly basis by USDA. Of course, our State of Illinois Department of Agriculture is in there quite often. They are always in there on an unannounced basis all the time. The local health department shows up also. We have no problems with any of those things. We work with them. We are happy to work with all of them.

One of the other issues that was brought up is we do have on our egg cartons "keep refrigerated." We do have safe cooking and handling labels inside the egg cartons also. And we do no repacking of eggs, never have done, never will do. There is no reason for that. Those eggs just belong to the breakers for further processing.

So from our standpoint, we really have no problems.

Senator VOINOVICH. Thank you very much. I am out of time, and I will turn it over to Senator Durbin.

Senator DURBIN. Thank you very much, Mr. Chairman.

Mr. DeVries, let me follow up on that because I think you are giving us valuable testimony about the real world out there. You said that you just don't repackage eggs. That has been a standard at your business for a long time, has it been?

Mr. DEVRIES. That is correct.

Senator DURBIN. And, Mr. Mussman, is it the same standard at yours?

Mr. MUSSMAN. Same standard. Everything goes either in restricted eggs and if it is broken, it goes in a barrel. If it is cracked, it goes to restricted for further processing.

Senator DURBIN. How did you happen to adopt that standard? Is that something that just made common sense to you, or did you have a bad experience?

Mr. MUSSMAN. In our particular instance—I heard him talking before—we are not a USDA-inspected plant. We fall in that 70 percent. We were a small business, but it has grown over the years. We were never required to so we haven't. But there is one thing that goes on our label that takes precedence over any USDA label, and that is Mussman's Back Acres. So it was common sense. We can't afford to put a product out there that may come back and bite us.

I know there are a lot of other egg producers in the same boat. It is not worth the risk.

Senator DURBIN. But let me just ask you this question: If we had a problem in Illinois with eggs, wouldn't it really be to your benefit if everyone is held to kind of a basic standard so that the bad actors don't get off the hook? You are two responsible egg producers and packagers. What I am driving at is this: You take pride in your label. Both of you do. But if we had an egg problem, people would perhaps stop buying your product for a while, too, uncertain as to whether or not you were the good guys or the bad guys.

When we establish a standard where consumers have some confidence, doesn't that help all egg producers?

Mr. DEVRIES. I would say yes to that effect. Absolutely it would help all egg producers. Just like when we had the scare with the

cholesterol things years ago, we saw our business go down. Now we got rid of that, and our business—the number of eggs eaten by consumers has gone up each year. We have seen things come down even though we are eating more eggs. It would be great to have everybody play by the same rules.

Senator DURBIN. Well, Mr. Mussman, let me ask you a question. Mr. DeVries talked about the fact that it is about 2 days between the laying of eggs and the packaging. Is that your experience as well?

Mr. MUSSMAN. Our operation happens to be in-line. We process 7 days a week, and the eggs come directly from the birds and they go right into the carton.

Senator DURBIN. So that is hours?

Mr. MUSSMAN. They are 5 hours old when they get to the cartons.

Senator DURBIN. And that, again, is a standard which you have put into your business place, is it not? It is not mandated by anyone, is it?

Mr. MUSSMAN. That decision was based somewhat on economics rather than just for a pure freshness situation. It just worked out for us to do it that way.

Senator DURBIN. But there is no regulation or law along that line?

Mr. MUSSMAN. No.

Senator DURBIN. Now, our State of Illinois is one of the 17 States, incidentally, in the Nation which requires a labeling on the egg cartons of an expiration date or a sell-by date, and we have sell by 30 days. But you mentioned 21 days as being a standard. Is that the UEP?

Mr. MUSSMAN. That number has been bandied around, and UEP has gone on record with a position that they would support 21 days if that was to come into effect.

Senator DURBIN. And that basically—does it start from the belief that the older the egg, the less likely it is going to taste good and it might even be less safe as it gets older?

Mr. MUSSMAN. That, and it doesn't appear as well on the plate. There are a number of reasons. But safety is certainly one of them.

Senator DURBIN. So it goes back to my earlier point. If I am traveling around the country and I am buying eggs in a restaurant here, there, or any other place, if there is a standard, a reasonable standard which your industry says helps us all, all egg producers—it strikes me that that helps you because you are playing by good rules, rules that you have assumed for your own business to make sure that when you put your name on a carton you feel proud. Is that not correct?

Mr. MUSSMAN. That is totally correct, and we would dream that everyone would play by the same rules. But what it still ultimately comes down to is, if I produce an egg that is 5 hours old when I put it in the carton and I deliver it tomorrow to the local restaurant, and they break it in a bucket and leave it sit out at room temperature for 13 hours, then it becomes a food-handling problem.

Senator DURBIN. And that is a good point, and I want to go back to Dr. Snowdon's point about the restaurant in Richmond, Virginia. I have not identified the chain, but I am going to now. It is IHOP.

And let me tell you what the Vice President for Operations for the Eastern United States, John Jordan, said in the Richmond newspaper of June 12, 1999. He said he was aware that the egg wash the restaurant used to prepare French toast had received a positive reading for *Salmonella* bacteria. He went on to say—in an effort to prevent further problems, Jordan said the restaurant will now be using processed and pasteurized eggs for its French toast batter rather than eggs in the shell.

For the record, I do not disagree with the premise that safe food handling is an important element in this. But in this situation, for whatever reason, there was a contaminated egg mixture which Mr. Jordan has acknowledged was part of the problem and said that they were going to steps to deal with it.

Can we stay for a moment on this question of pasteurization, which was this restaurant's chain response? Do you pasteurize shell eggs in your operation, Mr. DeVries?

Mr. DEVRIES. No, we don't.

Senator DURBIN. Mr. Mussman, do you?

Mr. MUSSMAN. No.

Senator DURBIN. How common is that in your experience in the State of Illinois? How many egg producers actually pasteurize shell eggs?

Mr. DEVRIES. I believe it may only be one or two people in the whole country, and it has just been——

Senator DURBIN. Just starting out?

Mr. MUSSMAN. It is the new technology.

Senator DURBIN. New technology.

Mr. DEVRIES. The thing about using the pasteurized eggs at the restaurants, too, that is not going to stop an illness if those aren't handled properly.

Senator DURBIN. Proper handling is part of the deal.

Mr. DEVRIES. The whole thing.

Senator DURBIN. Absolutely. Now, how about the management? How about the testing of your breeding flock? Are they tested for *Salmonella*? Has that happened, Mr. Mussman?

Mr. MUSSMAN. We buy 18-week-old pullets, so we have nothing to do with the breeding business. But we are assured that our breeding flocks are tested from the chickens that we get.

Senator DURBIN. OK. The same thing from Mr. DeVries?

Mr. DEVRIES. We grow our own birds, so we buy our birds a day old. And we have an SE testing program all the way through.

Senator DURBIN. You are the good guys here. I am really glad you are here, and I am glad you are from Illinois. That makes my job a little easier, Mr. Chairman, in regard to that.

I want to say to you, Mr. Mussman, if I thought that what we are about here, what I am about here is adding another layer of bureaucracy, I couldn't look you in the eye. What I am trying to do is to eliminate a few layers of bureaucracy. As you heard, this ball is being handed off from agency to agency, and we really think if it is put under one roof that really the buck is going to stop at some agency that really coordinates the efforts here and makes the product a little safer and the cost a little cheaper for taxpayers. And if it doesn't achieve that, it is going nowhere in Washington, D.C., and I certainly am not going to push for it. So you can tell

your father and friends that that is something we are going to try to work on.

Let me, if I can for a minute, talk about FoodNet, and, Dr. Jacobson, as I understand FoodNet, it is a Center for Disease Control survey of seven States, if I am not mistaken, where they went and took samples to reach this conclusion about a 44 percent decline in SE.

Mr. JACOBSON. Let me let Caroline Smith DeWaal take over here.

Senator DURBIN. OK.

Ms. DEWAAL. The FoodNet data that concluded that there was a 40 percent reduction was taken from just a few areas of the country. It was about eight sites, if I believe correctly, including a number of States. It represents about 7 percent of the U.S. population.

And if I just might add, the——

Senator DURBIN [presiding]. For the record, please state your name.

Ms. DEWAAL. It is Caroline Smith DeWaal, Director of Food Safety for the Center for Science in the Public Interest. The actual report that CDC issued where they mentioned the decrease in *Salmonella*, they say that the reasons for the decline are unclear. They do say that the implementation of these egg quality assurance programs with—and this is critical—microbial testing and egg diversion in some States may have contributed to the decline. And then they also mentioned that some of the improvements that are happening in the meat and poultry industry also may have contributed to it because right now there is an intensive effort in the poultry industry to reduce *Salmonella* levels to meet the new HACCP standards for poultry plants.

Senator DURBIN. I have it that the CDC project, FoodNet, tested in Connecticut, Minnesota, Oregon, selected counties in California, Georgia, Maryland, and New York. Interestingly enough, although there was a 44 percent decline in these sampled States and sampled localities, they found some wide variation. For example, the rate of evidence of *Salmonella* infection was more than 7 times higher in Maryland than it was in Georgia and New York, and they can't explain the differences there. But that appears to be part of the uncertainty about what we draw from this conclusion. It is certainly a lot better than a 44 percent increase. We have got to acknowledge that. So something is moving in the right direction, and I hope this hearing and some of the things that we have talked about today can bring us further along that course.

Let me conclude—the Chairman had to leave the hearing—by thanking Mr. DeVries and Mr. Mussman for coming here, and as I said, for whatever reason, your selection was the right one by the United Egg Producers because, as we listened to the standards which you have voluntarily imposed on yourself because of your pride in the product that you are selling, I am sure it gives consumers a good feeling that there are some good players out there, and probably the majority of egg producers are good players. I just want to get back to my original point here, and that is that we are embarking on a new era where food safety is an extraordinary issue for a lot of people. I literally had breakfast—I can't tell you the man's name or his company, but one of the major producers of

food in this country. I had breakfast with him last year, and I said I think food safety is a big issue of the future. And he kind of chuckled, and he said, "Senator, if that is all you have to worry about, why are you worrying at all? We have got the safest food supply in the world."

Well, I can't quarrel with that, but I will tell you within a month or two that man was hit with a food safety crisis in his company that cost him literally hundreds of millions of dollars. I think he takes a new attitude toward food safety. There is a vulnerability out there where, unfortunately, the bad actors are going to give some good actors a bad name if we are not careful. And for the consumer's sake and for the sake of egg producers who are doing the right job and using the right standards, I hope we have some sort of a code of conduct, an enforceable code of conduct, that we say this will stand by it. If it has UEP on the label, or whatever it is, you know that you are going to get a product that is a quality product whether you shop in Illinois or California, Florida or New York. That is what I think we should be moving toward.

I thank you all for your contribution today. It has been a great hearing, and you have helped to make it so.

The record will remain open for 5 days after the conclusion of the hearing. Thank you very much.

[Whereupon, at 12:27 p.m., the Subcommittee was adjourned.]

APPENDIX

United States General Accounting Office

GAO

Testimony

Before the Subcommittee on Oversight of Government Management, Restructuring and the District of Columbia, Committee on Governmental Affairs, U.S. Senate

For Release on Delivery Expected at 10 a.m. EDT Thursday July 1, 1999

FOOD SAFETY

U.S. Needs a Consistent Farm-to-Table Approach to Egg Safety

Statement of Lawrence J. Dyckman, Director, Food and Agriculture Issues
Resources, Community, and Economic Development Division

GAO/T-RCED-99-232

Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to discuss our work on the safety of eggs and egg products. Eggs are an important part of most Americans' diets. On average, each American consumes about 245 eggs annually. However, over the last decade, eggs contaminated with *Salmonella* Enteritidis bacteria have increasingly been implicated as the cause of foodborne illness in the United States. *Salmonella* Enteritidis may have caused about 300,000 illnesses in 1997, resulting in up to about 230 deaths. Between 1985 and 1998, when a cause could be identified, over three-quarters of the *Salmonella* Enteritidis outbreaks were linked to eggs, according to the Centers for Disease Control and Prevention.

Given the potential for eggs to become contaminated with illness-causing bacteria, it is critical that federal agencies, in cooperation with the states, have a consistent farm-to-table approach to ensure the safety of shell eggs and egg products. Of the 67 billion eggs produced in the United States in 1998, about 70 percent were sold whole (known in the industry as shell eggs). The remaining 30 percent of the eggs produced were broken, pasteurized, and processed into liquid, frozen, or dried egg products used, for instance, in commercial baked goods and ice cream. The Food and Drug Administration (FDA) has the primary responsibility for the safe production and processing of shell eggs, and the Food Safety and Inspection Service (FSIS) is responsible for food safety at egg products processing plants.

My testimony is based on a report we are issuing to Senator Durbin today on the adequacy of the nation's system for ensuring the safety of shell eggs and egg products.[1] The testimony will examine whether (1) prevention-based safety practices have been applied on egg farms and at processing plants; (2) implementation of a new federal policy on egg refrigeration will effectively reduce the risks associated with contaminated eggs, (3) federal and state policies and practices on serving eggs to vulnerable populations and dating egg cartons are consistent, and (4) federal egg safety resources are used efficiently and policies are coordinated effectively.

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[1]Food Safety: U.S. Lacks a Consistent Farm-to-Table Approach to Egg Safety (GAO/RCED-99-184, July 1, 1999).

In summary, we found the following:

- FDA has not established prevention-based procedures on egg farms or at shell egg processing plants that would reduce or eliminate *Salmonella* Enteritidis contamination by identifying, controlling, and monitoring known safety risks. At the state level, 13 states, responsible for about 38 percent of the nation's egg production, have established voluntary prevention-based programs for egg farms.[2] However, these programs do not provide a uniform level of risk reduction because they take different approaches in critical areas such as the frequency of testing for the presence of *Salmonella* Enteritidis. Moreover, FSIS does not require a prevention-based approach in processing plants where eggs are broken to create egg products.

- The first national requirement to refrigerate eggs at 45 degrees Fahrenheit or below from the time they are packed until they reach the consumer may not, for a variety of reasons, effectively reduce egg safety risks.[3] Implementation and enforcement of the requirements will be split between FSIS and FDA. FSIS has issued regulations, which take effect in August, requiring that eggs be refrigerated during storage and transportation. However, FDA has not yet proposed regulations to require that eggs be refrigerated after they arrive at retail locations such as restaurants and grocery stores. In addition, many experts believe that greater risk reduction could be achieved by controlling the internal temperature of the egg, something that the new regulations will not require.

- Inconsistent policies and practices in three other areas have weakened the nation's egg safety efforts. Certain groups, including the elderly in nursing homes, are more likely to suffer severe health consequences from eating contaminated eggs. Yet, only about half the states have followed FDA's recommendation that they require food service operators to use pasteurized eggs or egg products when serving these groups. Also, federal policies allow some eggs to be returned from grocery stores to processors to be repackaged,

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[2]The 13 states are Alabama, California, Connecticut, Louisiana, Maine, Maryland, Massachusetts, Michigan, New York, Ohio, Pennsylvania, South Carolina, and Utah.

[3]Refrigeration at 45 degrees or less delays the breakdown of the yolk membrane thereby retarding the growth of *Salmonella* in eggs.

redated, and returned to the retail level for sale. In addition, there are inconsistencies in how expiration dates are used on egg cartons. The inconsistencies in repackaging and expiration dating can mislead consumers about the eggs' freshness and may pose a food safety risk.

- The involvement of four federal agencies enforcing a variety of laws makes it difficult to direct resources to the areas of highest safety risk and to effectively coordinate egg safety policies. For example, FSIS is required by law to provide daily full-time inspection of egg products plants where eggs are pasteurized to kill harmful bacteria, whereas FDA almost never inspects egg farms where eggs can be contaminated. In addition, although we reported in 1992 on the need for better coordination between FDA and the Department of Agriculture (USDA) on egg safety issues, the agencies have still not agreed on a comprehensive unified approach for improving egg safety.[4]

Background

When *Salmonella* is found in eggs, *Salmonella* Enteritidis (SE) is the strain most commonly identified. SE was first associated with clean, intact shell eggs in 1988 and is believed to be deposited from infected hens' ovaries before the shells form around the eggs' contents. SE has progressed from an infrequent cause of human illness to one of the most common strains of *Salmonella*, growing from 5 percent of total *Salmonella* cases in 1977 to about 16 percent in 1987 and about 23 percent in 1997. Recently released data from the Centers for Disease Control and Prevention for 1996 through 1998 indicate a possible change in trends, as SE infections decreased by 44 percent in selected counties and states.

SE, as well as other strains of *Salmonella*, can cause such symptoms as abdominal pain, fever, headache, and vomiting, and can also lead to more severe conditions, such as blood stream infections, arthritis, and meningitis. It sometimes kills, particularly elderly residents of nursing homes. Refrigerating eggs at 45 degrees or less retards the growth of *Salmonella*, and pasteurization or thorough cooking can kill it.

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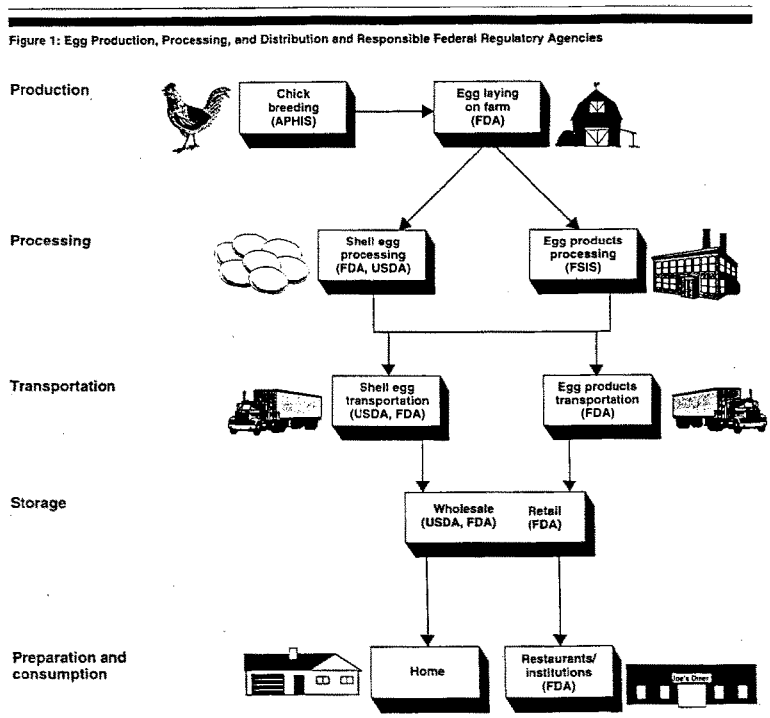
[4]Food Safety and Quality: Salmonella Control Efforts Show Need for More Coordination (GAO/RCED-92-69, Apr. 21, 1992).

As eggs make their way from the farm to the table, responsibility for egg safety shifts back and forth among four federal agencies in two departments and often two agencies in each state. (See fig. 1.) First, USDA's Animal and Plant Health Inspection Service manages the National Poultry Improvement Plan that establishes breeding practices to ensure that laying hens are born free from SE. At the next stage, the farms where eggs are laid, the Department of Health and Human Services' FDA is responsible for egg safety. Once the eggs arrive at processing plants where they are either packed as shell eggs or broken for egg products, the authority is split between two agencies–FDA for shell eggs and USDA's Food Safety and Inspection Service for egg products. While shell eggs are being processed, they may also be inspected by the USDA's Agricultural Marketing Service under a voluntary program to ensure shell egg quality. Once transported to the retail level, both shell eggs and egg products are under FDA's authority, but the millions of restaurants, institutions, and other retail food operations throughout the United States are generally inspected by either a state agriculture or health department under state laws. FDA encourages uniformity among state laws by publishing the Food Code, which recommends model practices for ensuring safer food, and by encouraging states to adopt its provisions.

Figure 1: Egg Production, Processing, and Distribution and Responsible Federal Regulatory Agencies



Notes: As eggs move from the farm to the table, state governments share egg safety responsibilities with the federal government.

USDA will assume responsibility for enforcing refrigeration requirements for shell eggs during storage and transportation in August 1999. FDA will retain overall responsibility for shell egg safety as well as responsibility for egg products after they leave the processing plant.

The Federal Government and the States Have Not Instituted a Consistent Prevention-Based Approach to Egg Safety

Outbreaks of egg-related illness are sometimes traced to egg production farms where laying flocks have become contaminated with SE. Although prevention-based approaches are generally recognized as the most effective method for identifying and reducing bacterial contamination, no federal program exists to reduce or eliminate this contamination during egg production on farms. Over the last few years, the federal government has introduced prevention-based hazard analysis and critical control point (HACCP) systems in meat, poultry, and seafood processing. HACCP systems are designed to actively monitor and control contamination throughout the food production process by identifying places where the greatest food safety risks exist, implementing methods to control the risks at those points, and then monitoring the efficacy of the controls.

In our 1992 report on SE in eggs, we recommended that the Secretary of Agriculture and the Commissioner of FDA work together to develop a comprehensive program to control SE throughout the egg production, distribution, and consumption process.[5] Six years later, in May 1998, USDA and FDA published an advance notice of proposed rulemaking in the Federal Register requesting comments on various proposals for improving farm-to-table egg safety. One of the proposals concerned using the HACCP approach on egg farms. Our analysis of the comments found strong support for a uniform, voluntary, national HACCP-based program to reduce the risks associated with SE contamination during egg production. As of June 1999, FDA, which has regulatory authority over shell egg production, had not taken any actions based on the comments received.

Thirteen states, in cooperation with the egg industry, have established voluntary statewide HACCP-based programs to control or eliminate SE during egg production. Seven elements are commonly found in such plans: (1) purchasing chicks from breeders approved by the National Poultry Improvement Plan, (2) controlling rodents and pests, (3) using bio-security procedures,[6] (4) cleaning and disinfecting henhouses, (5) conducting environmental testing for SE, (6)

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[5]GAO/RCED-92-69, Apr. 21, 1992.

[6]Bio-security procedures are designed to prevent SE from being carried into poultry houses from outside sources.

refrigerating eggs after packing, and (7) keeping records to document the implementation and monitoring of plan requirements.

Although the existing state egg safety programs include many of these elements, some significant variations exist. For example, under about half of the plans, testing the egg laying environment for the presence of SE is only done 8 weeks before the flock will stop producing eggs and be replaced with new birds. However, two states have more extensive testing regimens that start before a chicken begins to produce eggs and continues periodically throughout the 2 years that chickens in commercial production continue to lay eggs. This testing schedule allows problems to be identified before the chickens begin to produce contaminated eggs, whereas the testing done in the other states near the end of production provides less risk reduction. Moreover, 5 of the 13 plans do not include provisions for third-party oversight to assess the reliability and validity of the plan.

After eggs are produced on farms, they are sent to facilities where they are cleaned, processed, and packed. Egg packers and processors are not required to establish HACCP-based programs to prevent microbial contamination in the plants where shell eggs are processed and packed for consumers. FDA, which has regulatory authority over these plants, has not proposed HACCP-based requirements in this area.

Eggs that are not sold as shell eggs are sent to egg products plants where they are broken and pasteurized. FSIS, which has regulatory authority over egg products, does not require HACCP programs in these plants. FSIS has begun taking preliminary actions for a rulemaking to require HACCP. However, as of June 1999, the agency had not yet published a rule proposing such a requirement. In the absence of a federal requirement, some egg products plants have begun implementing HACCP plans on their own.

New Federal Refrigeration Requirements May Not Be as Effective as Possible

Beginning in August 1999, federal regulations will, for the first time, require that eggs for consumer use be refrigerated. But the new rules may not effectively reduce the risks from SE contamination in eggs. The Congress originally required egg refrigeration in the 1991

amendments to the Egg Products Inspection Act. Eight years later, USDA will begin implementing the requirement that eggs be refrigerated at an air temperature not to exceed 45 degrees from the time they are packed until they reach grocery stores, restaurants, or households.

Once eggs reach restaurants, institutions, grocery stores, and other retail locations, federal regulations will not require that they be refrigerated. The 1991 amendments to the Egg Products Inspection Act authorize FDA to ensure compliance with the egg refrigeration requirements, at locations not covered by FSIS, such as restaurants, institutions and grocery stores. In May 1998, FDA announced that it planned to propose regulations to mandate that shell eggs be stored for sale at 45 degrees or less in retail locations. But as of June 1999, FDA has not yet done so. In the absence of current federal regulations requiring the refrigeration of eggs at retail locations, responsibility shifts to the states. Our survey of regulatory officials found that 43 states require that eggs be kept at 45 degrees or less in retail locations, 3 states have temperature limits above 45 degrees, and 4 states have no requirements.

While implementing the 1991 amendments is an important first step, FSIS and other experts have raised concerns about the effectiveness of an air temperature requirement in improving egg safety. According to FSIS, maintaining the internal temperature of eggs at 45 degrees or below throughout processing and distribution would result in a greater reduction in illnesses from SE than would result from an air temperature requirement. However, when eggs are processed and packed, according to USDA, they are often in the 70- to 80-degree temperature range. Because of the way eggs are packed, even if they are immediately put into a cooler, research has shown that it may take from 3 to 6 days before the eggs' internal temperature is reduced to the air temperature. During this time, SE bacteria may multiply, and the more bacteria an egg contains, the more dangerous it will be if eaten raw or undercooked. New approaches show promise in cooling eggs more rapidly. For example, research has shown that cryogenic gases[7] can cool eggs internally to below 40 degrees in 12 minutes. One company has developed a prototype cooling method using cryogenic gases that it estimates will add 3 cents or less to the cost of a dozen eggs.

[7]Cryogenic gases are refrigerants used to obtain low temperatures.

Inconsistent Policies and Practices Hamper Egg Safety Efforts

Individuals with impaired immune systems who are in institutional or custodial care, the elderly in facilities such as nursing homes or hospitals, and preschool children in facilities such as day care centers are more susceptible than the general population to severe health problems as a result of eating eggs contaminated with SE. For example, the Centers for Disease Control and Prevention found that 54 of the 79 deaths associated with outbreaks of SE between 1985 and 1998 were of individuals in nursing homes.[8] Because of the problems associated with SE-contaminated eggs, FDA's Food Code recommends special procedures, such as substituting pasteurized eggs for raw eggs in certain situations, for food service operators serving highly susceptible populations.

However, according to our survey of state regulatory officials, many states have not adopted the FDA's recommendations on serving pasteurized eggs to highly susceptible populations. For example, 24 of the 50 states told us that they did not require food service operators that serve highly susceptible populations to use pasteurized eggs for any food item that usually contains raw eggs, such as Caesar salad dressing. Furthermore, in 26 states, food service operators are not required to use pasteurized eggs when they crack, combine, and hold a number of eggs for subsequent cooking.

An egg's natural defenses to SE can break down as the egg ages or is exposed to high or fluctuating temperatures. Consequently, concerns have surfaced about the practice of removing eggs from grocery stores a few days before their expiration or sell-by dates and returning them to an egg processing plant, where they are rewashed, repackaged, placed in cartons with fresh eggs, and given a new expiration date. While FDA, USDA, industry representatives, and several state officials told us that they do not believe this practice is widespread, some state and federal officials contend that it may present a food safety hazard. Eggs that are repackaged must be transported to the processing plant and therefore may be subject to temperature fluctuations as well as additional heating during rewashing.

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[8]An "outbreak" is defined as two or more people having a similar illness that has been traced to eating a common food. In addition, sporadic cases of illness occur outside of reported outbreaks. According to the Centers for Disease Control and Prevention, although foodborne diseases are extremely common only a fraction of the illnesses are reported. Therefore the numbers of illnesses and deaths linked to reported outbreaks of SE are much smaller than the best estimates of the actual prevalence of SE related illness and death.

USDA and FDA have reacted differently to concerns about repackaging and redating. USDA's Agricultural Marketing Service announced that, as of April 27, 1998, the practice of repackaging and redating eggs would be temporarily prohibited for the one-third of the nation's eggs that are graded and packed under its voluntary grading program because the practice can mislead consumers about the eggs' freshness. The Service is currently developing regulations to make this prohibition permanent. FDA, which has regulatory authority over all shell eggs, announced in May 1998 that it was considering appropriate measures to address repackaging, but as of June 1999, had not taken any action to prohibit the practice. The inconsistency in the federal government's approach to repackaging may be misleading to consumers because USDA-graded and non-USDA-graded eggs sit side by side in grocery store coolers. Our survey of state regulatory officials found that only 10 of the 50 states have laws prohibiting repackaging.

Federal policies are also inconsistent on the expiration dates stamped on egg cartons. Although neither the Agricultural Marketing Service nor FDA require cartons to be dated, many producers in the Service's voluntary grading program take this optional step. If they do, the Service requires that the expiration date be no more than 30 days from the date the eggs were packed. Egg processors that do not participate in the agency's grading program typically include expiration dates of either 30 or 45 days, although some do not provide any expiration date. In addition, our survey of state regulatory officials found that only 17 of the 50 states require either an expiration or a sell-by date on egg cartons sold in their states. These inconsistent expiration dating practices can be misleading to consumers. For example, when comparing carton dates, a consumer may be more likely to select the eggs not graded by USDA because a later date on the carton seems to imply that those eggs will be fresher for a longer period of time. But the eggs with the later date may actually be older than the USDA-graded eggs in the cooler.

Fragmented Structure Makes Effective Resource Allocation and Policy Coordination Difficult

Under the current regulatory and organizational framework, egg safety resources are not directed to the areas of highest risk. FDA has limited inspection resources and under its regulatory authority foods are generally allowed to enter the market without preapproval. Consequently, the agency almost never inspects egg production farms even though outbreaks of egg-related illness are sometimes traced to these locations. In contrast, FSIS is required by law

to conduct daily, continuous inspections of all egg products plants in the United States.[9] As a result, most federal resources for egg safety inspection are directed toward egg products even though during processing the eggs are pasteurized to kill harmful bacteria such as SE. In fiscal year 1998, FSIS had 102 full-time inspectors dedicated to daily, continuous inspection at all 73 egg products plants in the country. If HACCP systems are implemented in all egg products plants, it may be possible to reduce or eliminate the current practice of continuous inspection, which could allow inspection resources to be redirected to areas of higher risk.

Although USDA and FDA have worked together on various egg safety activities, including a consumer education campaign, an SE risk assessment study, and a foodborne disease monitoring network, progress on developing a comprehensive egg safety strategy have been slow. In our 1992 report on efforts to control SE, we reported that coordination difficulties resulted from the split regulatory structure and that consequently, the federal government had not agreed on a unified approach to addressing the problem of SE in eggs.[10] Now, 11 years after the problem of SE-contaminated eggs was first identified, the federal government still has not agreed on a unified approach to address the problem.

In May 1998, FDA and FSIS issued a joint advance notice of proposed rulemaking seeking to identify actions that would decrease the food safety risks associated with eggs as they move from the farm to the table. The notice recognized that eggs contaminated with SE continue to be a public health concern and sought comments by August 1998 on a wide range of actions that could be taken by the two agencies to improve farm-to-table egg safety. Although FSIS received about 70 comments from state regulatory agencies, industry associations, and other interested parties, no official FDA/USDA group has been formed to review these comments or to establish a unified regulatory strategy.

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[9]There are some minor exceptions to the continuous inspection requirement. For example, on weekends, plants are permitted to process dried pasteurized egg whites without inspectors present.

[10]GAO/RCED-92-69, Apr. 21, 1992.

In conclusion, Mr. Chairman, with responsibilities distributed among four federal agencies, the nation's egg safety efforts lack an organizational focus and contain gaps, inconsistencies, and inefficiencies. A prevention-based approach to food safety involving hazard analysis and critical control point principles has not been applied comprehensively to the production and processing of eggs and egg products. Federal regulations soon to be implemented on the refrigeration of eggs will not control this risk factor as effectively as possible because they do not apply at the retail level and because they address air temperature not the egg's internal temperature. Raw and undercooked eggs continue to be hazardous, particularly to highly susceptible populations such as the elderly in nursing homes. And finally, decisions about how to allocate the nation's egg safety inspection resources are not based on risk.

The report we are issuing today contains a matter for congressional consideration and three recommendations aimed at improving egg safety. To provide an organizational focus for the nation's egg safety policies and activities, we ask the Congress to consider consolidating responsibility for egg safety in a single federal department. To help improve safety on egg farms and in processing plants, we recommend that the Commissioner of the Food and Drug Administration develop a model HACCP-based SE reduction program for egg farms and processing plants that could be adopted by the states. To enhance safety protections in egg products processing plants, we recommend that the Secretary of Agriculture develop regulations to require these plants to implement HACCP systems. And finally, to reduce the time needed to lower an egg's internal temperature to 45 degrees, we recommend that the Secretary of Agriculture and the Commissioner of the Food and Drug Administration jointly study the costs and benefits of implementing rapid cooling techniques in egg processing and packing operations.

In commenting on the draft report, USDA and FDA agreed with all three of the report's recommendations. However, FDA said that before it can develop criteria for a model, HACCP-based SE reduction program, it must first develop prevention controls for egg production because science has not yet established the optimal strategy to control SE on farms. We agree with FDA that the scientific issues related to identifying and establishing effective SE control measures are complex. However, we believe FDA can take immediate action to develop a model program that contains controls that are based on the best currently available scientific information and the experience of existing state programs.

This concludes my prepared statement. I would be happy to respond to any questions that you and Members of the Subcommittee may have.

Contact and Acknowledgments

For further information, please contact Lawrence J. Dyckman at (202) 512-5138. Individuals making key contributions to this testimony included Stephen D. Secrist, Mary K. Colgrove-Stone, and Robert C. Summers.

(150151)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT

BY

MORRIS E. POTTER, D.V.M.

DIRECTOR

FOOD SAFETY INITIATIVES

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT, RESTRUCTURING, AND THE DISTRICT OF COLUMBIA

COMMITTEE ON GOVERNMENTAL AFFAIRS

UNITED STATES SENATE

JULY 1, 1999

FOR RELEASE ONLY UPON DELIVERY

I. Introduction

Mr. Chairman, Members of the Committee, I am Morris E. Potter, D.V.M., Director of Food Safety Initiatives, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration (FDA), Department of Health and Human Services (HHS). I am pleased to be here this morning, along with my colleague, Margaret Glavin, Associate Administrator, Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA) to testify on the Federal role in the oversight of egg safety and the related General Accounting Office's (GAO) report. I am accompanied by Dr. Terry Troxell, Director of FDA's Office of Plant and Dairy Foods and Beverages, and Dr. David Swerdlow, a medical epidemiologist from the Centers for Disease Control and Prevention (CDC).

Mr. Chairman, my testimony will address the coordination of Federal and State agencies with shared food safety responsibilities. This will include a general discussion of how eggs are regulated, with specific emphasis on FDA's role. Ms. Glavin's testimony will describe USDA's role in more detail. I also will describe the risks associated with Salmonella Enteritidis (SE) in eggs, and the Administration's accomplishments along the farm- to-table continuum to address the risks. Our goal is to have the best food safety system and we look forward to working with the Committee to that end.

HHS, USDA, and the States have a long history of working together to understand and initiate actions to reduce the risk of Salmonella in eggs. In the 1980s, SE was identified as a growing public health problem, and was linked to contaminated whole shell eggs in 1986. FDA, CDC, USDA's Animal and Plant Health Inspection Service (APHIS), and Agriculture Marketing Service (AMS) immediately responded by working together and with colleagues in State government, universities, and the egg industry to conduct research on SE and eggs and to put in place mechanisms to share new information on prevention and control as that information developed. Contrary to GAO testimony, our coordinated approach has led to many important achievements that are highlighted throughout this testimony.

Recent nationwide surveillance data show a decrease in cases of SE infection, particularly in the Northeast where egg quality assurance program efforts have been the most intense, and active surveillance in FoodNet sites demonstrates a 44 percent decline in SE infection rates between 1996 and 1998 in those areas of the country covered by this surveillance system. Although we are heartened by this progress, the rate of decline is too slow and the remaining public health burden of egg-associated SE infections requires the agencies to do more to address the problem.

Both FDA and FSIS announced initiatives this week that are major steps forward in the egg safety effort. FDA just sent to the *Federal Register* a proposed rule that would require refrigeration of shell eggs at retail and labeling to instruct consumers on safe

handling of eggs. FSIS also has just announced a directive that will implement its refrigeration requirements for storage and transport of eggs.

II. Regulation of Eggs

As you know, the Federal authority to regulate eggs for safety is shared by FDA and FSIS. FDA has jurisdiction over the safety of foods generally, including shell eggs, under the Federal Food, Drug, and Cosmetic Act. FDA also has authority to prevent the spread of communicable diseases under the Public Health Service Act. This authority includes regulating foods when foods may act as a vector of disease, as eggs do for SE.

USDA has responsibility for implementing the Egg Products Inspection Act (EPIA), which it carries out through programs in FSIS and AMS. FSIS has primary responsibility for the inspection of processed egg products to prevent the distribution into commerce of adulterated or misbranded egg products, while AMS conducts a surveillance program to ensure proper disposition of restricted shell eggs. APHIS administers programs for animal health, including an SE control program for flocks that supply hens to laying flocks, and is conducting a study to survey the current practices in the laying industry, and estimate the prevalence of SE in layer flocks. FDA has primary responsibility for the parts of the continuum that involve the production and processing of shell eggs.

In addition, the States play a key role, as they may have their own laws governing eggs, as long as they are consistent with Federal laws. Generally, State laws and regulations

focus on how eggs are packed and shipped for sale within their borders, and how eggs are handled by retail stores and food service establishments. FDA and USDA, with help from the States, strive to provide a coherent and comprehensive system to eliminate or reduce the risk of SE contaminated eggs and egg products in each link of the farm-to-table chain.

In May 1992, FDA and USDA signed a Memorandum of Understanding (MOU) to improve coordination of control efforts for egg production flocks, breeder flocks, pullet grow-out facilities, eggs during storage and transportation, labeling, research, consumer education, and retail and manufacturing establishments. In addition, in August 1996, FDA and AMS signed a second MOU establishing more formal methods of sharing inspection information regarding egg safety. While the jurisdiction may be divided, FDA and USDA efforts in exercising jurisdiction have been cooperative and coordinated.

III. Salmonella and Egg Safety

Until the mid-1980s, intact eggs rarely were the source of *Salmonella* infections. Since 1985, however, the number of egg-associated salmonellosis outbreaks and sporadic infections has increased. Shell eggs are the predominant source of SE infection in the United States for which a food vehicle is identified. Before I discuss each step of the farm-to-table continuum, let me describe the bacterium and the human illness it causes.

A. Salmonellosis

Salmonella of various serotypes are commonly found in the digestive tracts of animals, and frequently contaminate our environment. Human illnesses are usually associated with ingesting food contaminated with *Salmonella*, although transmission also may occur person-to-person by the fecal-oral route, when personal hygiene is poor, and by the animal-to-man route.

The disease salmonellosis is an intestinal infection with *Salmonella,* and is characterized by diarrhea, fever, abdominal cramps, headache, nausea, and vomiting. Symptoms of salmonellosis usually begin within 6 to 72 hours after consuming contaminated food, last for 4 to 7 days, and resolve without antibiotic treatment for most people who do not have underlying health problems. The infection can spread to the bloodstream and other areas of the body, however, leading to severe and fatal illness. Invasive, life-threatening disease is more likely in children, the elderly, and persons with weakened immune systems. In general, the greater the numbers of microorganisms ingested, the greater the likelihood of disease; however, the infectious dose (i.e., the number of microorganisms required to cause disease) can be very low. The likelihood of disease is also affected by the virulence of the microorganism and the susceptibility of the host. About 2 percent of those who recover from salmonellosis may later develop recurring joint pains and arthritis.

B. SE in Eggs

Until recently, *Salmonella* contamination of shell eggs was thought to occur most commonly by trans-shell penetration of bacteria present in the egg's environment. Our current experience with SE, however, has shown that an egg's contents can become contaminated with SE before the egg is laid. Though the mechanism is still not completely understood, SE infects the ovaries and oviducts of some egg laying hens, permitting transovarian contamination of the interior of the egg while the egg is still inside the hen. In general, only a small number of hens in an infected flock shed SE at any given time, and even infected hens lay many uncontaminated eggs. While the percentage of eggs that are contaminated is small, the number of contaminated eggs is large; it has been estimated that of the 47 billion eggs consumed annually as shell eggs, 2.3 million are SE-positive, exposing a large number of people to the risk of illness.

C. Epidemiology

Salmonellosis is a notifiable disease, i.e., physicians and medical laboratories are required to report identified infections to their local health department. The reports are forwarded to the State health department, which summarizes the information and sends it to CDC. This is the nationwide, passive reporting system for all serotypes of *Salmonella*. While the numbers of another common serotype, Typhimurium, have remained relatively stable, SE infections increased more than 8-fold from 1976 to 1995. Initially, the increases in the United States largely occurred in the Northeast. Later, the increase spread throughout the country. The numbers of SE infections decreased in 1996 and 1997, especially in the Northeast where control efforts began first and have been the most

intense. This demonstrates that committed application of good management and strong science during production and concerted efforts to improve egg handling during food preparation and service, especially institutional food service, will bring the numbers down.

The number of *Salmonella* infections reported to CDC underestimates the true number of infections that occur, however, and this progress should not make us complacent. Most persons infected with *Salmonella* do not seek medical care, many doctors do not order stool cultures, and some laboratories do not report *Salmonella* isolations to their health department. It has been estimated that only one in 39 *Salmonella* infections are reported to CDC; multiplying the 7,924 cases of SE that were reported to CDC in 1997 by 39, it can be estimated that up to 310,000 infections may have actually occurred. Clearly, we must do more to bring this public health problem under adequate control.

In addition to the routine passive surveillance for infections with all serotypes of *Salmonella,* CDC also maintains special surveillance of outbreaks of infections with SE. In 1985, when this outbreak surveillance began, States reported 26 SE outbreaks (i.e., occurrences of 2 or more cases of a disease related in time and place) to CDC. Nationwide, the numbers of reports peaked in 1990. The numbers of outbreaks increased first in the Northeast in the late 1980s and early 1990s, but have decreased dramatically in the late 1990s. This progress was partially offset by increasing numbers of outbreaks in the West during the early 1990s. From 1985 through 1998, there have been a total of 794 SE outbreaks reported to CDC involving 28,644 illnesses, 2839 hospitalizations, and

79 deaths. Many of these SE outbreaks were attributed to food served in commercial establishments, such as restaurants, hospitals, nursing homes, schools, and prisons, and most (more than 75 percent) were associated with food that contained undercooked eggs. Although most deaths that have occurred during SE outbreaks in recent years have occurred among the elderly in hospitals and nursing homes, salmonellosis can be fatal to an otherwise healthy person if a sufficient dose is ingested, and proper treatment is not administered.

In 1995, FDA, CDC, and FSIS began a collaborative project, The Foodborne Diseases Active Surveillance Network (FoodNet), to collect more precise information on the incidence of foodborne disease in the United States. This information collection included a *Salmonella* case-control study in 1997 that provided additional information on SE infections. FoodNet recently reported a 44 percent decrease in the infection rate for SE (2.5 to 1.4 per 100,000 U.S. population) from 1996 to 1998 in the areas of the country under surveillance. This decrease is substantial, and we are studying the data to understand the reasons for this decrease to help us refine our control efforts. Implementing egg quality assurance programs that include microbiological testing and egg diversion (i.e., sending eggs from infected flocks to pasteurizing plants), and improved refrigeration of eggs during transport, retail, and home use are likely to have contributed to this reported decrease. Part of the reported decrease also may be explained by a decline in the presence of *Salmonella* isolated from poultry and meat products because of recently implemented Hazard Analysis and Critical Control Point (HACCP) programs.

In sum, these three data sources on SE indicate that the public health problem is very large, yet we are encouraged that our combined efforts to control SE contamination of eggs and to prevent egg-associated illness have had substantial public health impact. The magnitude of the remaining problem, however, is simply unacceptable.

IV. Farm-to-Table: The Need for A Coordinated System

Farm-to-table oversight of egg safety involves risk management in five areas: production, processing and packing, transportation, retail, and consumption. I will describe each area, the risks posed, and actions taken by HHS, USDA, or States. These steps in the food production chain and the challenges each poses were described in detail in a joint FDA and FSIS, ANPR, "*Salmonella* Enteritidis in Eggs", published in the *Federal Register*, May 19, 1998. The ANPR sought to identify farm-to-table actions that will decrease the food safety risk associated with shell eggs. Comments were solicited on a variety of issues, including egg quality assurance programs, the potential for HACCP on the farm, and preventive controls during packing and processing. The agencies want to explore all reasonable alternatives and gather data on the public health benefits and costs of various regulatory and non-regulatory approaches before proposing a comprehensive food safety system for shell eggs. Comments from this ANPR are being evaluated by both agencies now, and will guide our decisions on the parameters of the comprehensive strategic plan we will propose this fall.

In addition, FSIS and FDA conducted a comprehensive risk assessment of SE, completed in June 1998, to identify possible strategies for enhancing the safety of shell eggs, and this will help focus attention on those factors most likely to have the greatest impact on egg safety.

A. Production

The egg production step in the farm-to-table continuum is an important area for prevention. We have learned a great deal about control of SE during production by research activities during the past decade, including programs like the Pennsylvania Egg Quality Program. The Pennsylvania program began as a pilot in 1992, and demonstrated key risk factors for the introduction and persistence of SE in the production environment.

A number of other States have since developed egg quality assurance programs. FDA has entered into partnership agreements with some to coordinate activities and facilitate tracebacks. Our current goal is a nationwide program of preventive controls during production. Aspects of egg quality assurance programs that have shown the most promise for minimizing risk of SE-infected laying hens include:

- purchasing replacement hens certified to be free of SE,
- environmental testing for SE,
- adequate assurance of rodent and pest control,
- biosecurity procedures,
- cleaning and disinfection of production houses between flocks, and
- *Salmonella*-free feed.

Controlling SE during production is crucial in mitigating the risk of SE in eggs, and will be part of our comprehensive strategy. Research in this area is being conducted by both FDA and ARS to uncover all important sources of the SE problem, and to develop ways to maintain SE-free laying hens. Our ability to now move forward on a comprehensive program for improving the safety of eggs is a direct result of the investments in research during the past several years.

An important omission in the GAO report was discussion of Federal research efforts, which have been underway since contamination of eggs with SE was identified, as a public health problem. This research has been critical to our better understanding of SE and efforts to develop science-based control schemes from farm-to-table.

For example, work done by ARS on transovarian infections of laying hens and factors that influence the frequency of SE contamination of eggs has been important in understanding the transmission of SE and the development of effective quality assurance programs. Progress has been impressive, but additional data are needed to solve this complex food safety problem. Thus, Federal agencies continue to aggressively identify, initiate, and support research needed to develop even more effective means for controlling this disease-causing microorganism. Examples of FDA research underway include studying the effects of stress on the immune system of poultry and subsequent contamination of shell eggs with SE, which will assess the effects on the immune system of potential factors such as competing organisms, crowding, temperature, air quality, and

lighting. FDA also is studying the pathogen transmission capacities of various insects found in the production environment.

As additional data gaps in our understanding of the dynamics of SE during production are filled so we can be certain that our control strategies will be both effective and efficient, we will initiate performance-based control programs, possibly including on-farm HACCP for eggs. While we are moving controls into place to prevent SE contamination of eggs, we also must react to episodes of contamination and the illness that results from it. In 1995, FDA assumed responsibility for investigating shell egg outbreaks, tracing back egg-associated SE illnesses to particular producers/flocks, sampling, diverting eggs, and collecting flock data to help track the presence of SE. Prior to 1995, APHIS conducted the traceback program. FDA and ARS continue to conduct research to improve the range of prevention and control options available to government and industry.

B. Processing and Packaging

Processing and packaging are steps in the farm-to-table continuum that involve the washing, grading, and packing of eggs for transport to distributors, retailers, or manufacturers of food products. The principal aspect of SE control during this phase is temperature control to prevent growth of SE already contaminating the internal contents of some eggs. The field and laboratory research focus in this area has been on the effects of rapid or delayed cooling, temperature fluctuations, temperatures that will prevent growth of SE, and technologies that achieve the desired time/temperature conditions. The agencies are aware of ongoing research discussed in the GAO report on methods of

rapid cooling. The overall impact on egg safety, costs, and potential problems of the methods being developed in North Carolina and California will be reviewed jointly by FDA and FSIS.

C. Transportation

Transportation of shell eggs is the next stage in the farm-to-table continuum. Temperature control is the focus of prevention efforts during transportation. Research has shown that internal egg temperatures of 45°F or lower are unlikely to promote SE growth, should SE be present in the egg. Therefore, on August 27, 1998, FSIS published a final rule implementing amendments to the EPIA, requiring that

- shell eggs packed for consumer use be stored and transported under ambient temperature not to exceed 45°F,
- the packed shell eggs be labeled to state refrigeration is required, and
- any shell eggs imported into the United States packed for consumer use include a certification that the eggs, at all times after packing, have been stored and transported at an ambient temperature of no greater than 45°F.

FSIS consulted with FDA during development of this final rule. The President just announced an FSIS Directive to implement this final rule.

D. Retail

FDA and FSIS work with the States to encourage uniformity among the State laws affecting food safety in retail and food service establishments. The principle mechanism for this is the Food Code, a model code published by FDA intended for adoption by State

and local authorities to use in regulating retail food and food service establishments. At present, 14 states have adopted the Food Code, and adoption is pending in 22 others.

FDA's Food Code requires in retail and food service establishments:

- Refrigeration of potentially hazardous foods, including shell eggs,
- Proper cooking of shell eggs, and
- Substitution of pasteurized eggs for raw eggs in the preparation of foods such as Caesar salad, egg nog, ice cream, Hollandaise or béarnaise sauce, and for pooled eggs that are served to highly susceptible populations.

The Food Code also contains specific guidance on egg safety for foodservice workers who prepare eggs and egg-containing dishes for highly susceptible persons, including nursing home residents. In addition, FDA is directing special guidance to elementary schools and day care centers and, through them, to parents of young children. FDA also is finalizing plans for a safe egg handling educational campaign for foodservice workers, health educators, and inspectors.

FDA also has been working on a proposed rule to address refrigeration and labeling of eggs that is consistent with the requirements of the FSIS rule. The FDA proposed rule, "Food Labeling: Safe Handling Statements: Labeling of Shell Eggs; Shell Eggs: Refrigeration of Shell Eggs Held for Retail Distribution " was just placed on public display at the office of the *Federal Register*. This proposal directly responds to and corrects problems outlined by GAO. It proposes requirements that all shell eggs be

stored and displayed at a temperature of 45° F or less, and would cover shell eggs sold both interstate and intrastate. It also proposes safe handling statements on labels of cartons of shell eggs that have not been treated to destroy *Salmonella*. The statement would read, "Safe Handling Instructions: Eggs may contain harmful bacteria known to cause serious illness, especially in children, the elderly, and persons with weakened immune systems. For your protection, keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly before eating." This label, once finalized will replace the label requirements included in the FSIS rule. FDA is aware that refrigeration and labeling solve only parts of the problem. The agencies view this regulation as one step in a comprehensive action plan.

E. Consumers

During final preparation of eggs and egg-containing dishes in our homes, we can protect ourselves by following simple food safety rules, including proper refrigeration and thorough cooking. The primary tool the agencies have for helping consumers reduce their own risk of foodborne disease is education on safe food handling, and our proposed labeling requirements will be an important adjunct to our other efforts to inform the public. HHS, FSIS, and the Department of Education are partners with consumer groups and industry in a consumer education campaign begun in 1997 as part of the President's Food Safety Initiative. This campaign builds on our previous efforts. The Fight BAC! Campaign covers all aspects of food safety, including information that pertains to safe handling of eggs. September is National Food Safety Month, and this year's theme, "cook thoroughly," will contain special emphasis on eggs.

The agencies have coordinated other efforts to enhance egg safety during food preparation. The rulemakings on labeling, discussed above, provide consumers with an immediate reminder of how to safely handle eggs. Both FDA and FSIS publish electronically and in print various educational materials to enhance consumer knowledge on the safety of eggs and egg products. Additionally, both FDA and FSIS have taken extra measures to reduce the risk to vulnerable populations, such as the immune compromised or elderly. FDA and FSIS developed fact sheets on egg safety for the food service industry and consumers, to raise consumer awareness of safe handling practices. These fact sheets will be sent to food service directors serving populations who are especially at-risk for illness such as day care center and nursing home food service directors. Egg safety information also will be distributed to consumers through our national and regional offices and through the news media. Special mailings will be sent as well to media outlets and organizations who serve at-risk populations encouraging the inclusion of information on egg safety and encouraging the use of pasteurization in their publications and newsletters.

V. Where do we go from here?

The President's Council on Food Safety will create within 120 days a farm-to-table approach for addressing SE and eggs. The information from recent research, the joint FSIS/FDA 1998 *Salmonella* Enteritidis Risk Assessment, and the comments we received on the joint ANPR of May 19, 1998 referenced above, will be used by the task force to help finalize its recommended strategic plan for a comprehensive system to assure the safety of eggs and egg products. Strategic planning will be a coordinated interagency

effort, and will feature a strong element of public input similar to the process used in our development of good practices guidance for fresh produce.

VI. Conclusion

As you know, managing the risks of SE contamination in eggs in each step of the process from farm to table is a complex and challenging task. Since the time that CDC first identified the growing public health problem of SE infections and their association with eggs, HHS and USDA have worked diligently with their state partners, the food industry, and consumers to understand and control SE, and to encourage or require adoption of specific efforts to prevent contamination of eggs and illness among consumers. The decreasing numbers of infections and outbreaks encourages us. We recognize, however, that more progress must be made because the magnitude of the remaining public health problem is too great. SE and its association with eggs has been hard to understand and has revealed its secrets slowly, and the way toward its control has been less straightforward than we had hoped.

While much has been done to address these challenges, more is needed. We will conceive and construct a disease prevention and control strategy that will pull together all of the separate actions - whether HHS and USDA, or state-based - needed to provide for a more comprehensive, coordinated government approach. It is our expectation that the strategic plan we will release by the end of October 1999 will provide that approach.

Mr. Chairman, in response to the question posed by the title of this hearing, "Egg Safety: Are There Cracks in the Federal Food Safety System?" we feel that while there clearly are complex lines of jurisdiction over eggs between FDA, FSIS, and AMS, those lines are not "cracks," but seams. We are committed to smoothing out those seams and providing the country with a seamless coordinated national farm-to-table policy.

I would be happy to answer any questions.

United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

Statement of Margaret Glavin
Associate Administrator
Food Safety and Inspection Service
United States Department of Agriculture

Before the Senate Committee on Governmental Affairs
Subcommittee on Oversight of Government Management, Restructuring, and the District of Columbia

July 1, 1999

Mr. Chairman and Members of the Subcommittee, I am Margaret Glavin, the associate administrator of the Food Safety and Inspection Service (FSIS). I am pleased to appear before you to discuss the egg products inspection program of the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service. I will also briefly describe the activities of other agencies within USDA that relate to the quality and safety of shell eggs and egg products. Because several USDA agencies play a role in egg safety and regulation, I am joined today by Mr. Michael Holbrook of the Agricultural Marketing Service (AMS), Dr. Jane Robens of the Agricultural Research Service (ARS), and Mr. Thomas Myers of the Animal and Plant Health Inspection Service (APHIS).

Because FSIS and the Food and Drug Administration (FDA) share jurisdiction for eggs, we have been working together for many years to prevent illness associated with SE in eggs. Our combined efforts have allowed us to accomplish many improvements in the area of egg safety. My testimony will specifically highlight USDA's responsibilities in this area and our joint accomplishments.

Let me begin by emphasizing USDA's commitment to improving the safety of the foods it regulates—meat, poultry, and egg products. This commitment to a safer food supply is shared by the Food and Drug Administration (FDA), which has joint jurisdiction for eggs, and has resulted in a coordinated response to the problem of ensuring a safe food supply. Over the past several years, USDA has implemented a strategy for change that emphasizes the need to prevent food safety problems before they happen and the need to address food safety hazards all along the farm-to-table chain. This strategy also emphasizes the responsibility of industry to produce safe food and the responsibility of government to establish and monitor science-based food safety standards and to ensure that they are met.

We have made much progress in implementing this strategy for change, and data available show that our efforts are paying off. For example, results for the first year of large plant *Salmonella* testing for meat and poultry show that *Salmonella* prevalence in broilers, swine, ground beef, and ground turkey was lower after implementation of Hazard Analysis and Critical Control Points (HACCP) systems than in baseline studies completed before HACCP. Prevalence decreased between 25.3 percent and 45.5 percent, depending on the product. While HACCP does not currently apply to egg products, FSIS is in the process of developing such a proposal.

In addition, data from the Foodborne Diseases Active Surveillance Network (FoodNet) show a 13 percent decline in the rate of human *Salmonella* infections between 1996 and 1998 and a 44 percent drop in the rate of *Salmonella* Enteritidis (SE), which has been associated with shell egg contamination.

We have not won the war against foodborne illness by any means, and eggs still remain a major source of SE. But the steps we have taken are making a difference, and we at USDA are committed, along with our HHS colleagues, to further progress in reducing the incidence of foodborne illness.

USDA Reorganization Act of 1994

FSIS has a long history of inspecting meat and poultry products, but the Agency's involvement in egg products inspection is relatively new. The USDA Reorganization Act of 1994 set the stage for FSIS involvement in egg products inspection by transferring this responsibility from AMS to FSIS.

Under the Egg Products Inspection Act (EPIA), FSIS is responsible for continuous Federal inspection in plants processing liquid, frozen, and dried egg products. The regulations governing the inspection of egg products specify minimum requirements for plant facilities, equipment, sanitation, processing procedures, and the testing of pasteurized products for *Salmonella*. The regulations also require continuous inspection of the packaging and labeling of egg products. During fiscal year 1998, 102 FSIS inspectors monitored operations at 73 egg products plants around the country. FSIS also had cooperative agreements with six States to provide inspection of egg products.

FSIS also oversees the importation of egg products into the United States. Two countries—Canada and the Netherlands—are approved to export egg products to the United States, but Canada is the only country now using that approval. FSIS also certifies egg products for export on request.

The current statutory framework for egg safety established by Congress presents a fragmented system of oversight, but the agencies are working well under this system and are trying to do better. I do want to make the point that USDA activities regarding shell eggs and egg products go beyond FSIS, and any effort to adjust the current statutory framework for egg safety should consider the broad range of activities carried out by USDA and HHS.

For example, the AMS administers a voluntary grading program for shell eggs, supported by user fees, that addresses egg quality as a service to shell egg processing plants. AMS also is responsible for the shell egg surveillance program, which enhances fair competition in the sale of consumer grade eggs. Under the program, eggs are graded to assure that product moving in commerce contains no more restricted eggs—often described as dirty, cracked, or leaking—than are permitted in the U.S. Consumer Grade B. AMS visits shell egg handlers and hatcheries four times each year to ensure conformance with these requirements. AMS also has developed a comprehensive voluntary grading and sanitation service for egg processors that participate in the shell egg grading program. This fee-for-service program allows processors to place a USDA shield on egg cartons verifying that the plant has complied with USDA's sanitation and good manufacturing practices. In addition, AMS, on a voluntary, fee-for-service basis, conducts third-party monitoring for the United Egg Producers' 5-Star quality assurance production program.

On April 27, 1998, AMS announced a prohibition on the repackaging of eggs packed under its voluntary grading program so the Agency could conduct further study on the issue. AMS is working on a proposed rule to address this matter more fully.

APHIS conducts activities related to animal health, and several of its activities have a public health impact by reducing the risk of diseases in layer flocks. APHIS administers the National Poultry Improvement Plan (NPIP), which certifies that poultry breeding stock and hatcheries are free from certain diseases. Breeders of egg-type chickens can use this program to monitor their flocks for *Salmonella*. Although it is a voluntary program, NPIP participation is necessary for those producers that ship interstate or internationally.

Under the Egg Products Inspection Act (EPIA), FSIS has responsibility for imported shell eggs for table use and for imported restricted eggs (dirty, cracked, leaking, etc.). Due to AMS' expertise in these areas, AMS carries out these tasks on behalf of FSIS. FSIS also has the responsibility for monitoring the importation of shell eggs from countries that are not free of certain poultry diseases. Due to APHIS' expertise in this area, APHIS carries out this program on behalf of FSIS.

APHIS' National Animal Health Monitoring System is currently conducting a nationwide survey of the egg industry. This study, entitled "Layers '99," will be used to estimate the national prevalence of SE in layer flocks. The study will also identify quality assurance programs. In cooperation with AMS, APHIS personnel will soon be available to conduct on-farm, third-party monitoring of industry quality assurance programs aimed at reducing the incidence of SE in shell eggs.

USDA also carries out food safety research through ARS and through the National Research Initiative Competitive Grants Program administered by USDA's Cooperative State Research, Education & Extension Service (CSREES). For example, Washington University in St. Louis, Missouri has received a three-year grant to study

how *Salmonella* adheres to chicken cells, and Indiana's Purdue University is in the midst of a project to develop an oral vaccine against SE.

Through ARS research, we have gained important knowledge, such as the fact that hens infected with SE can produce eggs that are contaminated internally, and that feed withdrawal may increase the transmission of SE infections in flocks. We have new methods for detecting strains of SE that are epidemiologically important, and we have helped to develop new products that competitively exclude *Salmonella* from chickens.

USDA also plays a role in educating consumers about the handling of eggs. FSIS has developed numerous publications on egg safety and uses a variety of networks to get this information to the grass roots level. For example, USDA cooperative extension agents work directly with consumers around the country to educate them about food safety.

Additionally, USDA plays a role in collecting processing data and distribution information for the economic analysis of the egg products industry through the National Agricultural Statistics Service (NASS).

Thus, USDA agencies carry out a variety of inspection, certification, research, education, and data collection activities that together help to improve the safety of shell eggs and egg products.

FSIS/FDA Cooperation

Of course, FSIS shares statutory authority for egg safety with the Food and Drug Administration (FDA). FSIS and FDA have worked closely together to develop a coordinated approach to the problem of SE in eggs and egg products. This cooperative approach is not new to the two agencies. Over the past several years, we have worked together on a number of food safety issues. For example, FSIS and FDA have worked closely on HACCP implementation for various foods. We have worked closely with HHS on foodborne disease surveillance and outbreak response. And we both are working to strengthen the *Food Code* and to encourage its adoption by States and local jurisdictions.

I would like to review our accomplishments on egg safety over the past several years, with an emphasis on this cooperation.

On November 22, 1996, FSIS and FDA published an Advance Notice of Proposed Rulemaking (ANPR) to seek input on approaches the two agencies should take to foster food safety improvements during the transportation and storage of potentially hazardous foods. The ANPR addressed all foods regulated by the two agencies, including eggs and egg products. Among the alternatives offered for consideration in the ANPR were temperature performance standards, mandatory HACCP systems, and voluntary guidelines.

On May 19, 1998, FSIS and FDA jointly published an ANPR to initiate a comprehensive and coordinated process of addressing the SE problem in shell eggs and to solicit input from the public on strategies.

On August 27, 1998, FSIS published a final rule to implement the requirements for the refrigeration and labeling of shell eggs that were mandated by the 1991 amendments to the EPIA. The rule requires that shell eggs packed for consumers be stored and transported under refrigeration at an ambient temperature not to exceed 45-degrees F, that all packed shell eggs be labeled to state that refrigeration is required, and that any shell eggs imported into the United States packed for consumer use include a certification that they have been stored and transported at an ambient temperature of no greater than 45-degrees F. The rule becomes effective on August 27th of this year, and yesterday, we issued a directive that details the procedures FSIS will follow to enforce these requirements. We believe that this refrigeration rule is a step in the right direction toward controlling SE during transportation.

Also in the summer of 1998, the final report on the joint USDA-FDA SE Risk Assessment was released. This was our first quantitative, microbial risk assessment, and it is the first in a series of risk assessments the two agencies are working on together.

We began the risk assessment in response to an increasing number of human illnesses attributed to the consumption of contaminated eggs. The risk assessment had several objectives. First, it was intended to characterize, using the data available, the adverse public health effects associated with consuming shell eggs and egg products contaminated with SE. A second goal was to identify data needs and prioritize future data collection efforts. Third, the risk assessment was designed to identify and evaluate potential risk reduction strategies, along the farm-to-table continuum.

The risk assessment extended from the production to consumption of shell eggs and egg products, reflecting our belief that to appropriately address the problem of SE, a comprehensive strategy with multiple interventions is needed.

From the risk assessment, we have a much better idea of the prevalence of illness attributable to SE in shell eggs and egg products. But even more importantly, we have a farm-to-table model—a computer program—we can use to determine the effects of specific interventions on the estimated likelihood of illness. In fact, it was through this model that we evaluated the 45-degree F. ambient temperature requirement mandated by Congress, in terms of the impact it would have on human illnesses.

Upcoming Initiatives

The risk assessment will enable us to better evaluate interventions in terms of public health impact as we further develop our food safety strategy for shell eggs and processed eggs. For example, the risk assessment is being used to develop a proposed rule that would address HACCP for egg products.

The risk assessment also will be helpful in the development of a strategic plan for shell eggs and processed egg products that is being carried out by the strategic planning taskforce of the President's Food Safety Council. It will parallel the broader strategic planning effort that already is underway by the Council. We want the strategic plan for shell eggs and egg products to run on a fast track in order to make immediate progress, and we are committed to completing it within 120 days. We expect the strategic plan to address the broad issue of controlling pathogens, including SE, in shell eggs and egg products, and to take a farm-to-table approach. We also expect it to address research needs and enhance additional Federal-State partnerships.

We are pleased with the progress made so far on the safety of shell eggs and egg products and with the emerging data that show reductions in foodborne illness attributed to SE. We look forward to continuing to work closely with FDA on a broad strategy for change. This concludes my testimony and I thank you for the opportunity to be here today. I, and those accompanying me from other mission areas within USDA, will be happy to answer any questions you or other Members of the Subcommittee may have.

CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
Publisher of *Nutrition Action Healthletter*

Testimony of Michael Jacobson, Ph.D.
Executive Director
and Caroline Smith DeWaal
Director of Food Safety
before the
Senate Committee on Government Affairs
on
"Egg Safety: Are There Cracks in the Federal Food Safety System"

Washington, DC
July 1, 1999

Good morning. I am Michael Jacobson, Executive Director of the Center for Science in the Public Interest (CSPI). CSPI is a non-profit consumer-advocacy organization with one million members that focuses on nutrition, food safety, and alcohol issues. Accompanying me today is Caroline Smith DeWaal, director of food safety at CSPI, who co-authored CSPI's report, *Scrambled Eggs: How a Broken Food-Safety System Let Contaminated Eggs Become a National Food Poisoning Epidemic.*[1] We have attached a copy of that report to this testimony for inclusion in the hearing record.

Most consumers think that the government is making sure their food is safe. But the government watchdogs were asleep while eggs contaminated with *Salmonella* grew into a

[1] Elizabeth Dahl and Caroline Smith DeWaal, *Scrambled Eggs: How a Broken Food Safety System Let Contaminated Eggs Become a National Food Poisoning Epidemic*, (Washington, DC: Center for Science in the Public Interest, May 1997).

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national public-health epidemic. Fifteen to twenty years ago, a strain of *Salmonella* called "*enteritidis*" developed the ability to infect a chicken's ovaries and enter the egg before it is laid. The advent of that enterprising new strain of bacterium means that it is no longer safe to eat runny eggs, taste cookie dough, or enjoy raw eggs in desserts and salads.

Today, infected chickens lay an estimated 2.3 million eggs each year seeded with *Salmonella* inside the shell, any one of which could cause an illness or an outbreak of food poisoning.[2] According to data collected by CSPI from the Centers for Disease Control and Prevention (CDC) and other sources, since 1990, eggs have been directly linked to at least 123 separate outbreaks of food poisoning, mostly from *Salmonella enteritidis* (SE) (See Appendix A).[3] While those data represent just a partial listing of outbreaks from eggs, they clearly show that the tiny bacterium has fostered a major public health problem.

A recent risk assessment on eggs conducted by the US Department of Agriculture (USDA) said that SE-contaminated eggs have caused an average of 661,633 illnesses and 331 deaths annually.[4] While recent CDC data suggest that the number of outbreaks and illnesses linked to SE has begun to decline[5] (a fact probably linked in part to focused consumer education

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[2] *Salmonella enteritidis* Risk Assessment Team, for the U.S. Department of Agriculture, Food Safety and Inspection Service, "*Salmonella enteritidis* Risk Assessment. Shell Eggs and Egg Products. Final Report," June 12, 1998, p. 1 [hereinafter cited as *Salmonella enteritidis Risk Assessment*].

[3] Center for Science in the Public Interest, "Outbreaks Traced to FDA-Regulated Foods, 1990-1999," Updated June 18, 1999.

[4] *Salmonella enteritidis Risk Assessment*, p. 1.

[5] Centers for Disease Control and Prevention, "Incidence of Foodborne Illnesses: Preliminary Data from the Foodborne Diseases Active Surveillance Network (FoodNet) -- United States, 1998," *Morbidity and Mortality Weekly Report*, Vol. 48, No. 9 (1999), pp. 189-194.

on the hazards of eggs), many more illnesses could be prevented with better government oversight of the egg industry.

In 1986, CDC first identified SE in eggs as a public-health problem, when a food-poisoning outbreak in seven states sickened more than 3,000 people.[6] Since then, the fractured federal food-safety system has taken only baby steps to remedy this serious problem.

What has happened during the last 13 years? With four government agencies sharing responsibility for regulating eggs and the egg industry, consumers certainly expect that the SE problem would have been dealt with expeditiously. But this may be a case of too many cooks spoiling the broth:

- The Food and Drug Administration (FDA), at the Department of Health and Human Services, has food-safety oversight of shell eggs and some processed eggs, but rarely inspects those plants.
- The Food Safety and Inspection Service (FSIS), an agency of the USDA, has responsibility over most pasteurized egg products, which pose only a minimal risk, and inspects those plants daily.
- USDA's Agricultural Marketing Service (AMS) provides voluntary shell egg grading services and inspects shell egg plants four times a year for cleanliness and quality control.
- Finally, USDA's Animal and Plant Health Inspection Service (APHIS) has responsibility for preventing the spread of animal diseases.

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[6] U.S. General Accounting Office, *Food Safety and Quality: Salmonella Control Efforts Show Need for More Coordination*, (Washington, DC: U.S. General Accounting Office, April 1992), p. 10.

Not one of those agencies has taken the necessary steps to keep eggs safe, either by preventing the spread of SE among chicken flocks, or by diverting SE-contaminated eggs to egg-pasteurization plants.

This chart highlights just some of the ways that a tiny foodborne bacterium outsmarted the federal government:

- In 1986, *Salmonella enteritidis* caused almost 6,000 *reported* cases of food poisoning.[7] Those cases represent just a small fraction of all cases.
- In 1987, APHIS decided not to establish a mandatory *Salmonella* control program for egg producers.[8] By contrast, in the early 1980s, USDA spent at least $60 million to combat an outbreak of Avian Influenza, a virus that affects poultry but poses no human health threat, by destroying flocks and reimbursing owners.[9] For SE, however, USDA opted for a voluntary control program to avoid having to reimburse flock owners for their losses.[10] As those instances demonstrate, APHIS has put the health of the poultry industry ahead of the health of consumers.

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[7] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "*Salmonella* Isolations from Human Sources by Serotype and Year Reported to CDC, 1985-1995," *Salmonella Surveillance: Annual Tabulation Summary 1993-1995* (Atlanta: U.S. Department of Health and Human Services), Table 3 [hereinafter cited as *Salmonella Isolations, 1985-1995*].

[8] Bruce Ingersoll, "U.S. to Mandate Testing of Poultry for *Salmonella*," *Wall Street Journal*, February 20, 1990, p. B5 [hereinafter cited as *Testing of Poultry for Salmonella*].

[9] Telephone conversation with Dawn Kent, Public Affairs, APHIS, Washington, D.C., April 29, 1997; 9 C.F.R. § 53.2.

[10] *Testing of Poultry for Salmonella*, p. B5.

- In 1989, 8,500 cases of food poisoning from SE were reported, a 40% increase in just three years.[11] Clearly, USDA's voluntary program was not working. But instead of working together, USDA and FDA simultaneously began developing competing mandatory SE-control programs. FDA officials refused to discuss with APHIS their proposed plan, which required testing of all laying flocks in the U.S., until after FDA had publicly announced it. Later in 1989, APHIS announced its own significantly weaker SE-control program, and FDA withdrew its stronger plan. Clearly, resources were wasted while the agencies developed competing plans and, in the end, the agencies failed to achieve the highest level of public-health protection.
- By 1991, APHIS finally had its mandatory SE-control program in place. Unfortunately, that program didn't require on-farm testing for the SE bacteria for the entire egg industry. Egg producers had to clean up their farms only when traceback investigations *proved* that eggs from their flocks had caused food poisonings or if the laying hens were from already-identified infected breeder flocks.[12] To make matters worse, the investigations that traced cases of food-poisoning back to a given producer

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[11] *Salmonella Isolations, 1985-1995.*

[12] 9 C.F.R. §§ 71, 82.

were expensive and time-consuming, so APHIS completed only a small number each year.[13]

- Also in 1991, Congress passed a law requiring eggs to be refrigerated during transportation and storage.[14] Refrigeration helps prevent the SE bacteria from multiplying inside infected eggs. However, due to bureaucratic delays and opposition from some parts of the industry, in the last eight years USDA has never enforced that law. (It is finally scheduled for implementation this August, after the House Appropriations Committee threatened to withhold some funding from FSIS.[15])
- In 1992, USDA, the Pennsylvania government, and Pennsylvania egg producers began a voluntary pilot program.[16] The program required that all participating producers test their flocks for SE bacteria.[17]
- In 1995, with over 10,000 cases of food poisoning from SE being reported nationwide, it was clear that APHIS's program was a failure.[18] But the news from Pennsylvania was better. The pilot program apparently reduced

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[13] "SE Traceback Program Decreased in Effectiveness, USDA Office of Inspector General Reports," *Food Chemical News*, January 15, 1996, p. 23.

[14] 21 U.S.C. § 1034(e).

[15] Department of Agriculture, Food Safety and Inspection Service, "Refrigeration and Labeling Requirements for Shell Eggs, Final Rule and Request for Comments," *Federal Register*, Vol. 63, No. 166 (1998), p. 45663.

[16] Pennsylvania Poultry Producers, et al., "*Salmonella enteritidis* Pilot Project Progress Report," May 22, 1995, p. 1.

[17] Pennsylvania Poultry Federation, "Pennsylvania Egg Quality Assurance Program," May 1994.

[18] *Salmonella Isolations, 1985-1995.*

the number of SE-infected flocks.[19] Despite those encouraging results, at the urging of the egg industry, Congress eliminated USDA's funding for the pilot program, thereby preventing USDA from expanding the program nationally.[20]

In 1997, in an effort to jump-start government efforts, CSPI petitioned the FDA to develop a mandatory on-farm control program for SE in eggs, modeled after the Pennsylvania program.[21] CSPI also petitioned FDA to require a warning label on egg cartons alerting consumers to the risk from SE and advising them not to eat eggs raw or undercooked.[22]

There has been little visible action since CSPI petitioned the FDA. Last summer, FDA and USDA issued an advance notice of proposed rulemaking that included several of CSPI's proposals,[23] but no new rules have emerged. This August, USDA finally will implement the Congressionally mandated 45-degree refrigeration requirement for eggs during transportation and storage.[24] That action comes eight years after Congress first instructed the agency to do so, and

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[19] Allan Hogue, et al., *Salmonella enteritidis Review Team Report*, Final, January 18, 1997, pp. 1-3, 9-10.

[20] Conversation with Robert Tauxe, CDC, Washington, DC, Oct. 30, 1996; "FSIS Budget Set by House, Senate 'Not Encouraging,' Official Says," *Food Chemical News*, October 2, 1995, p. 43.

[21] Center for Science in the Public Interest, "Petition for Regulatory Action to Require That (1) Warning Labels About the Risks of *Salmonella enteritidis* (SE) Be Placed on Shell Egg Cartons and (2) SE Control HACCP Programs Be Implemented on All Egg-Producing Farms," FDA Docket No. 97-P0197, May 14, 1997, pp. 12-15.

[22] *Ibid.*, pp. 9-11.

[23] Department of Agriculture, Food Safety and Inspection Service, and Department of Health and Human Services, Food and Drug Administration, "*Salmonella enteritidis* in Eggs, Advance Notice of Proposed Rulemaking; Request for Comments," *Federal Register*, Vol. 63, No. 96 (1998), pp. 27502-27511.

[24] Department of Agriculture, Food Safety and Inspection Service, "Refrigeration and Labeling Requirements for Shell Eggs, Final Rule and Request for Comments," *Federal Register*, Vol. 63, No. 166 (1998), p. 45663.

two years after Dateline NBC aired a story on egg safety highlighting the agency's failure to mandate temperature requirements.[25]

While those modest actions signal an increased willingness to tackle egg safety, FDA and USDA have so far failed to utilize the most effective public-health measure to combat SE: on-farm Hazard Analysis and Critical Control Points (HACCP) programs for shell-egg producers. Though temperature controls and labeling help prevent illnesses from contaminated eggs, on-farm HACCP programs would help prevent eggs from being infected with SE in the first place.

A mandatory on-farm HACCP system should be the cornerstone of a comprehensive regulatory program for shell eggs. HACCP systems are flexible, they are effective and they are economical, especially when the costs of preventing food poisoning are factored in.

Under an on-farm HACCP program, eggs from any flocks that test positive for SE could be diverted to egg-pasteurization plants, which sell liquid and powdered egg products. In a risk assessment of the shell-egg production system, researchers estimated that diverting 25 percent of eggs from SE-positive flocks from the shell egg market would reduce human illness by 25 percent,[26] and diversion of a greater number of eggs should have a proportionately greater public health impact. On-farm HACCP, coupled with egg diversion, is the only measure that would greatly reduce the number of SE-contaminated shell eggs reaching consumers.

While an anticipated White House announcement on egg safety will represent the first significant effort to coordinate policy between USDA and FDA, a farm-to-table SE-control

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[25] *Ibid;* Dateline NBC, air date September 17, 1996. Dateline also ran a story last year highlighting the practice of redating and repackaging old eggs. Dateline NBC, air date April 7, 1998, update April 21, 1998. USDA took steps to address that practice in AMS's voluntary grading program. For other eggs, the practice is allowed.

[26] *Salmonella enteritidis Risk Assessment,* p. 25.

program would be far easier to implement if a single agency were responsible for ensuring shell-egg safety. The examples I have cited previously of overlapping responsibilities between agencies, the irrational assignment of inspectors, and agencies developing duplicative and competing SE-control programs illustrate the clear need for more central federal oversight of food safety. That is why we strongly support legislation sponsored by Senator Durbin to unite the federal food- safety programs into a single independent Food Safety Administration.[27]

Thank you for your attention to this important public health problem. I would be happy to answer your questions.

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[27] Safe Food Act of 1999, S. 1281, 106th Cong.

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Appendix A

Outbreaks Traced to Eggs, 1990-1998

	Date	Vehicle	Etiology	Reported Cases	States/ Provinces
1	June 1990	Hollandaise sauce (shell eggs)	Salmonella enteritidis	169	1:CT
2	June - July 1990	Egg dishes	Salmonella enteritidis	94	1:PA
3	Aug. 1990	Hollandaise sauce (shell eggs)	Salmonella enteritidis	42	1:KY
4	Oct. 1990	Bread pudding (shell eggs)	Salmonella enteritidis	1,100	1:IL
5	Oct. 1990	Banana pudding (shell eggs)	Salmonella enteritidis	6	1:TN
6	1991	Bread stuffing (shell eggs)	Salmonella enteritidis	393	1:NY
7	Oct. 1991	Caesar salad dressing (shell eggs); raw egg dishes	Salmonella enteritidis; Salmonella Group D	38	Not available
8	1992	Egg sandwich	Salmonella enteritidis	Not available	1:NY
9	1992	Ice cream (shell eggs)	Salmonella typhimurium	31	Not available
10	Feb. 1992	Lasagna (shell eggs)	Salmonella enteritidis	9	1:OH
11	Feb. 1992	Ice cream (shell eggs)	Salmonella enteritidis	10	1:PA
12	Apr. 1992	Banana pudding w/meringue (shell eggs)	Salmonella enteritidis	191	1:NJ
13	May 1992	Cracker pudding (shell eggs)	Salmonella enteritidis	42	1:PA
14	May 1992	Fish w/ aioli sauce (shell eggs)	Salmonella enteritidis	31	1:CT
15	July 1992	Meringue pies (shell eggs)	Salmonella enteritidis	7	1:PA

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Outbreaks Traced to Eggs,
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	Date	Vehicle	Etiology	Reported Cases	States/ Provinces
16	July 1992	Crab cakes (shell eggs)	Salmonella enteritidis	5	1:MD
17	July 1992	Egg salad	Salmonella enteritidis	27	1:PA
18	July 1992	Monte Cristo sandwiches (shell eggs)	Salmonella enteritidis	74	1:MA
19	July 1992	Rice pudding (shell eggs)	Salmonella infantis	113	1:GA
20	Aug. 1992	Egg batter	Salmonella enteritidis	434	1:NY
21	Aug. 1992	Crab cakes/balls (shell eggs)	Salmonella enteritidis	25	1:MD
22	Aug. 1992	Imitation crab meat pancakes (shell eggs)	Salmonella enteritidis	118	1:MD
23	Aug. 1992	Ice cream (shell eggs)	Salmonella enteritidis	15	1:OH
24	Aug. 1992	Spanish cream (shell eggs)	Salmonella enteritidis	8	1:PA
25	Sept. 1992	Ravioli (shell eggs)	Salmonella enteritidis	6	1:PA
26	Oct. 1992	Coconut cream/lemon meringue pie (shell eggs)	Salmonella enteritidis	27	1:PA
27	Sept. 1992	Chicken salad (shell eggs)	Salmonella enteritidis	194	1:DE
28	Sept. 1992	Egg sandwich	Salmonella enteriditis	75	1:NH
29	Dec. 1992 - Jan. 1993	Egg dishes	Salmonella enteritidis	6	1:CA
30	Jan. 1993	Lemon meringue pie (shell eggs)	Salmonella enteritidis	4	1:MD
31	Feb. 1993	Pancakes (shell eggs)	Salmonella enteritidis	22	1:IL
32	Feb. 1993	Hollandaise sauce (shell eggs)	Salmonella enteritidis	23	1:CA
33	Feb. 1993	Egg dishes	Salmonella enteritidis	47	1:PA
34	Mar. 1993	Mayonnaise (shell eggs)	Salmonella enteritidis	38	1:CA
35	Mar. 1993	Egg dishes	Salmonella enteritidis	22	1:NV
36	Mar. 1993	Lasagna (shell eggs)	Salmonella enteritidis	7	1:NY
37	Mar. 1993	Stuffed shells (shell eggs)	Salmonella enteritidis	25	1:CT

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	Date	Vehicle	Etiology	Reported Cases	States/ Provinces
38	Apr. 1993	Egg rolls (shell eggs)	Salmonella enteritidis	130	1:TX
39	Apr. 1993	Rellenos (shell eggs)	Salmonella enteritidis	4	1:WA
40	July 1993	Ice cream (shell eggs)	Salmonella enteritidis	8	1:MD
41	July 1993	Stuffing (shell eggs); egg dishes	Salmonella enteritidis	11	1:PA
42	July 1993	Chocolate meringue pie (shell eggs)	Salmonella enteritidis	23	1:VA
43	Aug. 1993	Potato filling (shell eggs)	Salmonella enteritidis	29	1:PA
44	Sept. 1993	Chocolate mousse (shell eggs)	Salmonella enteritidis	70	1:NJ
45	Sept. 1993	Egg rolls (shell eggs)	Salmonella enteritidis	19	1:TX
46	Sept. 1993	Hard boiled eggs	Salmonella enteritidis	175	1:VT
47	Sept. 1993	Ice cream (shell eggs)	Salmonella enteritidis	13	1:FL
48	Sept. 1993	Tiramisu (shell eggs)	Salmonella enteritidis	5	1:NY
49	Sept. 1993	Baked ziti (shell eggs)	Salmonella enteritidis	23	1:CT
50	Oct. 1993	Lasagna (shell eggs)	Salmonella enteritidis	21	1:MA
51	Nov. 1993	Bearnaise sauce (shell eggs)	Salmonella enteritidis	13	1:IL
52	Nov. 1993	Stuffing (shell eggs)	Salmonella enteritidis	10	1:PA
53	Nov. 1993	Shrimp and bearnaise sauce (shell eggs)	Salmonella enteritidis	52	1:NC
54	Aug. 1994	Hollandaise sauce (shell eggs)	Salmonella enteritidis; Salmonella Group D	56	1:DC
55	Jan. 1995	Rice pudding (shell eggs)	Salmonella enteritidis	7	1:PA
56	Feb. 1995	Lasagna (shell eggs)	Salmonella enteritidis	7	1:CA
57	June 1995	Scrambled eggs	Salmonella enteritidis	40	1:IN
58	June 1995	Caesar salad dressing (shell eggs)	Salmonella enteritidis	28	1:NY
59	June 1995	Ice cream (shell eggs)	Salmonella enteritidis	27	1:VA

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	Date	Vehicle	Etiology	Reported Cases	States/ Provinces
60	June 1995	Egg dishes	Salmonella enteritidis	8	1:CA
61	June 1995	Ice cream (shell eggs)	Salmonella Group D	7	1:MD
62	June 1995	Baked eggs	Salmonella enteritidis	≈70	1:IN
63	June 1995	Caesar salad dressing (shell eggs)	Salmonella enteritidis; Salmonella Group D	28	1:NY
64	July 1995	Crab meat stuffing (shell eggs)	Salmonella enteritidis	23	1:NJ
65	July 1995	"Jamaican malt" beverage (shell eggs)	Salmonella enteritidis	3	1:NY
66	Aug. 1995	Eggs benedict w/ Hollandaise sauce (shell eggs)	Salmonella enteritidis	13	1:WI
67	Aug. 1995	Cake (shell eggs)	Salmonella enteritidis	16	1:CA
68	Sept. 1995	Spinach souffle (shell eggs)	Salmonella enteritidis	13	1:CT
69	Sept. 1995	Cheesecake (shell eggs)	Salmonella enteritidis	18	1:PA
70	Oct. 1995	Bearnaise sauce (shell eggs)	Salmonella enteritidis	3	1:PA
71	Dec. 1995	Eggnog (shell eggs)	Salmonella enteritidis	5	1:NY
72	Jan. 1996	Egg containing dishes	Salmonella enteritidis	20	1:CA
73	Jan. 1996	Chicken fried steak (shell eggs)	Salmonella enteritidis	30	1:UT
74	May 1996	Egg containing foods	Salmonella enteritidis	30	1:GA
75	May 1996	Salad dressing (shell eggs)	Salmonella enteritidis	21	1:CA
76	June 1996	Ice cream (shell eggs)	Salmonella enteritidis	2	1:OH
77	June 1996	Ice cream (shell eggs)	Salmonella enteritidis	32	1:CA
78	July 1996	Ice cream (shell eggs)	Salmonella enteritidis	109	1:OH
79	July 1996	Rice pudding (shell eggs)	Salmonella enteritidis	26	1:PA
80	July 1996	Ice cream (shell eggs)	Salmonella enteritidis	11	1:OH
81	July 1996	French toast (shell eggs)	Salmonella enteritidis	6	1:OH

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	Date	Vehicle	Etiology	Reported Cases	States/ Provinces
82	July 1996	Multiple eggs dishes	Salmonella enteritidis	15	1:NY
83	July 1996	Ice cream (shell eggs)	Salmonella enteritidis	21	1:CA
84	July 1996	Egg rolls (shell eggs)	Salmonella enteritidis	18	1:CA
85	Aug. 1996	Raw egg dishes	Salmonella enteritidis	10	1:CA
86	Aug. 1996	Baked ziti (shell eggs)	Salmonella enteritidis	12	1:NY
87	Sept. 1996	Egg salad (shell eggs)	Salmonella enteritidis	250	1:SC
88	Sept. 1996	Eggs	Salmonella enteritidis	250	1:SC
89	Oct. 1996	Ice cream (shell eggs)	Salmonella enteritids	NA	1:NM
90	Nov. 1996	Raw eggs in dish	Salmonella enteritidis	22	1:VA
91	Dec. 1996	Ice cream (shell eggs)	Salmonella enteritidis	14	1:PA
92	Feb. 1997	Eggs benedict	Salmonella enteritidis	7	1:CA
93	Apr. 1997	Bearnaise sauce (shell eggs)	Salmonella enteritidis	30	1:NJ
94	Apr. 1997	Pastries (shell eggs)	Salmonella enteritidis	17	1:CT
95	May 1997	Omelets	Salmonella enteritidis	9	1:WI
96	May 1997	Crab cakes (shell eggs)	Salmonella enteritidis	6	1:MD
97	July 1997	Crab cakes (shell eggs)	Salmonella enteritidis	14	1:PA
98	July 1997	Omelets	Salmonella enteritidis	3	1:OH
99	July 1997	Sushi with egg	Salmonella enteritidis	77	1:CA
100	Aug. 1997	Bearnaise sauce (shell eggs)	Salmonella enteritidis	50	1:PA
101	Aug. 1997	Cheescake (shell eggs)	Salmonella enteritidis	13	1:CA
102	Aug. 1997	Chicken fried rice (shell eggs)	Salmonella enteritidis	13	1:OH
103	Sept. 1997	Chopped boiled eggs	Salmonella enteritidis	192	1:SC
104	Sept. 1997	Chile relleno (shell eggs)	Salmonella enteritidis	5	1:CA
105	Oct. 1997	Lasagna (shell eggs)	Salmonella enteritidis	43	1:DC

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	Date	Vehicle	Etiology	Reported Cases	States/ Provinces
106	Nov. 1997	Eggs benedict	Salmonella enteritidis	27	1:WI
107	Nov. 1997	Pooled egg dishes	Salmonella enteritidis	55	1:CA
108	Nov. 1997	Hollandaise sauce (shell eggs)	Salmonella enteritidis	93	1:NV
109	Jan. 1998	Tiramisu (shell eggs)	Salmonella enteritidis	8	1:MD
110	Jan. 1998	Turkey stuffing (shell eggs)	Salmonella enteritidis	5	1:CA
111	Jan. 1998	Lasagna (shell eggs)	Salmonella enteritidis	26	1:CA
112	Mar. 1998	Cream pies (shell eggs)	Salmonella enteritidis	19	1:VA
113	Mar. 1998	Eggs	Salmonella montevideo	5	1:OH
114	July 1998	Chile rellenos (shell eggs)	Salmonella enteritidis	58	1:AZ
115	July 1998	Ice cream (shell eggs)	Salmonella enteritidis	6	1:PA
116	Aug. 1998	Eggs	Salmonella enteritidis	40	1:HI
117	Aug. 1998	Ice cream (shell eggs)	Salmonella enteritidis	11	1:TX
118	Sept. 1998	Mexican cake (shell eggs)	Salmonella enteritidis	50	1:MD
119	Sept. 1998	Ziti (shell eggs)	Salmonella enteritidis	71	1:NV
120	Oct. 1998	Chile rellenos (shell eggs)	Salmonella enteritidis	18	1:CA
121	Nov. 1998	Stuffing (shell eggs)	Salmonella enteritidis	12	1:PA
122	Dec. 1998	Stuffing (shell eggs)	Salmonella enteritidis	21	1:PA
123	Dec. 1998	Oyster stuffing (shell eggs)	Salmonella enteritidis	7	1:PA

Compiled by CSPI
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Scrambled Eggs

HOW A BROKEN FOOD SAFETY SYSTEM LET CONTAMINATED EGGS BECOME A NATIONAL FOOD POISONING EPIDEMIC

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EXECUTIVE SUMMARY

Eggs used to be safe. Parents, without worrying, could let their children lick the bowl after preparing cakes and cookies. Consumers, without fear, could eat raw or undercooked eggs in salad dressings, egg nog and stuffing. Sunny-side-up eggs with runny yolks were great with toast. Now those same cooking practices can lead to severe illness and even death, if the eggs are contaminated with *Salmonella*.

What happened to safe eggs? Why are eggs today associated with more food poisoning outbreaks than any other single food? Why are public health officials now urging us to eat only fully cooked shell eggs or to use pasteurized egg products?

The answers to those questions involve a complex story with numerous plot twists: a biological adaptation that allowed bacteria to enter otherwise sterile eggs; federal agencies inspecting frequently to assure egg quality but never providing regulations adequate to ensure egg safety; and industry lobbyists dictating Congressional action.

The result is that eggs have become the number one contributor to food poisoning outbreaks in the nation, with annual consumer costs in the hundreds of millions of dollars. Hundreds, and possibly thousands, of people die every year from contaminated eggs.

The story began when a strain of *Salmonella* bacteria called *enteritidis* found its way first into the ovaries of chickens and then into their eggs. The problem was identified by federal disease detectives in the mid 1980s. The first farms producing contaminated eggs were located in the northeastern U.S. and with quick action, the problem might have stopped there. But the numerous federal agencies with oversight responsibilities for eggs didn't act. Instead they competed with each other, stumbled over each other, and ultimately backed down in the face of industry pressure. Meanwhile, *Salmonella enteritidis* (SE) reached epidemic proportions.

Today, internally contaminated eggs are showing up from coast to coast. There is no way to tell without laboratory testing which eggs contain *Salmonella* and which ones are contamination-free. Grading programs run by the United States Department of Agriculture continuously check Grade A eggs for blood spots and yolk size, but have no controls for the harmful bacteria found in eggs. That responsibility falls to the Food and Drug Administration, which inspects egg plants an average of once every 10 years and merely recalls already-tainted food instead of preventing contaminated food from reaching the market. Consumers are generally unaware of the hazard and continue to eat raw and undercooked eggs, without realizing that such practices are risky.

Key Conclusions and Recommendations

The history of the federal government's failure to curb the SE epidemic illustrates the ineffectiveness of having multiple government agencies responsible for regulating the same food. The agencies were further hamstrung by a Congress that cut funding for a pilot control program just as it was beginning to show results and an industry that, except for producers in Pennsylvania, resisted attempts to prevent egg contamination on the farm.

Effective government action could have prevented many illnesses and deaths over the past twenty years and could prevent countless future unnecessary tragedies. To protect consumers from the hazards of SE, we recommend the following steps.

- FDA should mandate that egg producers implement on-farm Hazard Analysis and Critical Control Point (HACCP) programs to control SE. The SE control programs should be modeled after the successful Pennsylvania Egg Quality Assurance Program. The programs should include testing of manure and eggs. That testing should be monitored by FDA.

- Shell egg plants should be inspected for safety at least several times per year. These inspections should verify that plants only accept eggs from farms with SE testing programs in place and should ensure that eggs from infected flocks are diverted to pasteurization plants.

- FDA and FSIS should act quickly to implement science-based regulations mandating egg refrigeration at 41 degrees F during transportation and storage. Temperature requirements should be standardized across all the government agencies that regulate food, including the state and local governments responsible for enforcing temperatures at the retail level. Retailers and consumers should be informed that eggs should be kept refrigerated.

- Until the egg industry has effective programs in place to control SE, consumers must be warned that they risk illness from eating raw or undercooked eggs. FDA should mandate that the following label be placed on the tops of egg cartons: "Caution: Eggs may contain illness-causing bacteria. Do not eat raw. Cook until yolk is firm."

- FDA's Food Code should recommend that restaurants and other establishments not pool unpasteurized eggs unless they are cooked immediately.

- Food safety responsibility for eggs should be consolidated under the clearly defined authority of one of the two food safety agencies, either FSIS or FDA. Clear jurisdiction is needed to avoid agency competition and miscommunication.

- Congress should significantly increase funding for FDA's food safety functions and should fully fund FSIS's and FDA's efforts to address SE in eggs. President Clinton's request for additional funding for food safety is an important step in ensuring that these agencies can adequately protect the public health.

INTRODUCTION

Eggs, once considered a safe food, have become increasingly contaminated over the last 15 years by a strain of *Salmonella* bacteria known as *Salmonella enteritidis,* or SE. While *Salmonella* sometimes is present on the outside of egg shells, no one ever thought the *inside* of eggs could be contaminated by bacteria. It was a surprise when government scientists first linked human illness from SE to internally contaminated eggs in 1986.[1]

Since the early 1980s, the SE problem in shell eggs (fresh eggs purchased in cartons) has ballooned out of control. The Centers for Disease Control and Prevention (CDC) reported five times as many SE cases in 1995 as in 1980. (See Figure 1.) By 1994, SE caused an estimated 200,000 to one million human cases of salmonellosis each year. Contaminated eggs cause at least 80 percent of these illnesses, according to data from CDC.[2]

Illness from SE can be fatal to the elderly, children, and those with weakened immune systems.[3] *The SE bacteria caused more reported deaths between 1988 and 1992 than any other foodborne pathogen.*[4] *Hundreds or even thousands of people die from eating SE-tainted eggs each year.*[5]

SE is responsible for the lion's share of food poisoning illnesses, about a third of all food poisoning outbreaks where the cause is known. (See Figure 2.) The estimated annual cost of illness from SE ranges from $118 million to $767 million.[6] The magnitude of the current SE crisis was not inevitable. Before 1984, SE outbreaks were largely confined to one geographical area, the northeastern United States. The problem spread to the mid-Atlantic states in the late 1980s. In 1992, a government-supported control program began in Pennsylvania that required testing of hens and cleaning of poultry houses. This program showed promise in reducing the number of food poisonings from SE. However, federal support for that program was discontinued in 1995, and no nationwide program has ever been implemented.

The government response to SE-tainted eggs has been inadequate and ineffective. When *Salmonella* showed up on the outside of egg shells in the 1970s, government programs helped to curb the problem. Unfortunately, no similar programs were developed to stop the internal contamination of eggs with SE. A number of factors have contributed to the federal government's failure to control the SE epidemic: overlapping and unclear lines of jurisdiction between different government agencies; inter-agency competition; lack of support from Congress; and a lack of urgency among health officials.

Among other absurdities, a system has developed in which shell eggs are monitored continuously for quality and cleanliness by a federal marketing agency, but are inspected for microbiological and chemical contamination by the leading federal food safety agency *only once every ten years,* on average. Egg product plants (plants that produce liquid, frozen or powdered egg products) are inspected continuously by yet a third agency.

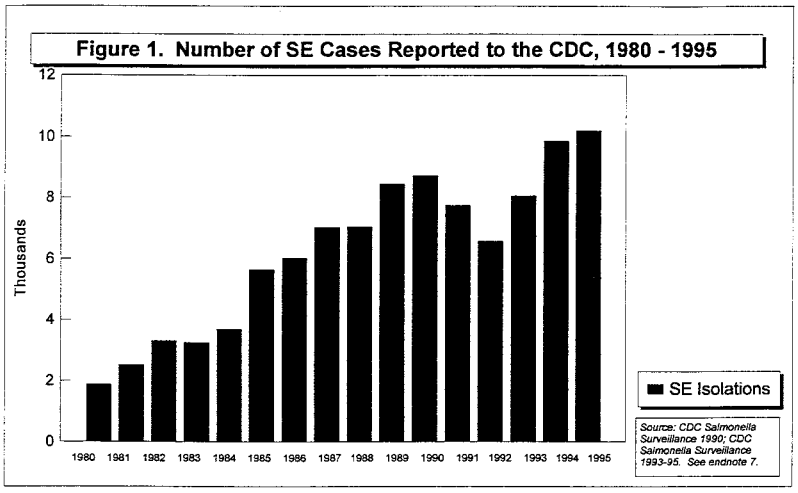


Figure 1. Number of SE Cases Reported to the CDC, 1980 - 1995
Thousands
12
10
8
6
4
2
0
1980 1981 1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995
SE Isolations
Source: CDC Salmonella Surveillance 1990; CDC Salmonella Surveillance 1993-95. See endnote 7.

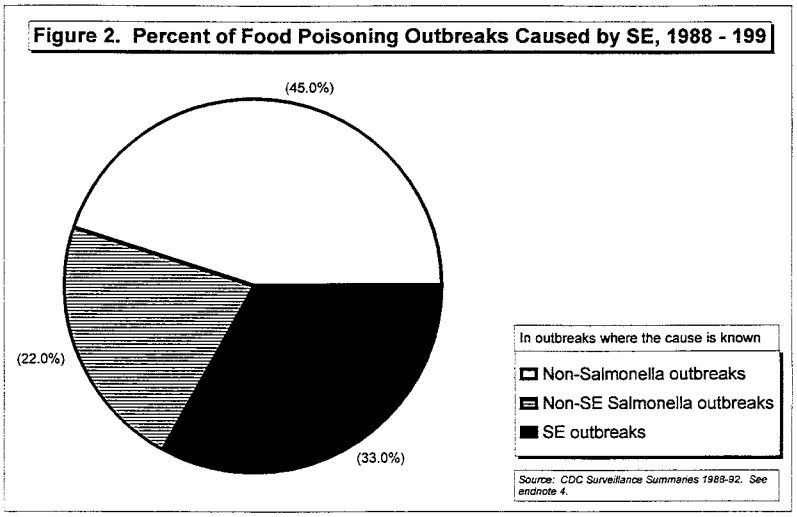


Figure 2. Percent of Food Poisoning Outbreaks Caused by SE, 1988 - 199
(45.0%)
(22.0%)
(33.0%)
In outbreaks where the cause is known
Non-Salmonella outbreaks
Non-SE Salmonella outbreaks
SE outbreaks
Source: CDC Surveillance Summaries 1988-92. See endnote 4.

SE Has Increased Throughout the Nation

Between 1980 and 1995, the number of SE cases reported in the U.S. increased by more than fivefold.[7] SE, which had been present in low levels, began growing out of control in the northeastern United States and then steadily increased across the country.

By 1984, SE began appearing in larger numbers outside the Northeast.[8] (See Figures 3 and 4 and Appendix.) By 1986, the year CDC first linked SE to consumption of raw and undercooked eggs that were internally contaminated, the incidence of SE in the Northeast had increased more than sixfold over 1976 levels.[9] While the number of cases of illness leveled off in the Northeast between 1990 and 1994, cases in the Rocky Mountain region doubled and cases in the Pacific region quadrupled during that same time period.[10] In 1994, California accounted for about a quarter of the nation's laboratory-confirmed cases of SE.[11] A USDA survey showed that the frequency of SE isolates in unpasteurized liquid eggs nearly doubled in the northeastern and western U.S. between 1991 and 1995.[12]

To make matters worse, a more virulent form of SE, known as SE phage type 4, has appeared in five SE outbreaks in California and has also appeared in Utah, Arizona and Nevada.[13] Although scientists do not yet know why, this new type causes five times as many human salmonellosis cases as other types of SE in the regions where it appears.[14] In Europe, phage type 4 has become the predominant form of SE.[15]

Even though CDC data in 1986 clearly documented the increase in the number of human illnesses from SE, federal food safety officials allowed SE to continue to spread around the country, resulting in millions of illnesses and thousands of deaths over the past 10 years. (See Table 1.) The federal government partially funded and pilot-tested an SE control program from 1992 to 1995 in Pennsylvania. However, this program did not develop into a comprehensive, nationally coordinated approach to testing for and controlling SE. Instead, in 1995, at the urging of the egg industry, Congress cut the federal funding for this program and prohibited USDA employees from working on the SE problem.[16]

Figure 3. Number of Confirmed SE Cases, 1995

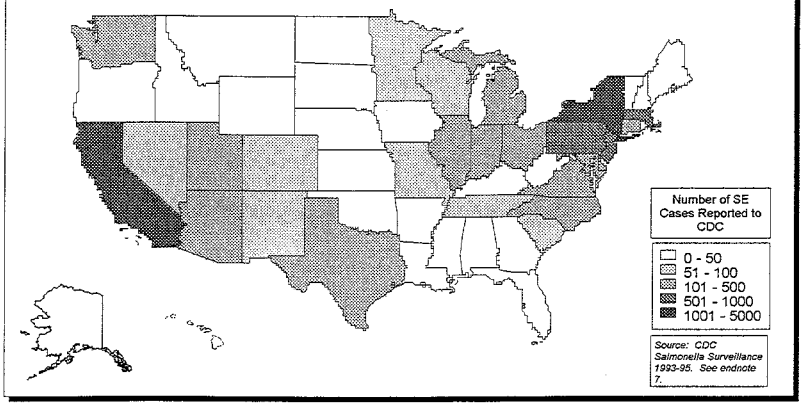
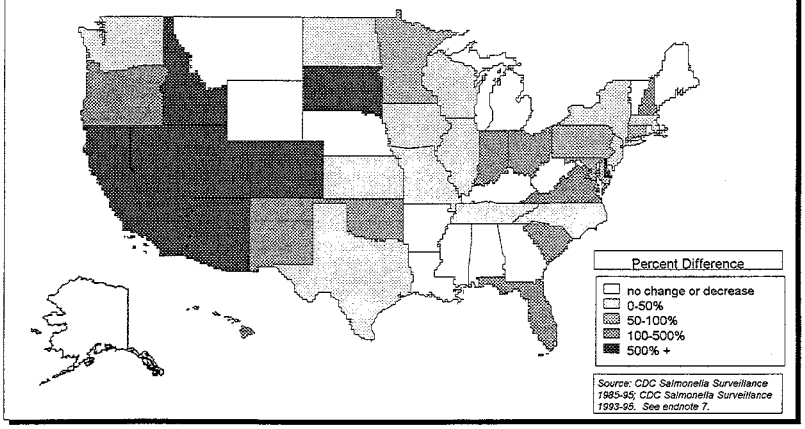


Figure 4. Increase in SE Cases, 1985-1995



Consumers Are at Risk of Illness from SE in Eggs

SE is found inside eggs laid by otherwise healthy hens that are infected by the bacteria.[17] It is estimated that one out of every 10,000 eggs, or about 4.5 million eggs each year, are infected with SE.[18] Consumers have no way of knowing which eggs are infected. The SE bacteria multiply inside eggs that are not properly refrigerated (to an internal temperature of 45 degrees F.) As few as 10 to 100 SE organisms may be enough to cause illness in elderly people, children, and the immuno-compromised.[19]

The elderly residents of nursing homes are especially at risk of death from SE: 85 percent of reported deaths from SE between 1988 and 1992 were from this group.[20] SE infection causes flu-like symptoms, such as diarrhea, abdominal pain, nausea, fever and chills, and can have more serious complications, such as rheumatoid arthritis, meningitis, kidney or heart disease, and death.

Thorough cooking of eggs will kill the bacteria. However, many common egg-preparation practices are not sufficient to kill SE. Some high-risk practices include:

- serving eggs "sunny side up," lightly poached, soft-boiled, or any other style where the yolk is still runny
- preparing French toast with an egg coating that is not thoroughly cooked
- using raw eggs in cookie dough or cake batter which is eaten before cooking
- using raw eggs in salad dressing, such as Caesar salad or homemade mayonnaise
- using raw eggs in eggnog
- using lightly cooked eggs in desserts, such as meringue and tiramisu

Another high-risk practice common in restaurants, nursing homes, and other institutions is pooling eggs in a large container after breaking and before cooking them. One SE-positive egg can contaminate dozens of others. This practice can result in major outbreaks of human illness if the pooled eggs are allowed to remain too long at room temperature and then are not fully cooked.

A recent government survey found that about half of all consumers surveyed had eaten undercooked eggs in the past year.[21] Although the SE problem in eggs has been fully documented for more than ten years, this survey, combined with the increase in human illnesses, demonstrates that both industry and government have failed to sufficiently inform consumers about the risk of consuming undercooked eggs.

Table 1. A Ten-Year History:
How a Tiny Foodborne Bacteria Outsmarted the Federal Government

SE Increases Throughout the Nation	Year	Federal Government Fails to Act
Almost 6,000 SE food poisonings reported for the year	1986	After an outbreak sickens 3,000, CDC identifies eggs as a source of SE food poisoning
	1987	USDA decides not to establish a mandatory SE control program
Almost 8,500 SE food poisonings reported for the year	1989	FDA and USDA simultaneously develop competing SE control programs
	1991	• USDA begins control program targeted only at flocks that have been identified as the cause of human illness through tracebacks • Congress passes law requiring egg refrigeration; USDA never enforces it
	1992	USDA, Pennsylvania government, and industry begin voluntary pilot program
Over 10,000 reported SE food poisonings for the year	1995	Congress cuts funding for successful pilot program and for traceback program, at egg industry request

GOVERNMENT'S INADEQUATE RESPONSE ALLOWED THE SE PROBLEM TO GROW OUT OF CONTROL

As many as 45 percent of all egg-laying flocks in the U.S. are now infected with SE, according to government estimates.[22] Yet the spread of SE throughout the nation could have been stopped, or at least substantially slowed, years ago with appropriate government intervention. Control of SE is possible when government, with the cooperation of producers, demonstrates a commitment to eliminating the human health risk of this pathogen. In Sweden, for example, only five SE-infected flocks have been identified in the entire country since 1987.[23] The Swedish government has a rigorous control program directed at all types of *Salmonella* in both laying hens and broilers. The program requires testing of laying flocks at least three times during their lives, with destruction of all flocks that are found to be SE-positive.

By contrast, the U.S. government failed to take effective action when confronted with evidence of human illness from SE-contaminated eggs. Any one of the following steps could have substantially cut today's high level of SE infections:

- Rigorous, regularly scheduled testing and sanitation requirements on the farm could have identified SE-positive flocks and forced producers to clean up their henhouses.

- Regulators could have required eggs from SE-positive flocks to be sent to pasteurization plants instead of allowing them to be sold as shell eggs. Inspection at egg packing plants could have verified compliance.

- Refrigeration requirements to minimize the growth of SE during transportation and storage could have been enforced.

- Consumers could have been warned through labels of the risk of eating raw or undercooked eggs.

Instead, the federal agencies that share responsibility for regulation of eggs and the egg industry made only minimal and sometimes counterproductive efforts to stop SE. A confusing array of laws, regulations, and voluntary programs divides responsibility among four federal agencies:

- U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), which continuously inspects egg product (pasteurized liquid or powdered egg) plants;

- USDA's Agricultural Marketing Service (AMS), which provides voluntary shell egg grading services and inspects shell egg plants four times a year for cleanliness and quality control;

- USDA's Animal and Plant Health Inspection Service (APHIS), which is responsible for preventing the spread of animal disease; and

- the U.S. Department of Health and Human Services' Food and Drug Administration (FDA), which is responsible for keeping adulterated food out of the marketplace, preventing the spread of communicable diseases from animals to people, and for inspecting all food products other than meat, poultry, and some egg products.

In addition, state governments may inspect poultry houses, egg packing and processing plants, and retail establishments such as restaurants and supermarkets.

This crazy quilt of jurisdiction over eggs led to government inaction and inefficiency in the face of the emerging SE problem. The government agencies failed to take effective action at any of four key steps in egg production where SE could have been controlled: (1) on the farm; (2) at the packing and processing plants; (3) during transportation; or (4) at the retail level. The agencies were also hindered by Congress, which failed to establish clear jurisdiction for egg safety in one federal agency and placed the concerns of egg producers over public health.

Failing to Stop SE on the Farm: The Agencies Compete Rather than Cooperate

The response of both FDA and USDA to reports of increasing numbers of SE food poisoning traced to eggs was to compete with each other, rather than to cooperate to solve the problem. Although the two agencies at first worked together during discussions about the problem, they did not cooperate in developing a solution.

The two agencies were initially unsure who had jurisdiction over infected laying flocks.[24] APHIS is responsible for preventing the spread of communicable diseases among poultry and other domestic animals.[25] However, FDA also has broad authority under the Public Health Service Act to make and enforce regulations to prevent the spread of communicable diseases from animals to humans.[26] Further, the Food, Drug and Cosmetic Act gives FDA authority to prevent "adulterated" foods from entering interstate commerce.[27] These two laws give FDA the power to recall eggs produced by infected flocks or to require them to be diverted to pasteurization plants.

In 1987, USDA officials decided not to establish a mandatory SE control program out of fear that the government would have to reimburse infected flock owners for substantial losses from the destruction of their flocks.[28] Ironically, in the early 1980's, USDA spent at least $60 million to combat an outbreak of Avian Influenza, a virus that affects poultry but poses no human health threat, by destroying flocks and reimbursing owners.[29] In contrast to USDA's approach, Canada's federal government requires destruction of laying flocks that are linked to human illnesses from SE, with full compensation to the producers.[30] To date, the SE problem in Canada has remained comparatively small.

In August 1988, APHIS and FDA approved an industry-developed voluntary SE control program, but took no regulatory action.[31] When it became clear that the voluntary SE control program was not slowing the spread of SE, a disagreement emerged between the two agencies as to how to solve the problem. FDA urged a mandatory program, while APHIS wanted to continue with the voluntary program.[32]

For a period of time in 1989, FDA and APHIS were actually simultaneously developing competing mandatory SE control programs. Rather than working cooperatively, FDA officials were unwilling to discuss their proposed plan, which required testing of all laying flocks in the U.S., with APHIS. FDA publicly announced the plan before sharing it with APHIS.[33]

In December 1989, to the surprise of FDA officials, APHIS announced a mandatory SE control program that targeted only flocks already implicated in SE food poisoning incidents.[34] FDA then withdrew its stronger plan and supported APHIS's plan.

A Slow and Ineffective Program to Trace Human SE Illnesses Back to the Farm

APHIS's plan targeted only those flocks to which human illness could be traced. Rather than sampling a large number of flocks to determine how widespread the problem was, the agency adopted a purely reactive approach, waiting until illnesses and deaths occurred before taking any regulatory action.

APHIS's SE control regulations, issued in 1991, applied to laying flocks whose eggs were implicated in SE food poisoning incidents, or that included hens from already-identified infected breeder flocks. Once a flock was identified as meeting one of those two conditions, the regulations required testing of manure and equipment from the laying houses, and of the internal organs of chickens. Chickens or eggs from those flocks could not be moved out of state (unless the eggs were sent to pasteurization plants) until extensive testing, including tests of the hens' internal organs and the poultry houses, show the complete absence of SE.[35] The regulations place no limits on marketing eggs from contaminated flocks within a state.

The effectiveness of the tough-sounding regulations depended on successful tracing of human illness from SE back to the farm. In 1990, 19 outbreaks were traced back to flocks under the program, a success rate of 86%. By 1993, the success rate had declined to 14% (three of 21 outbreaks).[36] The program was criticized for slow and redundant tracebacks. The average traceback took four months from the time of an outbreak until the decision was made to test a suspected flock. The tracebacks were so slow in part because APHIS refused to accept traceback work that had already been completed by state agencies.[37]

APHIS's relationship with the states was not the only weakness in the program. APHIS also failed to work cooperatively with FDA. In one example, APHIS conducted an investigation of an outbreak of SE food poisoning in New York. The investigation implicated a Pennsylvania chicken flock, which tested positive for SE. However, APHIS waited almost a month before notifying FDA of the test results. By then, it was too late for FDA to find and recall eggs from the infected flock that had already been shipped to market[38] and consumers were unnecessarily exposed to SE.

Though the regulations remain in place, APHIS no longer does tracebacks from SE food poisoning incidents to implicated flocks. Responsibility for the traceback program shifted to another USDA agency, FSIS, under the USDA Reorganization Act of 1994.[39] One year later, in 1995, Congress cut funding for the program at the behest of industry groups.[40] Since that time, the traceback function has been taken over by the FDA.[41] As of December 1996, FDA had undertaken four traceback investigations.

The Pennsylvania Pilot Program: A Successful Control Program Is Abandoned

In April 1992, USDA began a voluntary pilot program to control SE in Pennsylvania with the help of egg producers and state government agencies.[42] The goal was to reduce SE contamination in shell eggs in Pennsylvania, a state that had been particularly hard hit by SE. The program contained the following requirements for producers:

- Chicks for layer flocks had to be obtained from breeder flocks that were monitored for SE.
- Manure samples from layer flocks were required to be regularly tested for SE. All testing was to be monitored by a neutral third party.
- Where testing of eggs showed that some were positive for SE, all eggs from that flock were diverted to pasteurization plants. Before the eggs from that flock could be sold as shell eggs again, a total of 4,000 eggs over eight weeks had to test negative for SE.
- Biosecurity programs (programs to prevent bacteria from being carried into poultry houses from outside sources) and rodent control measures for layer houses had to be implemented.
- Eggs were to be kept refrigerated at all times.[43]

USDA was supposed to monitor the program's requirement that eggs from contaminated flocks be diverted to pasteurization plants. USDA's Office of Inspector General found that USDA was failing in this regard. There were no shipping controls in place to ensure that eggs from infected flocks went to pasteurization

plants. Two pasteurization plants were also selling fresh shell eggs, unaware that they were receiving eggs from known SE-positive flocks.[44]

Even without full enforcement by USDA, the Pennsylvania program apparently reduced the incidence of SE in the flocks. When the program was implemented in 1992, multiple manure and other samples were taken from the houses of 70 laying flocks. In 1992, 38 percent of laying houses had at least one SE positive sample, but by 1995, only 13 percent of flocks had a positive SE sample. In 1992, 23 percent of all the samples taken tested positive for SE, down to only 3.2 percent of samples in 1995.[45] Human illness from SE in the market area for Pennsylvania eggs (New York, New Jersey, and Pennsylvania) also decreased between 1992 and 1995.[46] A team of 15 scientists from federal and state government agencies attributed at least part of this decrease to the Pennsylvania program and recently recommended that the interventions in the Pennsylvania program be implemented by all egg producers.[47]

Despite the apparent success of the program, in 1995, Congress cut $3 million in funding for USDA's SE control task force, which included all funding for the Pennsylvania pilot program, after lobbying by the egg industry. USDA employees were prohibited from spending any time on the program.[48] The program, now called the Pennsylvania Egg Quality Assurance Program, is still operating on a voluntary basis in Pennsylvania, and about 85 percent of the state's producers participate. However, without federal involvement, the plan will not be expanded nationwide.

Failing to Stop SE at the Packing and Processing Stage: No Inspection for Safety

The spread of SE could have been slowed by more stringent inspection at the packing and processing level. Eggs that came from SE-infected flocks should have been diverted to pasteurization plants, rather than sold as shell eggs. Eggs that came from geographical areas with known high SE rates should have been sampled to determine if they contained SE.

Nevertheless, although three agencies have responsibility for inspecting eggs during processing, no government agency has been monitoring eggs for SE. In fact, even when USDA knew of SE-infected flocks in Pennsylvania, it continued to allow some eggs from these flocks to be marked "Grade A" and sold in supermarkets.

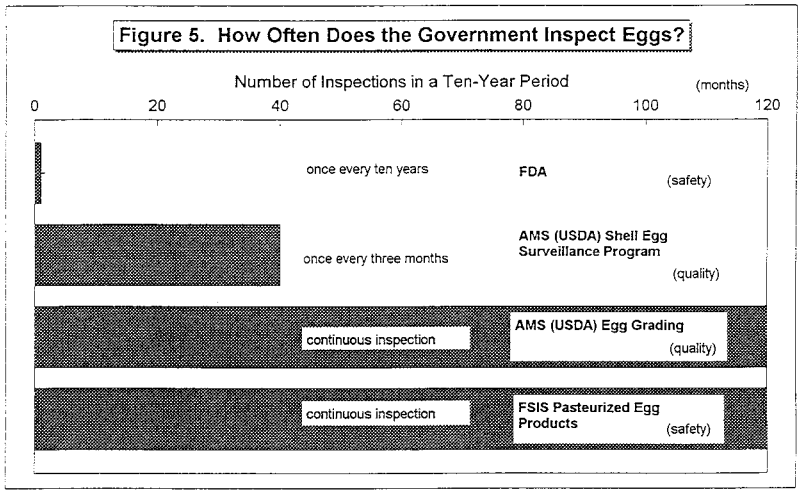
FDA occasionally inspects shell egg-packing plants and is responsible for monitoring whether eggs are contaminated with SE. However, FDA's inspection resources are so limited that it inspects most food manufacturing plants under its jurisdiction an average of only once every ten years.[49] (See Figure 5.) Ironically, USDA inspects egg plants much more frequently, but does not check for SE contamination.

USDA, through its Agricultural Marketing Service (AMS), provides a voluntary grading program for shell eggs that is paid for by participating producers. Approximately 40 percent of the nation's shell egg producers participate.[50] The program grades eggs for quality, but does not inspect eggs to determine whether they are free of microbial contaminants such as SE. Participating egg-packing plants are inspected for sanitation and proper washing of eggs.

AMS is also responsible for the Shell Egg Surveillance Program.[51] AMS inspectors visit shell egg plants four times a year to ensure that dirty eggs, cracked eggs, and eggs with blood spots are properly disposed of and are not sold to consumers in cartons. However, this program does not include testing eggs for SE and diversion of infected eggs to pasteurization plants.

Until November 1995, AMS was also responsible under the Egg Products Inspection Act for inspection of egg product plants, plants that produce liquid, frozen, or powdered egg products.[52] While these products are generally pasteurized and pose little threat from SE, under the Act, AMS provided continuous safety inspection of egg product plants.[53] Congress shifted the inspection of egg products to USDA's FSIS effective May 1995 and now FSIS conducts continuous inspection in these plants. In contrast, there is no continuous inspection in shell egg plants, or any safety inspection at all beyond FDA's infrequent visits.

Figure 5. How Often Does the Government Inspect Eggs?



Failing to Stop the Growth of SE During Transportation and Storage: Inadequate and Unenforced Refrigeration Requirements

Refrigeration requirements are a key element of any SE control program. If SE is present inside the eggs, refrigeration can help prevent the SE organisms from multiplying. To prevent SE growth, eggs should be refrigerated at an internal temperature of 45 degrees F or lower from the time they leave the farm until they reach the supermarket.[54] However, the government agencies have been unable to provide a cohesive strategy for regulation of refrigeration temperatures during transportation and storage.

The way eggs are processed means that they often leave packing plants warmer than room temperature. They are washed in hot water, immediately placed in cartons, stacked in pallets of several dozen cartons, and then, frequently, shrink-wrapped in plastic. These industry practices make it difficult to cool eggs sufficiently, especially those eggs at the center of a pallet of cartons.

By a 1991 amendment to the Egg Products Inspection Act, Congress required USDA to issue regulations mandating that eggs be held under refrigeration at an ambient temperature of 45 degrees F after packing and during transportation.[55] Ambient temperature refers to the temperature of the air in the area where the eggs are, *not* to the eggs' internal temperature.

Both USDA and FDA were given enforcement authority under this amendment. Although an internal temperature, rather than an ambient temperature, of 45 degrees F is necessary to prevent the growth of SE, many observers agree that the ambient temperature standard would be better than the complete absence of a temperature requirement, which is the current situation. After they leave the plants, eggs in some states can legally be shipped, stored, and displayed in supermarkets at room temperature.

In October 1992, USDA issued a proposed rule requiring storage and transportation of eggs at an ambient temperature of 45 degrees F, but never finalized it.[56] FSIS, which was given responsibility for implementing the law when egg safety functions were transferred from APHIS to FSIS, believed that the ambient temperature at which eggs are kept is not the relevant factor in assuring the safety of eggs and declined to enforce the requirement.

Since 1992, USDA has never mandated either the 45 degree F ambient temperature or the scientifically superior internal temperature standard for the egg industry. To further complicate matters, yet another USDA agency has a conflicting temperature requirement based on quality, not safety considerations. The AMS voluntary grading service requires an ambient temperature of 60 degrees F or less in egg handling and storage areas. About 40 percent of the egg industry participates in this program.

The 1991 amendment also gave authority to FDA to ensure that food manufacturing establishments, institutions, and restaurants comply with the ambient 45 degrees F requirement.[57] FDA does not inspect many of these facilities and has failed to enforce the Congressional mandate.

Failing to Warn Consumers of SE in Eggs at Supermarkets and Restaurants

Since the government has not taken steps on the farm, during processing, or during transportation and storage to prevent SE outbreaks, the last opportunity to prevent illness is to warn consumers not to eat raw or undercooked eggs. A warning label on egg cartons informing purchasers how to protect themselves could have prevented many illnesses and deaths. A government survey recently found that half of all consumers had eaten undercooked eggs in the last year.[58] Despite this, the federal agencies have not taken critically needed steps to warn consumers of the risk of SE.

FDA, the agency with the legal authority to require egg carton labels, has required warning labels on foods with a far smaller public health impact than SE-tainted eggs, such as low-calorie protein products (60 deaths) and iron-containing products (3,210 illnesses and two deaths). Yet FDA has not taken the simple step of requiring a label on egg cartons, which could help to prevent the 200,000 to one million illnesses from SE each year.

In contrast, USDA issued a regulation requiring safe-handling labels on meat and poultry sold in supermarkets shortly after the 1993 Jack in the Box outbreak caused by tainted hamburger. Those labels have provided valuable information to consumers. One survey has shown that 66 percent of all respondents and 70 percent of parents with children under the age of 12 have noticed the safe-handling instructions.[59] Another survey found that six out of 10 shoppers surveyed were aware of the safe-handling labels and that 43 percent of these shoppers had changed their meat and poultry handling practices as a result.[60] The surveys show that labeling can be an effective way to provide food safety information to consumers.

FDA has also been ineffective in advising restaurants and other establishments on safe egg handling. FDA delayed for years publication of an updated version of its food safety recommendations for restaurants (known as the Food Code), so that safe-handling guidelines for eggs were not included until 1993. In the 1993 Food Code, FDA recommended that eggs (along with all other perishable foods) be refrigerated at an ambient temperature of 41 degrees F or lower.[61] FDA also recommended that eggs be cooked to at least 145 degrees F, or that pasteurized egg products be used for uncooked foods or for highly susceptible populations.[62] No warning against pooling eggs was included. FDA recommended that restaurants provide a consumer warning about the risk of eating undercooked animal foods, but no suggested language was provided, and the recommen-dation has been adopted by only a few states.

Both FDA and USDA's FSIS provide safe egg cooking advice to consumers. However, this information is generally available only upon request from the agencies. The recommendation given out on USDA's safe food-handling hotline is to cook eggs until the white is firm and the yolk is just beginning to set (and is no longer runny).

CONCLUSION AND RECOMMENDATIONS

The history of the federal government's failure to curb the SE epidemic illustrates the ineffectiveness of having multiple government agencies responsible for regulating the same food. Instead of providing additional food safety protection, the numerous agencies charged with regulating eggs actually hindered each other in stopping the SE problem. The agencies did not identify which of them was responsible for controlling SE in eggs; they competed with each other instead of cooperating; and, when faced with decisions about how to regulate to solve the problem, chose the least protective approach. The agencies were further hamstrung by a Congress that cut funding for a control program just as it was beginning to show results and an industry that, except for producers in Pennsylvania, resisted attempts to prevent SE contamination on the farm.

Effective government action could have prevented many illnesses and deaths over the past twenty years and could prevent countless future unnecessary tragedies. To protect consumers from the hazards of SE, we recommend the following steps.

- FDA should mandate that egg producers implement on-farm Hazard Analysis and Critical Control Point (HACCP) programs to control SE. The SE control programs should be modeled after the successful Pennsylvania Egg Quality Assurance Program. The programs should include manure and egg testing that is monitored by FDA. (If the vitally needed HACCP programs are not required, producers who implement FDA-monitored voluntary programs should be allowed to inform consumers of their programs through the use of a special label or symbol on egg cartons.)

- Shell egg plants should be inspected for safety at least several times per year. These inspections should check that plants accept eggs only from farms with SE testing programs in place. They should ensure that eggs from infected flocks are diverted to pasteurization plants.

- FDA and FSIS should act quickly to implement science-based regulations mandating egg refrigeration at 41 degrees F during transportation and storage. Temperature requirements should be standardized across the government agencies that regulate food, including the state and local governments responsible for enforcing temperatures at the retail level. Eggs should not be left unrefrigerated at any time.

- Until the egg industry has effective programs in place to control SE, consumers must be warned that they face the risk of illness from eating raw or undercooked eggs. FDA should mandate that the following warning notice be placed on the lids of egg cartons: "Caution: Eggs may contain illness-causing bacteria. Do not eat raw. Cook until yolk is firm." The notice should be designed and positioned to maximize visibility and consumer compliance.

- FDA's Food Code should recommend that restaurants and other establishments not pool unpasteurized eggs unless they are cooked immediately.

- Jurisdiction for food safety scattered among different agencies impairs protection of the public's health, results in duplication of efforts, inhibits needed actions, and wastes government resources. Until food safety functions are consolidated into a single federal food agency, the safety regulation of each food product, such as eggs, should fall under the clearly defined authority of one of the two primary food safety agencies, either FSIS or FDA. Clear jurisdiction is needed to avoid agency competition and miscommunication.

- Congress should significantly increase funding for FDA's food safety functions and should fully fund FSIS's and FDA's efforts to address SE in eggs. President Clinton's recent announcement of additional funding for food safety is an important step in ensuring that these agencies can adequately protect the public health.

Endnotes

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2. Statement of David Satcher, Director of Centers for Disease Control and Prevention, before the Committee on Government Reform and Oversight, Subcommittee on Human Resources and Intergovernmental Relations, U.S. House of Representatives, May 23, 1996, p. 13-14 [hereinafter cited as *Satcher Statement.*]

3. *Salmonella Control Efforts*, p. 8-9.

4. Centers for Disease Control and Prevention, "Surveillance for Foodborne-Disease Outbreaks-United States, 1988-1992," *Morbidity and Mortality Weekly Reports, CDC Surveillance Summaries*, Vol. 45, No. SS-5 (Atlanta: U.S. Department of Health and Human Services, October 25, 1996), p. 11 [hereinafter cited as *CDC Surveillance Summaries 1988-92*].

5. *Ibid.* This estimate is based on Satcher's estimate that there are between 200,000 and one million cases of SE illness each year. The SE fatality rate is estimated at 0.1 to 0.5 percent, according to Jeremy Sobel of the CDC. Thus, the number of deaths each year is likely to be between 200 and 5,000. CDC data, which is widely acknowledged to reflect only a small fraction of total food poisonings, recorded 27 deaths between 1988 and 1992. *CDC Surveillance Summaries 1988-92*, p. 11.

6. $118 million estimate from *Salmonella Control Efforts*, p. 2; $767 million estimate derived from U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Center for Infectious Diseases, Division of Bacterial and Mycotic Diseases, Foodborne and Diarrheal Diseases Branch, Table 1A, "The 20 Most Frequently Reported *Salmonella* Serotypes from Human Sources Reported to the CDC in 1993," *Salmonella Surveillance: Annual Tabulation Summary 1993-1995* (Atlanta: U.S. Department of Health and Human Services) [hereinafter cited as *CDC Salmonella Surveillance 1993-95*]. SE represented 21.9 percent of all *Salmonella* serotypes reported in 1993. U.S. Department of Agriculture, Economic Research Service, Agricultural Economic Report Number 741, Jean C. Buzby, et al., Table 7, "Cost Summary for U.S. Salmonellosis Cases, 1993," *Bacterial Foodborne Disease: Medical Costs & Productivity Losses*, (Washington, D.C.: U.S. Department of Agriculture, August 1996), p. 19. U.S. foodborne salmonellosis cases from all types of *Salmonella* cost a maximum of $3.5 billion annually.

7. Table 3, "*Salmonella* Isolations from Human Sources by Serotype and Year Reported to CDC, 1985-1995," *CDC Salmonella Surveillance 1993-1995*; U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Center for Infectious Diseases, Division of Bacterial Diseases, Enteric Diseases Branch, Table 3, "*Salmonella* Isolations from Human Sources by Serotype and Year Reported to CDC, 1980-1990," *Salmonella Surveillance: Annual Summary 1990,* (Atlanta: U.S. Department of Health and Human Services) [hereinafter cited as *CDC Salmonella Surveillance 1990*]; U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Center for Infectious Diseases, Division of Bacterial and Mycotic Diseases, Foodborne and Diarrheal Diseases Branch, *Salmonella Surveillance: Annual Summary 1985-1995*, (Atlanta: U.S. Department of Health and Human Services).

8. *Satcher Statement*, p. 13.

9. Michael St. Louis, *et al.*, "The Emergence of Grade A Eggs as a Major Source of *Salmonella enteritidis* Infections," *Journal of the American Medical Association*, Vol. 259, No. 14 (1988), p. 2103.

10. Table 6, "*Salmonella* Reported from Human Sources, 1990," *CDC Salmonella Surveillance 1990*; Table 6B, "*Salmonella* Reported from Human Sources, 1994," *CDC Salmonella Surveillance 1993-94.* In 1990, 1,125 laboratory-confirmed SE cases were reported in New England, 195 from the Mountain region, and 659 from the Pacific region. In 1994, there were 1,209 SE cases reported from New England, 417 from the Mountain region, and 2,790 from the Pacific region. According to a CDC official, these reported illnesses likely represent only 5 percent of total SE illnesses.

11. Centers for Disease Control and Prevention, "Outbreaks of *Salmonella* Serotype Enteritidis Infection Associated with Consumption of Raw Shell Eggs—U.S., 1994-1995," *Morbidity and Mortality Weekly Reports*, Vol. 45, No. 34 (Atlanta: U.S. Department of Health and Human Services, August 30, 1996), p. 741.

12. U.S. Department of Agriculture, "APHIS Report of Accomplishments in Animal Production Food Safety FY 1995," March 1996, p. 2.1-1.

13. Memorandum from Robert V. Tauxe, Acting Chief, Foodborne and Diarrheal Diseases Branch, and Mitchell L. Cohen, Director, Division of Mycotic Diseases, National Center for Infectious Diseases, CDC, Update on Surveillance for Outbreaks of *Salmonella* Serotype Enteritidis (SE) Infections, October 18, 1995; Allan Hogue, *et al.*, *Salmonella Enteritidis Review Team Report*, Final, January 18, 1997, p. 2.

14. Telephone conversation with Jeremy Sobel, M.D., CDC, Atlanta, GA, March 7, 1997.

15. E. F. Coyle, *et al.*, "Salmonella enteritidis Phage Type 4 Infection: Association with Hen's Eggs," *The Lancet*, December 3, 1988, p. 1295.

16. Committee Report, House Report 104-172, "Food Safety and Inspection Service: Committee Provisions," Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 1996. "Funding is not included to continue the Salmonella enteritidis program"; "Animal Production Food Safety Efforts Will Be Non-HACCP, Industry-Oriented: Taylor," *Food Chemical News*, November 6, 1995, p. 28. CSPI has been told by industry and government sources that the lobbying effort was led by United Egg Producers, a trade association. See also "S. Enteritidis Proposed Changes Draw Industry Criticism," *Food Chemical News*, September 13, 1993, p. 27 (United Egg Producers urged elimination of SE traceback program).

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33. *Salmonella Control Efforts*, pp. 18-19.

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54. Joe G. Bradshaw, et al., "Growth of *Salmonella enteritidis* in Yolk of Shell Eggs from Normal and Seropositive Hens," *Journal of Food Protection*, Vol. 53, No. 12 (1990), p. 1034.

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Appendix. Salmonella Enteritidis Increases Throughout the Nation

Isolations from Human Sources Reported to CDC

State	1985 Reported SE Cases	1995 Reported SE Cases	Percent Difference Between 1985 and 1995	State	1985 Reported SE Cases	1995 Reported SE Cases	Percent Difference Between 1985 and 1995
AL	39	21	- 46	MT	3	0	- 100
AK	8	5	- 38	NE	not reported	0	undefined
AZ	17	139	+ 718	NV	0	70	undefined
AR	14	9	- 36	NH	13	49	+ 277
CA	249	2,332	+ 837	NJ	688	728	+ 6
CO	16	97	+ 506	NM	19	96	+ 405
CT	200	334	+ 67	NY	1,045	1,202	+ 15
DE	1	103	+ 10,200	NC	102	106	+ 4
DC	1*	40	+ 3,900	ND	11	13	+ 18
FL	3**	17	+ 467	OH	151	359	+ 138
GA	107	34	- 68	OK	8	22	+ 175
HI	7	29	+ 314	OR	13	38	+ 192
ID	1	17	+ 1,600	PA	459	905	+ 97
IL	336	406	+ 21	RI	23	15	- 35
IN	47	172	+ 266	SC	13	59	+ 354
IA	35	44	+ 26	SD	2	23	+ 1,050
KS	15	18	+ 20	TN	88	89	+ 1
KY	22	20	- 9	TX	87	101	+ 16
LA	38	22	- 42	UT	11	118	+ 973
ME	49	38	- 22	VT	22	19	- 14
MD	267	432	+ 62	VA	165	354	+ 115
MA	687	890	+ 30	WA	71	101	+ 42
MI	268	199	- 26	WV	40	35	- 13
MN	55	83	+ 51	WI	74	92	+ 24
MS	29**	9	- 69	WY	not reported	0	undefined
MO	71	97	+ 37	**TOTAL**	**5,690*** **	**10,201**	**+ 79**

* No data from 1985 is available. This figure is from 1986. Percent difference is between the number of cases reported in 1986 and 1995.
** No data from 1985 is available. This figure is from 1987. Percent difference is between the number of cases reported in 1987 and 1995.
*** Total includes data from states with no available 1985 data.

Source: *CDC Salmonella Surveillance 1985-1995; CDC Salmonella Surveillance 1990; CDC Salmonella Surveillance 1993-95.* See endnote 7.

Statement Before
the Senate Subcommittee on Oversight of Government
Management, Restructuring, and the District of Columbia

Testimony presented by

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July 1, 1999

**"EGG SAFETY:
ARE THERE CRACKS IN THE FEDERAL FOOD SAFETY SYSTEM?"**

Thank you for inviting the scientific and technical representative of the egg industry to be part of the proceedings that ensure the safety of food. The industry produced 67.3 billion eggs in 1998; seventy percent were sold as shell eggs. There are currently 757 producers in the United States who each have 3,000 or more hens.

My name is Dr. Jill Snowdon and I serve as the Director of Food Safety Programs at the Egg Nutrition Center (ENC). The Egg Nutrition Center serves as a scientific and technical resource on nutrition and food safety and is a joint effort between the American Egg Board (AEB) and the United Egg Producers (UEP). We are part of an industry network that works to ensure the safety of food.

This testimony will: highlight the current situation regarding eggs and *Salmonella* Enteritidis, reference egg industry accomplishments and industry commitment to producing a safe product, and summarize the successes in this challenging situation including the recent decrease in salmonellosis caused by SE.

I. SE AND EGGS CAN BE CONSIDERED A MODEL OF SUCCESS

A. GOOD NEWS FROM RECENT HEALTH STATISTICS

1. MULTIPLE LINES OF DATA FROM THE UNITED STATES

The pursuit of egg safety should be considered a success story and there's good news from recent health statistics to confirm it. The disease incidence of salmonellosis caused by *Salmonella enterica* subspecies Enteritidis serovar Enteritidis (otherwise known as "SE") has been on the decline in the United States. Multiple lines of evidence -- taken from data collected over the last three to eight years, from both national and regional levels, including both sporadic cases and outbreaks -- show the same downward trend.

Outbreaks -- where two or more people become ill at the same time -- from all sources of SE have decreased. The decrease has been from a high of 82 outbreaks (2327 cases) in 1990 to 45 outbreaks (666 cases) in 1998 as recorded and reported by the Centers for Disease Control and Prevention (CDC). Both the number of outbreaks and the number of people ill in each outbreak have declined. The decrease in the number of outbreaks is particularly evident in New York. New York is currently free of outbreaks from SE and has one of the lowest rates for SE as measured by another monitoring system called FoodNet. The decreases in outbreaks associated with eggs (some outbreaks are caused by non-food sources or foods other than eggs, see below) are likely due to changes in farm management practices, changes in food preparation practices in health care facilities like nursing homes, and national consumer education campaigns on safe egg handling.

Like any perishable food, eggs need to be treated with care. A graphic presentation of this decrease in outbreaks is included in Appendix A.

For several decades, the Centers for Disease Control and Prevention (CDC) has collected data on the incidence of salmonellosis in the U.S. Salmonellosis can be caused by over 2000 sub-types of bacteria; the incidence of these sub-types is also recorded in CDC's surveillance system. The decline in salmonellosis caused by SE on a regional basis is best presented in the graph appended to this testimony (Appendix B). Rates began to drop in the mid-Atlantic area after 1989 from a high of 10.5 cases per 100,000 population to 5.7 cases per 100,000 in 1997. The New England area dropped from 10 per 100,000 in 1995 to 4 per 100,000 in 1997. Disease incidence in the Pacific area has been declining ever since 1994 dropping to 5 per 100,000 in 1997. This is also reflected in data from five southern California counties which shows a return to low rates (Appendix C).

Perhaps the most compelling line of evidence for the decline of salmonellosis caused by SE is from CDC's FoodNet program which reported a 44% decline in salmonellosis caused by SE over the last three years. FoodNet collects all reports of salmonellosis (and selected other diseases) from all laboratories in a geographically defined area (a catchment area). Data from these catchment areas are analyzed to detect trends and to estimate disease incidence. The trend in disease from SE is downwards. At the start of the FoodNet program in 1996, the incidence rate for salmonellosis caused by SE was 2.5 per 100,000, which declined to 1.5 per 100,000 by 1998.

FoodNet data can also be used to estimate the incidence, or amount, of disease. Based on several studies specifically designed to improve the accuracy of the estimate, FoodNet data indicate 1.4 million cases of salmonellosis in the U.S. in 1997. Fifteen percent of the reported cases were caused by SE; one could estimate that there are about 210,000 cases of salmonellosis caused by SE in the U.S. in 1997.

FoodNet is the most sophisticated and accurate source of foodborne disease data in the U.S. and perhaps the world because it is based on scientific evidence not theory. But another line of reasoning can be used to corroborate the FoodNet data on SE. The *Salmonella* surveillance system, which is a passive, nationwide data collection system, recorded about 9,500 cases of salmonellosis from SE in 1997. The current thinking is that there are 20 to 40 cases of salmonellosis for every one that is reported; this would estimate total cases of salmonellosis caused by SE between 190,000 to 380,000 per year. This is in keeping with the FoodNet estimate above and confirms the validity of CDC's surveillance systems.

This general declining trend regarding SE is also seen in the proportion of salmonella isolates from human sources that were SE; the proportion has been dropping since 1994, from 27% to 23% in 1998. A similar decline in the incidence of salmonellosis from SE is also being observed on an international basis.

2. INVOLVEMENT WITH EGGS AND OTHER SOURCES OF SE

It should be pointed out that illness from SE is only a fraction of all cases of salmonellosis and that eggs account for only a portion of all reported cases of SE. A variety of foods and sometimes people can carry SE. The actual extent of the association with eggs is unknown and debatable; the

role of the environment and the role of non-food animals has not been studied. The most extensive data on this subject is from the state of New York. Twenty eight percent of the cases from SE outbreaks in New York (from 1980 to 1995) were proven to be from sources other than eggs; that is to say, 72% were associated with eggs. (The three most important factors contributing to the egg outbreaks were inadequate refrigeration of pooled eggs, contaminated ingredients and inadequate cooking. Proper food preparation practices would have prevented these outbreaks.) Using CDC data from 1998, eggs could be involved as little as 33% of the time (83% of the 40% of the outbreaks where food source is known) to 83% of all outbreaks.

The U.S. has the safest food supply in the world, however, there has always been, and always will be, risk associated with eating. There is risk in everything that you do and all foods have a certain amount of risk. Although even one person ill would be one too many, the risk of getting SE from eggs remains because few eggs (an average of one in 20,000) are contaminated with SE and thorough cooking kills SE. Eggs, like all other foods, must be produced, stored and prepared properly. Keeping food refrigerated deters the growth of bacteria and the heat of thorough cooking kills bacteria. Food preparation is the final line of defense in man's competition against foodborne microorganisms.

3. LOOKING AT ALL FOODBORNE DISEASE

The incidence of disease caused by SE should be put in the context of all foodborne diseases. There are about 50 bacterial pathogens, 20 viruses and 40 parasites known to be associated with foodborne disease. Additionally, there are mycotoxins, other toxins, intolerances and allergies associated with food. The reference for this information is: *Diseases Transmitted by Foods: A Classification and Summary*, second edition, US Dept. of Health and Human Services, Centers for Disease Control, 1982, HHS Publication No. (CDC) 83-8237. In each of these categories there are many sub-species; SE, for example, is one of about two thousand types of *Salmonella.*

The actual extent of all foodborne disease is unknown, published estimates vary widely and are controversial. The classic reference on the subject is the Carter Center study published in 1987 (Appendix D). This study estimated 6.5 million cases in the U.S. each year with up to 9,000 deaths. Most experts believe the number of ill to be in the millions; even 360 million cases of diarrheal diseases was proposed in a 1997 FoodNet report. CDC is in the process of updating these estimates. More funds for surveillance and research to substantiate and refine these figures would minimize the controversy.

Up until recently, salmonellosis has been the most common foodborne illness, and the most studied foodborne disease, in the world. But over half the time the vehicle that is carrying it into the food supply is never determined. Likewise, in over half the cases of foodborne illness, the microbiological agent that caused the illness is unknown; these unknown agents of disease are likely to be found to be caused by viruses and parasites which are expensive, difficult or impossible to detect. The relative importance of an established and well known pathogen like *Salmonella* will diminish as we conduct better investigations of foodborne outbreaks, and as we develop the analytical capability to detect viruses and parasites; more funds are needed for both enhanced epidemiological investigation and research to develop or improve detection techniques.

Perhaps only half of the cases of salmonellosis caused by SE are associated with eggs. At the

moment, in 1997, an estimate from FoodNet data is that 15% of 1.4 million cases (or 210,000) of salmonellosis are caused by SE; half (an arbitrary choice selected because it is a mid-point) of that number is 105,000. This is a small fraction of the total incidence of foodborne illness. If there are 105,000 cases of salmonellosis caused by SE and associated with eggs and if there are 100 million cases of foodborne illness each year (again an arbitrary choice for the sake of illustration), then salmonellosis from SE associated with eggs contributes to much less than one percent of all foodborne illness.

Phrases that attribute eggs as "the single largest source of identifiable foodborne disease" misrepresent the reality of the situation. This type of statement exaggerates that hazard because it looks at SE out of context. Data on the incidence of foodborne disease, while increasing in accuracy for a few bacterial species, is woefully inadequate. The federal government currently monitors about eight out of several hundred possible foodborne pathogens. Under these circumstances, to make generalizations about the relative importance of one pathogen is like doing a jig saw puzzle with only 10% of the pieces. Salmonellosis and the association with eggs are unique, well-known and studied extensively. For these reasons, this association can look more important than it is. SE occupies a small niche in the scheme of all foodborne diseases which are spread amongst all foodstuffs. Nonetheless, the goal is no foodborne disease and the industry continues to work to this effect.

B. UNIQUE PROPERTIES OF EGGS

There are a number of characteristics which make eggs unique. For example, eggs are the only food I know where the food safety risk is essentially limited to a specialized bacterial pathogen. This is due to the natural antimicrobial properties of eggs and the ability of SE to grow and prosper in the internal organs of the laying hen.

The most distinctive characteristic concerning SE is that it is a foodborne pathogen that is associated with the infection of an internal organ. If the reproductive organs of the hen are infected with SE, they can contaminate the egg as it is being formed. It is currently thought that the SE is deposited in the white of the egg. This is in great contrast to other foodborne pathogens which are typically associated with feces or dust. In this instance, the bacterium adapted itself in such a way as to be able to invade the organs of the laying hen, take "root," and grow. The discovery of this phenomenon has elicited both disbelief and fascination.

The egg, intended to be new life, has multiple properties that deter or destroy microorganisms. The shell is the first barrier, followed by two membranes around the egg white. The egg white is very viscous which restricts the availability of oxygen and the movement of microorganisms. The white also contains antimicrobial chemicals and has the ability to "tie-up" nutrients and make them unavailable. The yolk membrane serves as another barrier, segregating the nutrient rich yolk from any invading menace. Like people, microorganisms cannot grow without nourishment.

If the yolk membrane is intact, SE cannot grow. Therefore, the integrity of the yolk membrane determines the ability of SE, in the rare instance that it is present, to multiply. The integrity of the yolk membrane is controlled by time and temperature. Data from the United Kingdom indicate that SE will not grow in eggs for about 28 days if they have been stored at 60 F or less. Cool

temperatures can also deter the growth of SE if the bacterium gains access to the nutrient-rich yolk.

However, the security of the intact egg completely vanishes once the egg is broken and its contents mixed together. The delicious, nutritious egg can serve as food for bacteria and certain other microorganisms. The contrast between the relative security in the shell and the utter vulnerability once the shell is broken highlights the importance of proper food handling to ensure safe food. Once the natural antimicrobial properties are destroyed, the liquid egg has to be pasteurized, cooked thoroughly or held chilled to ensure that microorganisms do not grow.

The contamination of an egg with SE is an infrequent occurrence; the current frequency is believed to be one in 20,000. Infected flocks only contaminate eggs on an infrequent and erratic basis (which is one reason it is so difficult to detect suspect eggs). Additionally, the microorganism is present at very low levels; typically 10 or 20 microbes in a 60 gram egg. This is in contrast to other foodborne pathogens which can easily be present at levels of 10,000 per gram. Additionally, foodborne pathogens are found on raw animal carcasses frequently (near 30 % on certain products in recent years) in contrast to the 1 in 20,000 (or 0.005%) in eggs. In both instances, thorough cooking before eating ensures safety.

C. EGG INDUSTRY RESPONDS TO CHALLENGES

On a voluntary basis, the egg industry has addressed the SE issue with a variety of programs and initiatives. Research, the development of control programs, refrigeration and education have been the most effective tools to overcome the challenge of controlling a microorganism. Problems involving the basic biology of the microorganism, the challenge of distributing a fresh product, and the need to protect vulnerable populations have had to be solved.

For biological reasons, it is extremely difficult to find SE when you go to look for it. Very few flocks are infected, not all birds in a flock are infected, there are no visible signs of illness in the birds, only a small number of birds are shedding SE at any given time and an infected bird only occasionally lays an egg contaminated with SE. Currently, the best way to guess that a flock is shedding SE into eggs is to sample manure first, and if the test result is positive, divert the eggs to a pasteurization process while doing more testing. Eggs are tested by pooling 800 eggs into a single sample. Research has been done and is continuing to find a faster and more precise way to identify and divert any egg that is at risk.

Controlling the amount of time before the egg is consumed is as important as controlling the temperature. The egg producer generally ships the egg in a matter of hours or a few days. Eggs are moved rapidly from hen to the retail store, restaurant or further processor. The egg industry provides fresh eggs and has incorporated refrigeration during storage and shipment as one of its control mechanisms. Continued control of time and temperature is also needed after the eggs have been shipped and before they are consumed.

One of the most important challenges is to protect the "vulnerable" populations. At greatest risk from salmonellosis caused by SE are the very old, the very young and those recovering or sustaining an unrelated illness. The egg industry has long recommended that health care facilities,

especially nursing homes, use only pasteurized products. This however, will not address the instances where food preparation is blatantly inappropriate. Employees in a nursing home in New Jersey, for example, were wearing gloves when preparing food. Unfortunately, they didn't take the gloves off after cutting raw animal products and before tossing the green salad. The production of safe food needs to be accompanied by the safe preparation of food.

II. THE EGG INDUSTRY HAS TAKEN ACTION

A. OVERVIEW

The egg industry became aware of the problem, identified ways to combat it and implemented those actions. Now disease rates are dropping and the egg industry is continuing to look for additional techniques to combat SE. The egg industry remains committed to producing a safe product.

The egg industry's actions are too numerous to cover in these few minutes, so I have appended a list of industry activities to this testimony (Appendix E). Following are a few highlights of industry programs.

B. EXAMPLES OF EGG INDUSTRY PROGRAMS

1. PARTICIPATION IN QUALITY ASSURANCE PROGRAMS
Participation in industry-generated Quality Assurance (QA) programs continues to increase. These programs are designed to block the entry of SE into the hen house, stop infection of the bird and – in the instances where eggs become contaminated – divert these eggs for breaking and pasteurization. All QA programs in the egg industry have been based on the principles of Hazard Analysis Critical Control Points (or HACCP), which is the best technique to protect the food supply. The United Egg Producers developed the Five Star Plus program that is applicable across the nation. In a survey of large producers (those having 1 million or more birds) in the US, 38 out of the 41 that responded or 93% produce eggs under the guidelines of a QA program. There are over a dozen states that have formal QA programs. In a survey of representatives of the top six egg producing states (OH, CA, PA, IA, IN, GA -- accounting for 52% of the nations egg production), it is estimated that from 85 to 95% of the eggs in these states are produced under a QA program. Microbiological analysis of manure samples from these states detects SE about 3% of the time or less; further evidence that the presence of SE in laying houses is the exception not the norm.

2. THE AMERICAN EGG BOARD'S EDUCATIONAL PROGRAMS
The American Egg Board (AEB), a research and promotion board funded by the United States egg industry, continues to support and promote food safety. In addition to issuing public service announcements, AEB has been a charter member of the FightBac campaign, and has for many years funded and worked with the National Restaurant Association in developing educational materials for food service training. In addition, AEB has developed consumer education materials, including recipes that replace the traditional use of raw eggs in beverages, sauces, etc. with cooked eggs. AEB provides funds for food safety research and for the food safety program conducted at

the Egg Nutrition Center (ENC). An example of the combined AEB-ENC efforts are the food service recommendations in Appendix F. Also, the egg industry has worked closely with the Centers for Disease Control and Prevention, issuing cooperative educational fact sheets.

3. THE EGG NUTRITION CENTER

The ENC is the scientific and technical resource for the egg industry on the subjects of nutrition and food safety. As a source of accurate information on food safety and eggs, ENC procures and disseminates technical information, promotes safe preparation practices, develops programs to reduce outbreaks and sporadic disease caused by SE and guards against the release of misinformation. Current program plans include tracking information on health statistics, collaborating with other scientists, and developing communication networks amongst those that work to protect the food supply. Research activities include analyzing and refining health statistics, collecting descriptive information on egg industry practices, studying factors that influence the presence and concentration of SE in eggs and supporting the development of new detection techniques. ENC recently held a forum on the human epidemiology of SE and production practices that control SE. Future forums are planned on in-shell pasteurization and vaccines.

SUMMARY

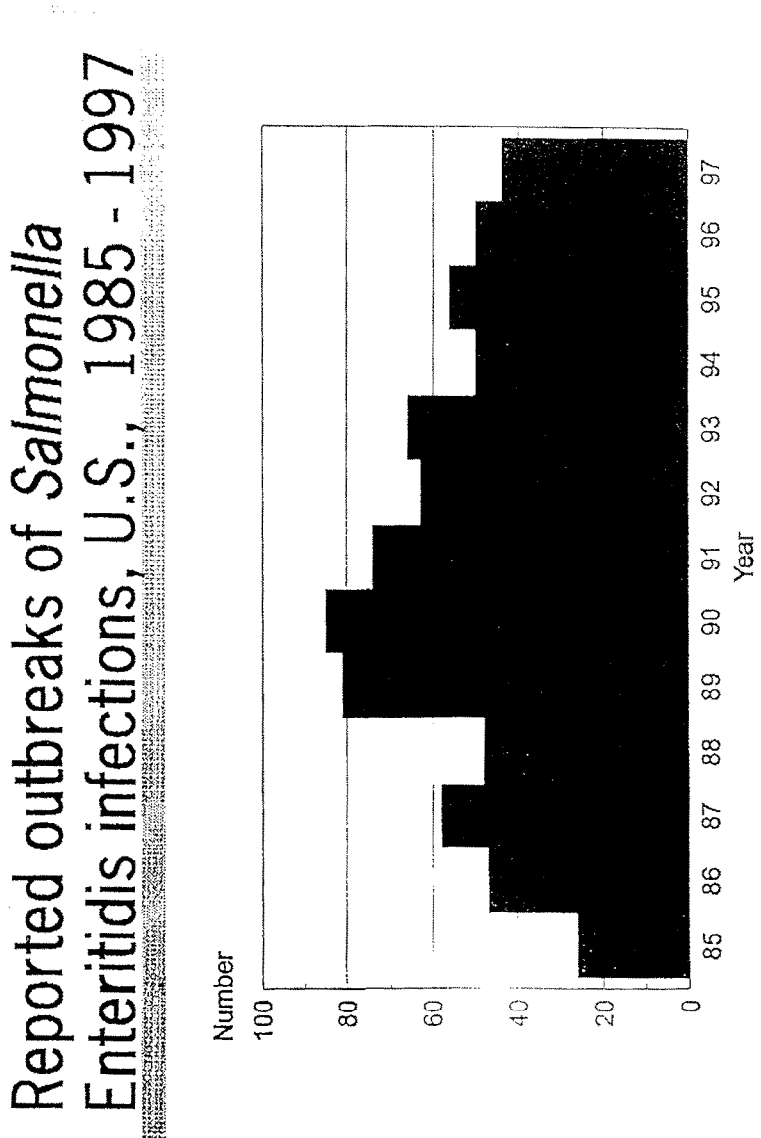
The pursuit of egg safety should be considered a success story. The public health community discovered the problem and placed much of the responsibility upon the egg producers. After years of effort – including extensive scientific research, unlimited and un-ending meetings, debate, controversy, education and changes in production and food preparation practices – the trend in disease incidence is downward.

The egg industry has contributed substantively to this success. The recent decline in both outbreaks and sporadic cases has occurred in geographic areas where control measures have been most intense.

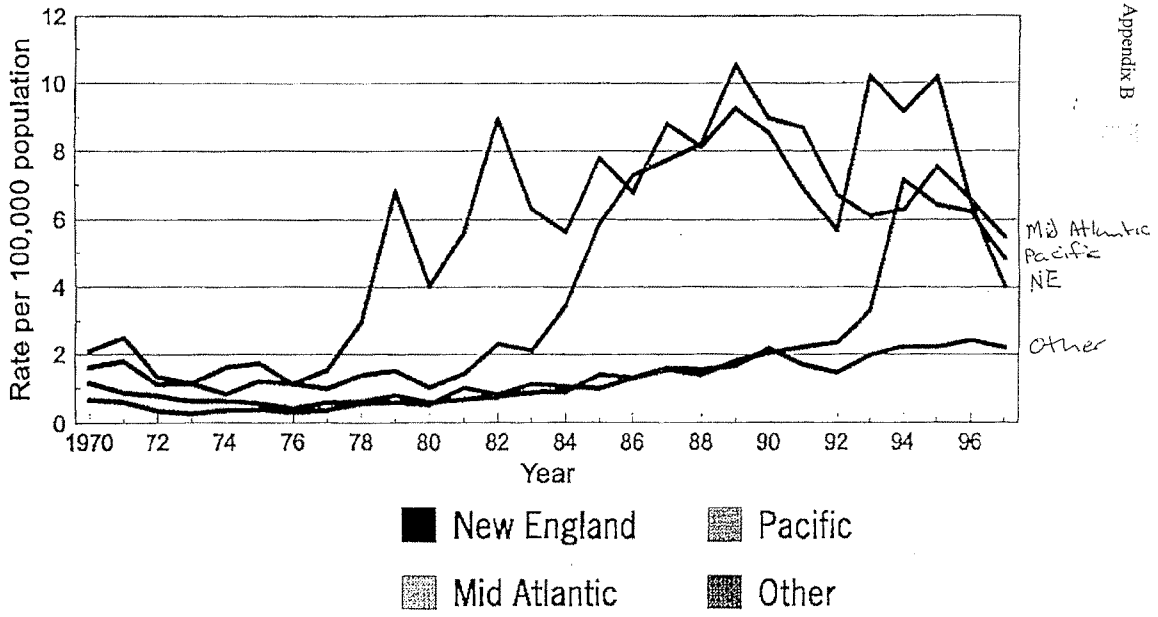
But even though the fruits of many labors are beginning to ripen, there is still more work that needs to be done. The egg industry remains committed to continuing to take the steps that continue to make the rates drop. The egg industry intends to solidify their gains and push the disease incidence down even further. The egg industry is working to implement more control methods and to unearth new and better control techniques. We might have to coexist with bacteria, but we don't have to let them win.

Thank you for inviting us to be part of this hearing and to be part of the process to ensure a safe food supply. Eggs are a nourishing, appealing, economical food that can continued to be enjoyed with assurance. The egg industry is committed to doing its part to keep it that way.

Appendix A

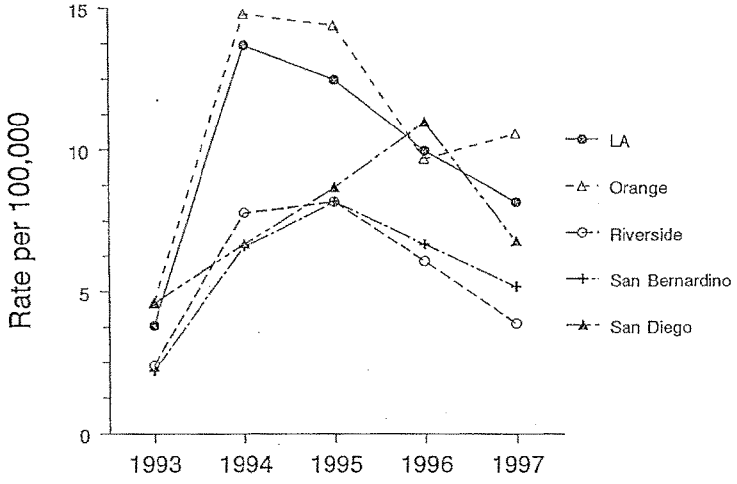

Reported outbreaks of Salmonella Enteritidis infections, U.S., 1985 - 1997
Number
100
80
60
40
20
0
85
86
87
88
89
90
91
92
93
94
95
96
97
Year
CDC SE Outbreak Surveillance N = 753

SE isolation rates by region, U.S., 1970-1997



CDC National *Salmonella* Surveillance System

SE INCIDENCE RATE IN SOUTHERN CALIFORNIA



Appendix C

Closing the Gap: The Burden of Unnecessary Illness

Edited by
Robert W. Amler
H. Bruce Dull

Oxford University Press New York, Oxford 1987
Appendix D

CLOSING THE GAP:
The Burden of Unnecessary Illness
Documentation and Intervention Strategies resulting from the Health Policy Consultation of the Carter Center of Emory University, November 26–28, 1984, Atlanta, Georgia

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Infectious and Parasitic Diseases

John V. Bennett, M.D., Scott D. Holmberg, M.D.,
Martha F. Rogers, M.D., and Steven L. Solomon, M.D.

Most of the health problems identified in *Closing the Gap* relate directly or indirectly to infectious diseases. Infections and infection-related deaths are important contributors to circulatory, respiratory, and gastrointestinal diseases, to infant morbidity and mortality, and to arthritis. Infections also play an important role in morbidity and mortality that may complicate unintentional injuries, malignancies, attempted homicides or suicides, and diabetes mellitus. Microbial agents probably play a crucial role in dental caries and periodontal disease. Further, in the past few years viruses have been found to cause malignancies in humans, and other oncogenic viruses will no doubt be identified. Because of these interrelationships, the information in this report overlaps with and complements information in other position papers of the Carter Center Health Policy Project.

The effective control of each health problem will reduce the morbidity and mortality associated with infectious disease. Conversely, improvements in infection prevention and treatment will reduce the morbidity and mortality associated with other health problems.

DATA SELECTION

Infectious and parasitic diseases occupy the International Code of Diseases (ICD) codes 1–113, but at least 125 additional specific ICD codes reflect infections. Indeed, only 17 percent of all deaths from infections can be identified within ICD codes 1–113. Some ICD codes represent entities that are not always caused by infectious agents (for example, bronchitis), and some codes encompass situations in which infections may be either primary events or secondary to other inciting episodes (for example, peritonitis). These deficiencies in classification make it difficult to obtain a clear picture of the true magnitude of infections from data systems based on ICD codes. For this reason, we relied on other data to establish the burden of illness caused by infections.

To estimate the negative impact of infectious diseases in the United States, we first divided all infectious diseases into mutually exclusive groupings, then used published material and survey data from the National Center for Health Statistics to derive morbidity and mortality estimates for each grouping. The groupings were then combined to give totals for all infectious diseases. We refer to this information as the consultants' data. (The details of this data set are presented in a 361-page appendix which is on file with the Carter Center.)

The second group of data, referred to as CDC Survey Data, was collected from experts in the various divisions of the Center for Infectious Diseases and the Center for Prevention Services, Centers for Disease Control (CDC). Data were provided in 1985 on the current incidence of symptomatic infections, current and estimated future case-fatality ratios attributable to these infections, and current and estimated future overall efficiency in preventing infections caused by 117 specific microbial agents or agent groupings (Table 1, first five columns). Estimates included the morbidity and mortality averted by use of all applicable intervention strategies in both the public and private sectors. Estimates are given of current effectiveness as well as likely future effectiveness deriving from known or likely upcoming improvements in the effectiveness of various intervention strategies. Estimates of the effectiveness of prevention efforts vary in reliability. In some instances, such as nosocomial infections, these estimates are well established. In other instances, such as rotaviruses, they are based on the assumed efficacy of a yet-to-be-fully-devel-

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oped vaccine. Some estimates represent solely the cautious guesses of experts.

The data provided in the CDC survey were then used to derive additional parameters by which prevention could be assessed as described in Table 2. The resulting estimates of the numbers of cases and deaths prevented now and in the future and other derivative data appear in the last nine columns of Table 1.

The 117 specific infections or infection groupings were assigned subsequently to appropriate, mutually exclusive etiologic groups and to one or more of 13 additional infection categories that were not necessarily mutually exclusive (Table 3). In some instances, such as the category "zoonotic," all infections potentially transmissible from animals to humans were included. In other instances, such as the category "foodborne," the proportion of each specific infection acquired in that fashion was estimated as indicated in Table 3, and only that proportion of overall morbidity and mortality attributable to foodborne acquisition was included under the "foodborne" heading. "Vaccine-preventable" infection data could not be apportioned reliably in this fashion, although it is recognized that the vaccine itself may sometimes not be responsible for all prevented cases (e.g., anthrax).

In general, the CID survey data underestimated the overall magnitude of infections compared with the consultants' data, since not all known specific infectious agents were included in the survey results, and clinically diagnosed infections of known and unknown causes were encompassed in the consultants' data. Thus, we have relied primarily on the consultants' data for estimates of negative impact and on the CDC survey data for prevention estimates.

SCOPE OF THE PROBLEM

The consultants' data indicate that more than 740 million infectious disease events and nearly 200,000 attributable deaths occur annually in the United States (Table 4). Included in the total incidence are infections that, although not life threatening for persons who have normal host defenses, may result in days lost from work (or other major activities) or that incur a direct financial burden. The total number of deaths attributed to infectious diseases includes those cases for which either prevention or successful treatment would have prolonged the life of the affected person.

We estimate that each year infectious diseases result in more than 2 million years of life lost before the age of 65, more than 52 million hospital days, and nearly 2 billion days lost from work, school, and other major activities. The total direct cost of infectious diseases—not including the cost of deaths, lost wages and productivity, reactions to treatment, or other indirect costs—exceeds $17 billion annually.

The leading contributors to these negative impacts, as assessed from the CDC survey data, are listed by nonexclusive category in Table 5. The five most important contributors to mortality from infections, in decreasing order of magnitude, are: bacterial infections, lower respiratory infections (pneumonia and influenza), nosocomial infections, vaccine-preventable infections, and viral infections. The five major causes of symptomatic infections, in decreasing order of magnitude of cases, are: viral, upper respiratory, cutaneous, vaccine-preventable, and bacterial infections.

The annual monetary costs of infectious diseases derive largely from the cost of hospital care. Nosocomial infections themselves account for the greatest direct costs; they complicate the course of recovery among hospitalized patients, increase the severity of illness, increase mortality, or prolong hospital stay, thus adding substantially to the consumption of expensive hospital services.

The consultants' data indicate that nosocomial infections account for almost 12 million excess hospital days annually and pose direct costs of close to $3.5 billion. Enteric and lower respiratory infections account for 9 million and 7.5 million hospital days, respectively, and are estimated to involve direct costs of $3 billion and more than $2 billion, respectively. Genitourinary tract infections, soft-tissue infections, and upper respiratory infections are not major causes of death. However, they result in appreciable costs for outpatient care. Approximately $5 billion was spent on genitourinary tract and upper respiratory infections, and $2 billion on soft-tissue infections.

ESTIMATES OF PREVENTION GAPS

We can prevent many additional infections every year simply by expanding our current efforts in prevention and utilizing recent technological advances. Specific infections or infection groupings where more than a million additional future cases may be preventable each year include infections caused by rotaviruses, enteroviruses, Norwalk and other 27-nanometer particles, campylobacter, salmonella, and toxoplasma (Table 1, column 12 minus

Table 1. Domestic infections, United States, 1985

Disease or agent	Current incidence[a]	Case/fatality ratio (%)[b] Now	Future	Effectiveness[c] Now	Future	Deaths now
Bacterial						
Chlamydia neonatal	50,000	0.0001	0.0001	0	35	0
Psittacosis	700	1.0	0.5	40	50	7
Trachoma	100	0.0	0.0	50	50	0
Mycoplasma pneumonia	1,000,000	0.01	0.01	0	1	100
Anthrax	1	5.0	5.0	99	99	0
Bacillus cereus	5,000	0.0	0.0	80	84	0
Botulism incl. infants	200	4.0	2.0	99	99.3	8
Brucellosis	400	0.5	0.5	97	99	2
Campylobacteriosis	2,100,000	0.1	0.02	75	95	2,100
Chancroid	4,000	0.0005	0.0001	50	80	0
Chlamydia trach. gen. inf.	2,200,000	0.05	0.02	5	50	1,100
Cholera	25	1.0	0.0	95	98	3
Clost. perfringens	10,000	1.0	0.0	80	85	100
Dial. pyrogen, py. reac., sep.	5,000	0.1	0.08	10	15	5
Diphtheria	10	10.0	3.0	>99.9	>99.9	1
E. coli–enteric.	200,000	0.2	0.1	90	98	400
End. bact.–aer. and anaer.	10,000	0.05	0.05	10	10	5
Gardnerella vaginale inf.	6,000,000	0.0	0.0	1	10	0
Gonococcal infection	2,000,000	0.05	0.02	40	65	1,000
H. influ. incl. menin.	20,000	5.0	5.0	3	75	1,000
Legionellosis	75,000	15.0	15.0	3	12	11,250
Leprosy	400	1.5	1.0	4	4	6
Leptospirosis	1,100	3.0	1.0	55	60	33
Listeriosis	220	12.5	12.5	1	35	28
Meningococcal inv.	6,000	10.0	10.0	4	50	600
Misc. unclass.	1,000	0.05	0.05	0	1	1
Miscellaneous enteric	200,000	1.0	0.5	50	80	2,000
Miscellaneous zoonotic	2,000	1.0	0.5	5	10	20
Mycobacteria nontb.	10,000	0.5	0.4	1	2	50
Mycoplasma hom. genital	100,000	0.002	0.001	1	25	2
Mycoplasma/ureaplasma	250,000	0.001	0.001	1	7.5	3
Pasteurella multocida	14,000	0.25	0.2	20	25	35
Pertussis	34,000	0.2	0.2	80	85	68
Plague	50	15.0	10.0	50	75	8
Pneumococcal invasive	400,000	8.0	6.0	4	55	32,000
Relapsing FVR.–tick/louse	264	0.5	0.5	5	5	1
Rickettsioses	2,000	5.6	5.0	5	10	112
S. aureus–TSS	4,500	3.0	1.5	75	90	135
S. aureus excl. TSS	8,900,000	0.08	0.05	3	5	7,120
Salmonellosis, nontyphi.	2,000,000	0.1	0.05	80	95	2,000
Shigella	300,000	0.2	0.2	55	75	600
Strep. Group A	10,000,000	0.03	0.02	1	1.5	3,000
Strep. Group B neonatal	7,000	20.0	15.0	5	25	1,400
Syphilis	70,000	0.08	0.01	75	85	56
Tetanus	150	30.0	30.0	98	99	45
Tuberculosis	27,000	5.0	4.0	40	40	1,350
Tularemia	402	1.0	0.8	15	17	4
Typhoid	600	6.0	5.5	95	99	36
Vibrio inf. excl. cholera	10,000	4.0	2.0	80	95	400
Yersiniosis excl. plague	5,000	0.05	0.04	0.5	2	3
Fungal						
Actinomycotic diseases	1,400	5.0	4.0	10	10	70
Aspergillosis	2,300	7.0	4.0	5	5	161
Blastomycosis	100	7.0	4.0	5	5	7
Candidiasis	4,000	10.0	2.0	5	5	400
Chromoblastomycosis	50	0.0	0.0	5	5	0
Coccidioidomycosis	8,000	4.0	2.0	10	10	320
Cryptococcosis	1,000	10.0	10.0	4	4	100
Dermatophytoses	18,000,000	0.0	0.0	1	1	0
Histoplasmosis	10,000	1.0	1.0	5	7	100
Mycetomas	25	0.0	0.0	0	0	0

	Without prevention		With prevention		Preventable annually[d]		Future incidence[e]	
	Cases	Deaths	Cases	Deaths	Cases	Deaths	Cases	Deaths
Bacterial								
Chla. neon.	50,000	0	0	0	17,500	0	32,500	0
Psittacosis	1,167	12	467	45	583	9	584	3
Trachoma	200	0	100	0	100	0	100	0
Mycopl. pneu.	1,000,000	100	0	0	10,000	1	990,000	99
Anthrax	100	5	99	5	99	5	1	0
B. cereus	25,000	0	20,000	0	21,000	0	4,000	0
Bot. in infant	20,000	800	19,800	792	19,860	797	140	3
Brucellosis	13,333	67	12,933	65	13,200	66	133	1
Campylobact.	8,400,000	8,400	6,300,000	6,300	7,980,000	8,316	420,000	84
Chancroid	8,000	0	4,000	0	6,400	0	1,600	0
Chla. tra. gen.	2,315,789	1,158	115,789	58	1,157,894	926	1,157,895	232
Cholera	500	5	475	2	490	5	10	0
C. perfring.	50,000	500	40,000	400	42,500	500	7,500	0
Dial. pyro.-sep.	5,556	6	556	1	833	2	4,723	4
Diphtheria	15,000	1,500	14,990	1,499	14,990	1,500	10	0
E. coli.-ent.	2,000,000	4,000	1,800,000	3,600	1,960,000	3,960	40,000	40
End. bac.-Ae&An	11,111	6	1,111	1	1,111	1	10,000	5
Gardner. vag.	6,060,606	0	60,606	0	606,060	0	5,454,546	0
Gonococcus	3,333,333	1,667	1,333,333	667	2,166,666	1,434	1,166,667	233
H. inf. in men	20,619	1,031	619	31	15,464	773	5,155	258
Legionellosis	77,320	11,598	2,320	348	9,278	1,392	68,042	10,206
Leprosy	417	6	17	0	16	2	401	4
Leptospirosis	2,444	73	1,344	40	1,467	63	977	10
Listeriosis	222	28	2	0	78	10	144	18
Meningo. inv.	6,250	625	250	25	3,125	312	3,125	313
Misc. unclass.	1,000	1	0	0	10	1	990	0
Misc. ent.	400,000	4,000	200,000	2,000	320,000	3,600	80,000	400
Misc. zoo.	2,105	21	105	1	211	12	1,894	9
Mycobac. nontb.	10,101	51	101	1	202	11	9,899	40
Mycop. hom. gen.	101,010	2	1,010	0	25,252	1	75,758	1
Mycop./ureapla.	252,525	3	2,525	0	18,939	1	233,586	2
Pasteur. multoc.	17,500	44	3,500	9	4,375	18	13,125	26
Pertussis	170,000	340	136,000	272	144,500	289	25,500	51
Plague	100	15	50	7	75	12	25	3
Pneumo. inv.	416,667	33,333	16,667	1,333	229,167	22,083	187,500	11,250
Relap. fever	278	1	14	0	14	0	264	1
Rickettsioses	2,105	118	105	6	210	23	1,895	95
S. aur.—TSS	18,000	540	13,500	405	16,200	513	1,800	27
S. aur. ex TSS	9,175,258	7,340	275,258	220	458,763	2,982	8,716,495	4,358
Salm.-nontyphi.	10,000,000	10,000	8,000,000	8,000	9,500,000	9,750	500,000	250
Shigellosis	666,667	1,333	366,667	733	500,000	1,000	166,667	333
Strep. gp. A	10,101,010	3,030	101,010	30	151,515	1,040	9,949,495	1,990
Strep. gp. B neo	7,638	1,528	638	128	1,974	678	5,664	850
Syphilis	280,000	224	210,000	168	238,000	220	42,000	4
Tetanus	7,500	2,250	7,350	2,205	7,425	2,227	75	23
Tuberculosis	45,000	2,250	18,000	900	18,000	1,170	27,000	1,080
Tularemia	473	5	71	1	80	2	393	3
Typhoid	12,000	720	11,400	684	11,880	713	120	7
Vibrio ex. chol.	50,000	2,000	40,000	1,600	47,500	1,950	2,500	50
Yersinio ex. pl.	5,025	3	25	0	100	1	4,925	2
Fungal								
Actinomycosis	1,556	78	156	8	156	22	1,400	56
Aspergillosis	2,421	169	121	8	121	77	2,300	92
Blastomycosis	105	7	5	0	5	3	100	4
Candidiasis	4,211	421	211	21	211	341	4,000	80
Chromoblastomy.	53	0	3	0	3	0	50	0
Coccidioidomyc.	8,889	356	889	36	889	196	8,000	160
Cryptococcosis	1,042	104	42	4	42	4	1,000	100
Dermatophytos.	18,181,818	0	181,818	0	181,818	0	18,000,000	0
Histoplasmosis	10,526	105	526	5	737	7	9,789	98
Mycetomas	25	0	0	0	0	0	25	0

Table 1. Continued

Disease or agent	Current incidence[a]	Case/fatality ratio (%)[b] Now	Future	Effectiveness[c] Now	Future	Deaths now
Paracoccidioidomycosis	2	0.0	0.0	0	3	0
Sporotrichosis	200	6.0	4.0	3	4	12
Zygomycosis	100	15.0	15.0	0	5	15
Nosocomial						
Acute care	2,200,000	1.2	1.2	6	32	26,400
Chron. care	1,900,000	1.3	1.3	1	16	24,700
Parasitic						
Amebiasis	12,000	0.3	0.01	50	50	36
Ascariasis	50,000	0.1	0.01	20	50	50
Babesiosis	20	10.0	10.0	10	10	2
Cryptosporidiosis	50	50.0	50.0	20	50	25
Echinococcosis	200	1.5	0.75	50	60	3
Filariasis	300	0.001	0.001	0	0	0
Flukes	9,000	0.001	0.0001	0	0	0
Giardiasis	120,000	0.0001	0.0001	50	90	0
Hookworm	200	0.0001	0.0001	90	95	0
Leishmaniasis	35	0.1	0.1	0	0	0
Malaria	2,500	1.0	1.0	75	98	25
Meningoencephal., amoebic	4	99.99999	50.0	0	10	4
Pediculosis	9,000,000	0.0	0.0	10	10	0
Pneumocystis	600	20.0	1.0	90	90	120
Scabies	10,000,000	0.0	0.0	1	1	0
Schistosomiasis	1,000	0.001	0.0001	75	90	0
Strongyloidiasis	10,000	1.0	1.0	1	20	100
Taeniesis/cysticercosis	1,000	1.0	0.2	50	80	10
Toxocariasis VLM	10,000	0.0001	0.0001	1	80	0
Toxoplasma congenital	3,000	15.0	2.0	5	50	450
Toxoplasmosis excl. cong.	2,300,000	0.0001	0.0001	5	50	2
Trichinosis	100,000	1.0	0.001	10	90	1,000
Trichomoniasis	5,000,000	0.0	0.0	5	10	0
Trypanosomiasis, African	2	10.0	5.0	0	0	0
Trypanosomiasis, Amer.	1	10.0	5.0	0	0	0
Viral						
Adenovirus	10,000,000	0.01	0.01	10	15	1,000
CMV congenital	1,900	15.0	10.0	30	60	285
Colorado tick fever	2,500	0.01	0.01	1	20	0
Coronavirus	18,080,000	0.0	0.0	0	0	0
Dengue–classical	46	0.0	0.0	25	60	0
Encephalitides, N.A.	5,000	12.0	1.0	20	75	600
Enteroviral dis.–nonpolio	6,000,000	0.001	0.0001	50	80	60
Hepatitis A	48,000	0.3	0.3	40	50	144
Hepatitis B	128,000	3.0	3.0	15	80	3,840
Hepatitis non-A non-B	50,000	0.4	0.4	0	15	200
Herpes simplex (gen.)	400,000	0.00001	0.00001	5	30	0
HIV	80,000	10.0	10.0	20	50	8,000
HSV neonatal	1,000	50.0	20.0	30	80	500
Influenza	20,000,000	0.005	0.005	5	7.5	1,000
Lymphocytic choriormenin.	200	1.0	0.01	10	10	2
Measles	2,500	0.01	0.01	>99.9	>99.9	0
Mumps	10,000	0.004	0.004	99.6	99.9	0
Norwalk/other 27 nmpar.	6,000,000	0.0001	0.0001	30	50	6
Papilloma virus	3,000,000	0.001	0.001	0	0	30
Poliomyelitis	7	10.0	10.0	99.9	99.9	1
Rabies	10	99.0	99.0	99	99	10
Rhinovirus	125,000,000	0.00001	0.00001	10	10	13
Rotavirus	8,000,000	0.01	0.01	0	50	800
Rubella congenital	70	50.0	50.0	99	100	35
Rubella excl. congenital	20,000	0.0001	0.0001	98.6	99.9	0
Varicella	3,500,000	0.003	0.0002	0	2	105
Virus, respiratory sync.	7,000,000	0.005	0.005	0	30	350

	Without prevention		With current prevention		Preventable annually[d]		Future incidence[e]	
	Cases	Deaths	Cases	Deaths	Cases	Deaths	Cases	Deaths
Paracoccidioid.	2	0	0	0	0	0	2	0
Sporotrichosis	206	12	6	0	8	4	198	8
Zygomycosis	100	15	0	0	5	1	95	14
Nosocomial								
Acute care	2,340,426	28,085	140,426	1,685	748,936	8,987	1,591,490	19,098
Chron. care	1,919,192	24,950	19,192	250	307,070	3,992	1,612,122	20,958
Parasitic								
Amebiasis	24,000	72	12,000	36	12,000	71	12,000	1
Ascariasis	62,500	63	12,500	13	31,250	60	31,250	3
Babesiosis	22	2	2	0	2	0	20	2
Cryptosporidio.	63	32	13	7	31	16	32	16
Echinococcosis	400	6	200	3	240	5	160	1
Filariasis	300	0	0	0	0	0	300	0
Flukes	9,000	0	0	0	0	0	9,000	0
Giardiasis	240,000	0	120,000	0	216,000	0	24,000	0
Hookworm	2,000	0	1,800	0	1,900	0	100	0
Leishmaniasis	35	0	0	0	0	0	35	0
Malaria	10,000	100	7,500	75	9,800	98	200	2
Meningoenc.–amo.	4	4	0	0	0	2	4	2
Pediculosis	10,000,000	0	1,000,000	0	1,000,000	0	9,000,000	0
Pneumocystis	6,000	1,200	5,400	1,080	5,400	1,194	600	6
Scabies	10,101,010	0	101,010	0	101,010	0	10,000,000	0
Schistosomiasis	4,000	0	3,000	0	3,600	0	400	0
Strongyloidiasis	10,101	101	101	1	2,020	20	8,081	81
Taeniasis/cys.	2,000	20	1,000	10	1,600	19	400	1
Toxocara vlm.	10,101	0	101	0	8,081	0	2,020	0
Toxoplas. cong.	3,158	474	158	24	1,579	442	1,579	32
Toxopla. ex. con.	2,421,053	2	121,053	0	1,210,526	1	1,210,527	1
Trichinosis	111,111	1,111	11,111	111	100,000	1,111	11,111	0
Trichomoniasis	5,263,157	0	263,157	0	526,316	0	4,736,841	0
Trypanosom.–Af	2	0	0	0	0	0	2	0
Trypanosom.–Am	1	0	0	0	0	0	1	0
Viral								
Adenovirus	11,111,111	1,111	1,111,111	111	1,666,667	167	9,444,444	944
CMV congenital	2,714	407	814	122	1,629	298	1,085	109
Colorado tk. fv.	2,525	0	25	0	505	0	2,020	0
Coronavirus	18,080,000	0	0	0	0	0	18,080,000	0
Dengue–classic	61	0	15	0	37	0	24	0
Encephaliti.–NA	6,250	750	1,250	150	4,688	734	1,562	16
Enterov. non-po.	12,000,000	120	6,000,000	60	9,600,000	118	2,400,000	2
Hepatitis A	80,000	240	32,000	96	40,000	120	40,000	120
Hepatitis B	150,588	4,518	22,588	678	120,471	3,614	30,117	904
Hepa. non-A non-B	50,000	200	0	0	7,500	30	42,500	170
Herpes sim.–gen.	421,053	0	21,053	0	126,316	0	294,737	0
HIV	100,000	10,000	20,000	2,000	50,000	5,000	50,000	5,000
HSV neonatal	1,429	714	429	214	1,142	657	287	57
Influenza	21,052,632	1,053	1,052,632	53	1,578,947	79	19,473,685	974
Lymph. choriom.	222	2	22	0	22	2	200	0
Measles	3,500,000	350	3,497,500	350	3,497,500	350	2,500	0
Mumps	2,500,000	100	2,490,000	100	2,497,500	100	2,500	0
Nor./oth. 27 nmp.	8,571,429	9	2,571,429	3	4,285,714	5	4,285,715	4
Papillomavirus	3,000,000	30	0	0	0	0	3,000,000	30
Poliomyelitis	7,000	700	6,993	699	6,993	699	7	1
Rabies	1,000	990	990	980	990	980	10	10
Rhinovirus	138,888,889	14	13,888,889	1	13,888,889	2	125,000,000	12
Rotavirus	8,000,000	800	0	0	4,000,000	400	4,000,000	400
Rubella congen.	7,000	3,500	6,930	3,465	7,000	3,500	0	0
Rubella ex. con.	1,428,571	1	1,408,571	1	1,427,142	1	1,429	0
Varicella	3,500,000	105	0	0	70,000	98	3,430,000	7
Virus–resp. syn.	7,000,000	350	0	0	2,100,000	105	4,900,000	245

Data from CDC survey

[a] Estimated true annual number of clinically significant infections.

[b] Attributable to the infection.

[c] Total effectiveness, in percent, of all public and private interventions in preventing cases.

[d] Assuming future effectiveness and case-fatality ratios.

[e] Unprevented morbidity and mortality.

column 10). Similarly, more than a thousand additional deaths might be preventable each year by improved prevention of infections caused by pneumococci, HIV-1 (human immunodeficiency virus–type 1), hepatitis B, *Staphylococcus aureus*, campylobacter, salmonella, and miscellaneous bacterial enteric pathogens (Table 1, column 13 versus column 11).

Similar analyses can be applied to categories of infection (Figure 1). Substantial increments are possible in the number of prevented cases of enteric (13 million), viral (12.9 million), bacterial (6.6 million), vaccine-preventable (5.4 million), zoonotic (4.3 million), foodborne (3.5 million), lower respiratory (3.0 million), and sexually transmitted infectious diseases (2.9 million). Marked increases in the proportion of infections prevented (cases prevented in the future divided by cases prevented now) are envisioned for nosocomial infections (6.9-fold), meningitis (5.1-fold), perinatal infections (3.4-fold but not shown in Figure 1 because numbers are too small for the scale used), lower respiratory infections (3.3-fold), sexually transmitted infections (2.5-fold), and day-care-center-related infections (2.4-fold).

Impressive gains in the numbers of deaths prevented (in decreasing order) can be achieved (Figure 2) with bacterial diseases (35,900), vaccine-preventable infections (25,300), lower respiratory infections (23,300), and nosocomial infections (11,100). The largest proportional gains in deaths prevented are envisioned with meningitis (10.5-fold), fungal infections (7.0-fold), nosocomial infections (6.8-fold), lower respiratory infections (6.7-fold), cutaneous infections (5.9-fold), day-care-center-related infections (4.2-fold), and vaccine-preventable infections (3.1-fold).

Prevention of infection translates readily into economic savings. The results of applying current and achievable effectiveness in preventing cases (from CDC survey data) to negative impacts (from the consultants' data) are depicted in Figure 3. Despite impressive accomplishments in prevention, substantial gaps between what we are achieving and what we could achieve in preventing infection remain. For example, we estimate that an additional $1.3 billion in direct costs, 56 million cases of infection, 3.2 million hospital days, and 144 million disability days could be saved merely by broader application of available or soon-to-be-available interventions.

The estimated gaps between current and future achievements in preventing deaths and reducing the number of years of life lost are shown in Figure 4. An additional 80,000 deaths and nearly 1 million years of life lost may be saved annually. Indeed, more than twice as many deaths as are annually prevented now are likely to be prevented in the future. These gains result both from improved primary prevention of cases and from improved diagnosis and treatment of cases that do occur. However, such gains could occur simultaneously with and be offset by increases in unprecedented deaths from any expanding lethal infection problem. Only HIV infections are foreseen to pose such a threat.

Table 2. Derivations of additional parameters from CDC survey data

Deaths now	= (*current cases*) (*current case-fatality ratio*[a,b])
Cases in absence of prevention	= (*current cases*) ÷ (1 − *current effectiveness*[a])
Deaths in absence of prevention	= (cases in absence of prevention) (*current case-fatality-ratio*[a])
Cases prevented now	= (cases in absence of prevention) (*current effectiveness*[a])
Deaths prevented now	= (deaths in absence of prevention) − (deaths now)
Cases prevented in the future	= (cases in absence of prevention) (*future effectiveness*[a])
Future annual cases	= (cases in absence of prevention) − (cases prevented in the future)
Future annual deaths	= (future annual cases) (*future case-fatality-ratio*[a])
Deaths prevented in the future	= (deaths in absence of prevention) − (future annual deaths)

[a] Expressed as a decimal.
[b] Italics: data provided by CDC survey.

NARROWING THE GAPS

Each prevention estimate in the foregoing material depends on the composite efficacy of applicable interventions. Thus, a detailed scrutiny of each intervention capable of preventing morbidity or mortality from infection seems appropriate.

Intervention strategies for preventing infectious diseases can be divided into two basic groups: (1) strategies that are generically applicable to all infectious diseases (indeed, to all diseases), such as disease surveillance, epidemiologic investigations, diagnosis, and treatment; and (2) strategies that are applicable to subsets of infectious diseases, such as immunization, chemo- or immunoprophylaxis,

screening, contact tracing, control of environmental sources and vehicles (food, water, air, medical devices), control of insect and animal reservoirs and vectors, isolation precautions and quarantine, and behavior modification. These 12 strategies interact synergistically with each other.

Rapid and accurate identification, both of individual cases and of clusters of disease, is important in preventing new cases as well as in initiating early and appropriate treatment of those who are already ill. The potential for the rapid identification of specific infectious diseases has been greatly enhanced in recent years by developments in the microbiology laboratory and by the revolution in data pro-

Table 3. Domestic infections, United States, 1985: percentage attributed to various infection categories

Disease or agent	Pneumonia and lower respiratory	Upper respiratory	Perinatal	Zoonotic	Cutaneous	Foodborne	Enteric	Waterborne	STD	Meningitis	Vectorborne	Day care	Vaccine preventable
Bacterial													
Chlamydia neonatal	100		100										
Psittacosis	100			100									
Trachoma					100								
Mycoplasma pneumonia	100												
Anthrax				100									100
Bacillus cereus						100	100						
Botulism incl. infants						90	100						
Brucellosis				100		5							
Campylobacteriosis				100		100	100	15					
Chancroid									100				
Chlamydia trach. gen. inf.									100				
Cholera						100	100						
Clost. perfringens						100	100						
Dial. pyrogen, py. reac., sep.													
Diphtheria		100											100
E. coli–enteric.						25	100	75				5	
End. bact.–aer. and anaer.	50									5			
Gardnerella vaginale inf.									100				
Gonococcal infection									100				
H. influ. incl. menin.	12									50		30	100
Legionellosis	98												
Leprosy					100								
Leptospirosis				100									
Listeriosis				100						60			
Meningococcal inv.										80		5	100
Misc. unclass.	1									1			
Miscellaneous enteric						95	100	5					
Miscellaneous zoonotic				100									
Mycobacteria nontb.	20									1			
Mycoplasma hom. genital									100				
Mycoplasma/ureaplasma									100				
Pasteurella multocida				100									
Pertussis	100											0.5	100
Plague	20			100						10	100		
Pneumococcal invasive	95									5		5	100
Relapsing FVR.–tick/louse				100							100		
Rickettsioses											100		
S. aureus–TSS													
S. aureus excl. TSS	1				75	17				1		2	
Salmonellosis, nontyphi.				100		96	100	3				1	
Shigella						30	100	10				25	
Strep. Group A	1	75			25	5				1		2	
Strep. Group B neonatal	20		100							50			
Syphilis									100				
Tetanus													100
Tuberculosis	85									0.6			
Tularemia				100							100		
Typhoid						80	100	10					
Vibrio inf. excl. cholera						90	100	10					
Yersiniosis excl. plague				100		65		35					
Fungal													
Actinomycotic diseases													
Aspergillosis	100												
Blastomycosis	95												
Candidiasis												5	
Chromoblastomycosis					100								

Table 3. Continued

Disease or agent	Pneumonia and lower respiratory	Upper respiratory	Perinatal	Zoonotic	Cutaneous	Foodborne	Enteric	Waterborne	STD	Meningitis	Vectorborne	Day care	Vaccine preventable
Coccidioidomycosis	100												
Cryptococcosis										60			
Dermatophytoses					100							5	
Histoplasmosis	100												
Mycetomas					100								
Paracoccidioidomycosis	100												
Sporotrichosis					100								
Zygomycosis					100								
Nosocomial													
Acute care	15				6								
Chron. care	11				16		8						
Parasitic													
Amebiasis							100					0.5	
Ascariasis							100					5	
Babesiosis											100		
Cryptosporidiosis							100					2	
Echinococcosis				100									
Filariasis											100		
Flukes							100						
Giardiasis							100	60				15	
Hookworm							100						
Leishmaniasis					90						100		
Malaria											100		100
Meningoencephal., amoebic										100			
Pediculosis					100							0.5	
Pneumocystis	100												
Scabies					100							0.5	
Schistosomiasis													
Strongyloidiasis							100						
Taeniasis/cysticercosis				100									
Toxocariasis VLM				100									
Toxoplasma congenital			100										
Toxoplasmosis excl. cong.				100									
Trichinosis				100		100							
Trichomoniasis									100				
Trypanosomiasis, African											100		
Trypanosomiasis, Amer.											100		
Viral													
Adenovirus		100										2	100
CMV congenital			100										
Colorado tick fever											100		
Coronavirus		100										1	
Dengue–classical											100		
Encephalitides, N.A.											100		
Enteroviral dis.–nonpolio							100					2	
Hepatitis A						10	100					15	
Hepatitis B			1										100
Hepatitis non-A non-B													
Herpes simplex (gen.)					100				100				
HIV			1						75				
HSV neonatal			100										
Influenza	100											1	100
Lymphocytic choriomenin.				100						95			
Measles					100								100
Mumps		100											100
Norwalk/other 27 nmpar.							100	5				0.5	
Papilloma virus					100				5				
Poliomyelitis							100						100
Rabies				100									100
Rhinovirus		100											
Rotavirus							100					10	100
Rubella congenital			100										100
Rubella excl. congenital					100								100
Varicella					100								
Virus, respiratory sync.	100											5	

Table 4. The annual negative impact of infections, United States: consultants' data

Cases	742,248,261
Deaths	194,704
Years lost before the age of 65	2,192,370
Hospital days	42,029,624
Disability days[a]	1,901,847,705
Cost[b]	$17,191,400,000

[a] Days lost from work, school, preschool, or housekeeping.
[b] Excludes costs of death, sequelae of infections, home care, and reactions to treatment.

Table 5. Current annual impacts by infection category, United States: CDC survey data

Infection group	Deaths[a]	Incidence[b]
Bacterial	68,200	36,026,000
Cutaneous	11,800	53,534,000
Day-care-related	2,600	3,713,000
Enteric	10,800	25,227,000
→ Food-borne	9,100	6,496,000
Fungi	1,200	18,027,000
Meningitis	3,500	229,000
Nosocomial	51,100	4,100,000
Parasitic	1,800	26,620,000
Perinatal	2,800	65,000
Pneumonia and lower respiratory	52,000	29,321,000
Sexually transmitted	8,200	16,234,000
Upper respiratory	3,300	160,590,000
Vaccine-preventable	40,400	38,623,000
Vector-borne	800	13,000
Viral	17,000	207,329,000
Water-borne	900	940,000
Zoonotic	5,300	6,536,000

[a] Rounded to the nearest 100.
[b] Rounded to the nearest 1,000.

cessing. Advances in molecular biology and microbial genetics have led to the development of rapid, sensitive, and specific diagnostic tests, and additional discoveries are imminent.

Surveillance and epidemiologic investigations establish risk factors for disease by defining the sources of infection, the means by which the causative agent is spread, and the host factors that make people susceptible to infection. Surveillance identifies new problems, focuses control efforts, and provides a means to monitor the effectiveness of control efforts.

Our ability to perform surveillance has been greatly enhanced by advances in data processing, which permit rapid transmission of data among public health agencies and health care providers and allow for immediate analysis of large amounts of data as they are gathered. Disease surveillance and investigation, combined with new diagnostic techniques, permit the other interventions discussed to be performed efficiently and effectively for specific infections. Potentially communicable persons and reservoirs within the environment can be identified, treatment or decontamination can be

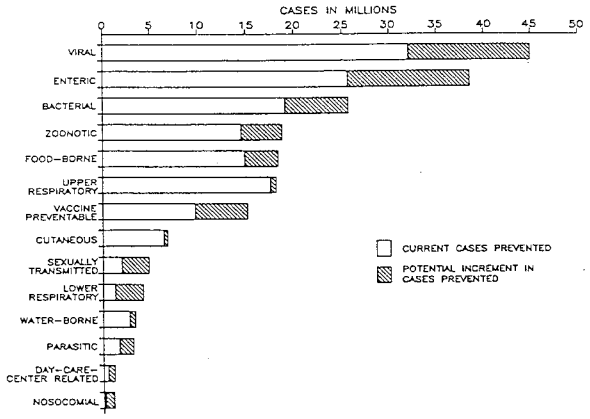


Figure 1. The prevention of infectious diseases in the United States, current and potential: number of cases prevented annually, by infection categories, based on CDC survey data.

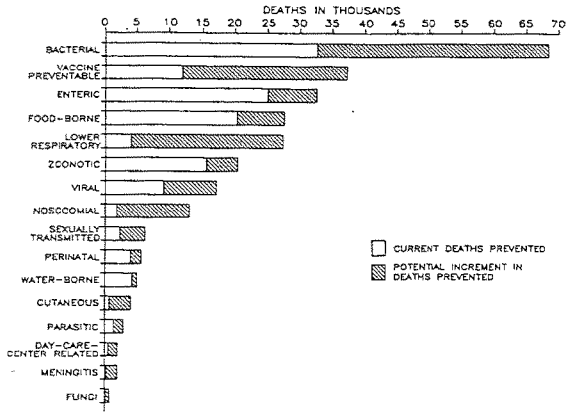
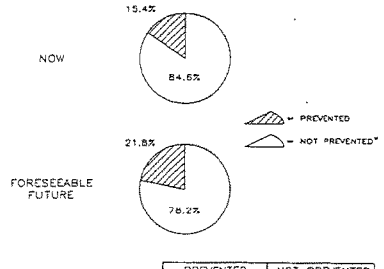


Figure 2. The prevention of infectious diseases in the United States, current and potential: number of deaths prevented annually, by infection categories, based on CDC survey data.

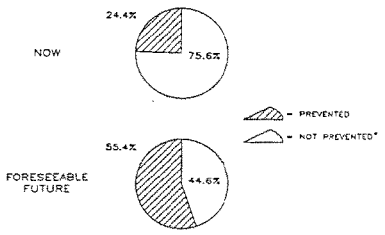
initiated, and, when necessary, chemoprophylaxis and immunoprophylaxis can be offered to exposed and potentially exposed persons. Disease investigations continue to identify new sources of transmission for well-known agents.



NEGATIVE IMPACTS	PREVENTED		NOT PREVENTED	
	NOW**	FUTURE**	NOW*	FUTURE**
COSTS (BILLIONS)	3.1	4.4	17.2	15.9
CASES (MILLIONS)	135.1	191.3	742.2	686.0
HOSPITAL DAYS (MILLIONS)	7.6	10.8	42.0	38.8
DISABILITY DAYS (MILLIONS)	346.2	490.1	1901.8	1757.9

*Figure 3. Annual morbidity from infections, United States. *Unprevented morbidity is equivalent to the current negative morbidity impacts shown in Table 4. **Derived from above prevention estimates and current negative morbidity impacts.*

Advances in molecular biology offer great opportunities to improve the immunogenicity, safety, and quantity of older vaccines and to develop highly effective and safe new ones. The production of more effective vaccines with a longer duration of protection in large quantities at low cost may ulti-



NEGATIVE IMPACTS	PREVENTED		NOT PREVENTED	
	NOW**	FUTURE**	NOW*	FUTURE**
DEATHS (THOUSANDS)	62.8	142.7	194.7	114.8
YEARS OF LIFE LOST (MILLIONS)	.7	1.6	2.2	1.3

*Figure 4. Annual mortality from infections, United States. *Unprevented mortality is equivalent to current negative mortality impacts in Table 4. **Derived from above prevention estimates and current negative mortality impacts.*

mately make routine immunization of the entire population with a variety of vaccines (e.g., hepatitis B, meningococcal vaccine) economically feasible. Improved vaccines might also play major roles in management of persons known or likely to be exposed to particular infectious agents, and make it possible to develop highly effective immunoprophylactic agents.

Ongoing research has led to new antimicrobial agents, especially antiviral and antifungal drugs, that are available or undergoing experimental trials. These drugs offer the promise of successful therapy for persons who have infections that until now have been untreatable. Such therapy will lessen the burden of illness and reduce the likelihood that the diseases will be communicated to others. Surveillance of microbial resistance of infectious agents improves the appropriateness and thus the effectiveness of both treatment and prophylaxis.

Contact tracing is often associated with finding persons exposed to sexually transmitted diseases. This method may also be used to identify people who are at risk for other infections, such as infections caused by eating contaminated food, by contact with persons who have communicable diseases in day care centers or institutions, or by exposure to contaminated pharmaceutical products and medical devices. The rapid institution of effective therapy in persons already infected, at times before the onset of symptoms, may be critical to the prevention of disability, mortality, and spread of infection.

Screening, the systematic and routine use of tests to detect infection, is especially useful when a large percentage of infected persons are without clinical symptoms, and the progress or spread of the infection can be influenced if its presence is known. Infections detected through screening contribute to surveillance and contact tracing and may lead to chemo- or immunoprophylaxis, immunization, or counseling to influence changes in behavior.

Environmental control is the process of ensuring that food, water, and air do not become a source of infectious diseases. Examples of areas where further progress can be made include finding ways to reduce antibiotic-resistant salmonella in meat products and developing new approaches to reduce the hazard of legionella in cooling towers and potable water.

The control of insects and animals involved in arthropod-borne and zoonotic infections continues to be of great importance. Expanded efforts at prevention will further reduce the impact of illnesses as diverse as campylobacteriosis, plague, rabies, and infectious encephalitis.

Quarantine, the detection and total physical isolation of infected persons, has some applicability in preventing the introduction of certain hazardous communicable infections from other parts of the world into the United States. However, it plays little part in the prevention of domestic infections. Isolation, the implementation of precautions appropriate for the known ways in which infections are spread, is effective in preventing spread from patients to other patients, hospital staff, and visitors.

The final intervention strategy is behavior modification. Convincing people to alter aspects of their lifestyles that predispose them to infectious diseases or that enable them to spread infections to others is difficult. Personal hygiene, sexual behavior, and the use of tobacco products, alcoholic beverages, and licit and illicit drugs, as well as a person's willingness to make appropriate use of health care providers and public health services, profoundly affect one's risk of becoming a victim of an infectious disease.

We believe that the interventions likely to have the most impact on closing the demonstrated gap between current achievements and future attainments in preventing cases and deaths from infections include improved epidemiologic services, improved diagnosis and treatment, more widespread immunization, more effective environmental control, and more effective behavior modification. The risks for infectious disease are multifactorial, and a broad-based approach to prevention that uses many intervention strategies will yield the best results.

SUMMARY

More than 740 million symptomatic infections occur annually in the United States, resulting in 200,000 deaths a year. Such infections result in more than $17 billion annually in direct costs, not including cost of deaths, lost wages and productivity, reactions to treatment, and other indirect costs. About 135 million infections, 63,000 deaths, and $3.1 billion in direct costs are now prevented annually, but an additional 56 million cases, 80,000 deaths, and $1.3 billion in direct costs could be prevented by using currently and soon-to-be-available interventions.

The advances made in preventing infectious diseases during this century have been among the most dramatic developments in medicine. However, it is likely that we will be able in the future to prevent nearly one and a half times more infections

and more than twice as many deaths as can be prevented now. Indeed, it is conceivable that we will be able during the next decade to match the entire accumulated progress to date in preventing morbidity and mortality from infections. Unfortunately, the presently expanding mortality from HIV infection will lessen the net effects of these remarkable advances in prevention.

The authors express appreciation to many persons at the Centers for Disease Control who provided information and estimates on the morbidity and mortality of specific infections. Special thanks are extended to the following reviewers: Drs. Miriam J. Alter, Libero Ajello, Larry J. Anderson, Paul A. Blake, Joel G. Breman, Claire V. Broome, Walter R. Dowdle, John C. Feeley, Steven C. Hadler, Ann M. Hardy, George R. Healy, Kenneth Herrmann, Alan R. Hinman, James M. Hughes, Dennis D. Juranek, Robert L. Kaiser, Arnold F. Kaufmann, and William G. Winkler.

EGG INDUSTRY RESPONSE SINCE LEARNING OF S.E. IN 1988.

Established SE Task Force (Industry - USDA - CDC - FDA)

Secured $3.4 million annually from congress for SE Pilot Project

Promoted technology transfer to industry Quality Assurance programs

Called for breeder testing through National Poultry Improvement Plan

Supported eggs being on FDA's potentially hazardous foods list

Proposed and helped pass National Refrigeration Law

Proposed legislation requiring egg packages to include "Keep Refrigerated" statement

Recommended pasteurized egg products be used in food service and institutional settings

Developed nation-wide food safety programs for egg production and processing
– United Egg Producers "5-Star Plus" program

Requested validation and third party monitoring for "5-Star Plus" program

Supported the use of vaccines; introduced them into the "5-Star Plus" program

United Egg Association/Producers HACCP workshop for egg production and processing

Published egg handling and preparation tips for food service and consumers (Am. Egg Board)

Supported U. S. Animal Health Association in the development of Best Management Practices

Supported nationwide survey: USDA/APHIS/National Animal Health Monitoring Survey

Most importantly, have extended industry cooperation to government

Established SE Risk Assessment II Working Group - a cooperative industry/government effort

Partnered with President Clinton on Food Safety Initiative (American Egg Board)

Funded food safety research (American Egg Board)

Established a Ph. D. level food safety position and program (Egg Nutrition Center)

Provided comments in response to requests on egg safety in the Federal Register

Suggested revisions to outbreak/traceback program to improve efficacy

Appendix E

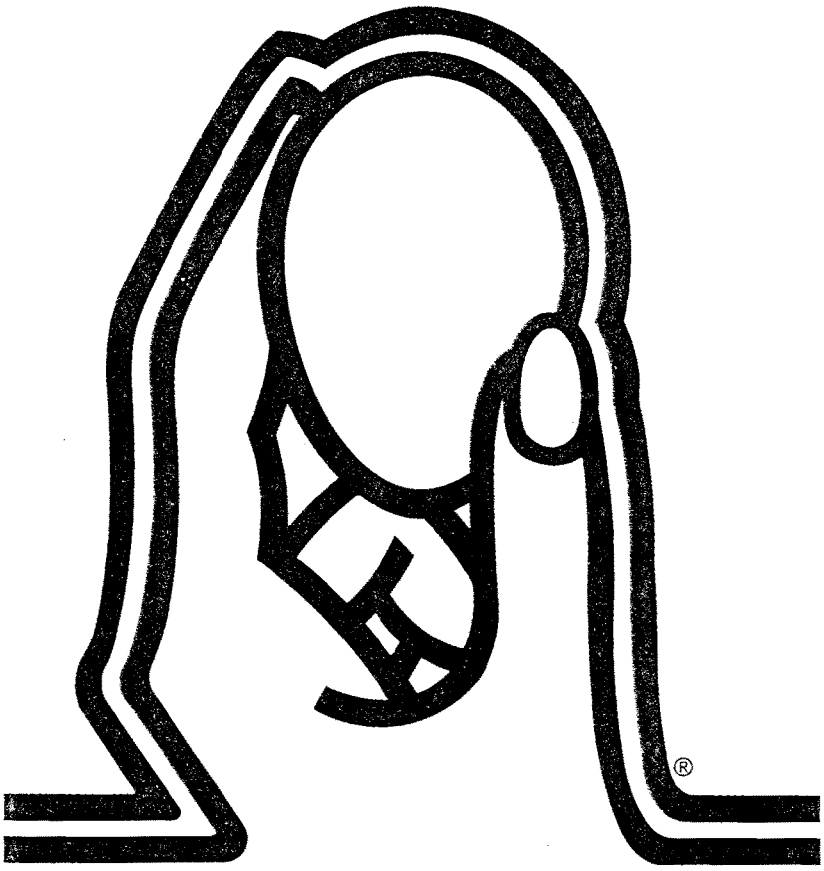
RECOMMENDATIONS FOR SAFE HANDLING OF EGGS DURING FOODSERVICE OPERATIONS

Jill A. Snowdon, Ph. D., Director of Food Safety Programs, Egg Nutrition Center

- eggs should have clean, intact shells
- use only fresh eggs -- those within 3 weeks of the pack date
- rotate stock
- keep shell eggs in cold storage until immediately before use
- fresh batters and sauce need to be placed in clean pitchers, bowls, etc.
- wash and sanitize utensils, bowls, blenders, etc. that have been used with eggs before using them again, even for the same recipe
- replace raw shell egg recipes with cooked shell egg recipes or pasteurized egg products
- egg-containing dishes & pooled eggs should be cooked promptly or held at less than 40 F
- cook eggs and egg-containing dishes thoroughly; to 160 F or 140 F for 3.5 min
- pre-heat oven and cook deep-dish casseroles completely (as confirmed by a thermometer)
- cook egg-containing dishes, especially sauces, precisely as directed (use a thermometer)
- thaw and cook frozen foods containing eggs (ex. Croquettes, lasagne) completely
- hold hot cooked eggs at temperatures of 140 F or more
- leftover food needs to be placed in shallow pans and cooled rapidly
- food service workers should not work when ill with diarrhea
- food service workers should wash their hands often

ADDITIONAL RESOURCES

- American Egg Board, 1460 Renaissance Drive, Park Ridge, IL 60068-1340 (847) 296-7043
- National Restaurant Association, the Educational Foundation Appendix F 250 South Wacker Drive, Suite 1400, Chicago, IL 60606



The Incredible Edible Egg

A Natural For Any Foodservice Operation

The Egg And You

Can you think of a more popular item on any foodservice menu today than The incredible edible egg?

Foodservice operators are looking to egg dishes as a quick and easy way to improve their operations through a more varied menu and lower food and labor costs. Even operations that aren't set up to operate at a profit can profit from The incredible edible egg.

The public is also turning to egg dishes. That's because egg dishes are not only delicious and economical, but also in tune with the trend toward lighter meals.

This booklet will help you to better understand The incredible edible egg and how best to use it. And that could easily lead to an improvement in both your menu and your operation.

Table of Contents

For more detailed information regarding eggs and egg dishes, contact your local egg association or:

Foodservice Department
American Egg Board
1460 Renaissance Drive
Suite 301
Park Ridge, IL 60068
(See back cover for additional information)

The Real Beauty Of Eggs

Take a look at the benefits of featuring eggs on your menu:

Familiarity Practically everyone in your operation, from kitchen help to managers, is familiar with eggs and knows generally how to use them.

Versatility Eggs work wonders as everything from garnishes to side dishes, from appetizers to entrees.

Nutrition Eggs are a good source of protein and contain Vitamins A, B, and D, among others, and a variety of minerals, including iron.

Low Food Cost Eggs are really economical when compared with other sources of protein. If you're a commercial operator, eggs can be a new source of profits. Or, if you're a non-commercial operator, they can be a way to cut costs.

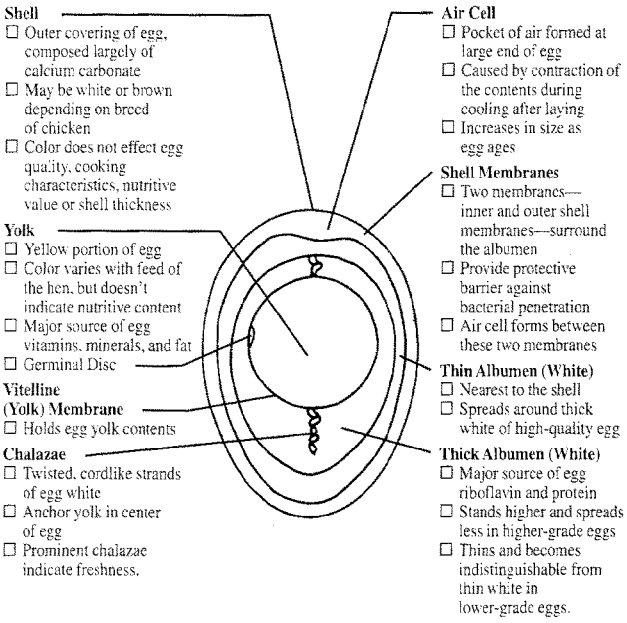
Low Labor Cost Eggs are almost labor free. Add that to their low cost and you can see the real financial benefit of eggs.

Merchandisability The merchandising potential of eggs is almost endless. For example, give your menu a contemporary look by featuring dishes such as omelets, quiches, and souffles. Or use egg garnishes to give other dishes added value at very little real cost.

To Know 'Em Is To Love 'Em

It's only natural that eggs are so popular because eggs are 100% natural. Take a look:

Egg Composition



Egg Color

Shell Color – It can be either white or brown and is determined by the breed of the hen. It has no effect on quality, cooking properties or nutritive value.

Yolk Color – It's determined by the feed of the hen.

NUTRIENT VALUES FOR A LARGE RAW EGG*

Based on 59 g. shell weight with 50 g. total liquid whole egg, 33.4 g. white, and 16.6 g. yolk.

NUTRIENT AND UNIT	WHOLE	WHITE	YOLK
Proximate			
Water—g.	37.66	29.33	8.10
Food energy—C.	75	17	59
Protein (N x 6.25)—g.	6.25	3.52	2.78
Total lipid—g.	5.01	—	5.12
Total carbohydrate—g.	.61	.34	.30
Ash—g.	.47	.21	.29
Lipids			
Fatty acids—as triglycerides—g.	4.327	—	4.428
Saturated—total	1.550	—	1.586
8:0 Caprylic	.002	—	.002
10:0 Capric	.002	—	.002
12:0 Lauric	.002	—	.002
14:0 Myristic	.017	—	.017
16:0 Palmitic	1.113	—	1.139
18:0 Stearic	.392	—	.401
20:0 Arachidic**	.005	—	.005
Monounsaturated—total	1.905	—	1.949
14:1 Myristoleic**	.005	—	.005
16:1 Palmitoleic	.149	—	.152
18:1 Oleic	1.736	—	1.776
20:1 Eicosenoic	.014	—	.014
22:1 Erucic	.002	—	.002
Polyunsaturated—total	.682	—	.698
18:2 Linoleic	.574	—	.587
18:3 Linolenic	.017	—	.017
20:4 Arachidonic	.071	—	.073
20:5 Eicosapentaeonic	.002	—	.002
22:6 Docosahexaenoic	.018	—	.019
Cholesterol—mg.	213	—	213
Lecithin—g.**	1.15	—	1.11
Cephalin—g.**	.230	—	.219
Vitamins			
A—IU	317	—	323
D—IU**	24.5	—	24.5
E—ATE	.525	—	.525
B_{12}—mcg.	.50	.07	.52
Biotin—mcg.**	9.98	2.34	7.58
Choline—mg.**	215.06	.42	215.97
Folic Acid (Folacin)—mcg.	23	1	24
Inositol—mg.**	5.39	1.38	3.95

NUTRIENT VALUES FOR A LARGE RAW EGG*

Based on 59 g. shell weight with 50 g. total liquid whole egg, 33.4 g. white, and 16.6 g. yolk.

NUTRIENT AND UNIT	WHOLE	WHITE	YOLK
Vitamins (Continued)			
Niacin—mg.	.037	.031	.002
Pantothenic acid (B_3)—mg.	.627	.040	.632
Pyridoxine (B_6)—mg.	.070	.001	.065
Riboflavin (B_2)—mg.	.254	.151	.106
Thiamin (B_1)—mg.	.031	.002	.028
Minerals			
Calcium—mg	25	2	23
Chlorine—mg**	87.1	60.0	27.1
Copper—mg	.007	.002	.004
Iodine—mg**	.024	.001	.022
Iron—mg	.72	.01	.59
Magnesium—mg	5	4	1
Manganese—mg	.012	.001	.012
Phosphorus—mg	89	4	81
Potassium—mg	60	48	16
Selenium—mcg	15.4	5.878	7.503
Sodium—mg	63	55	7
Sulfur—mg**	82	56	25
Zinc—mg	.55	.03	.52
Amino Acids—g.			
Alanine	.348	.203	.143
Arginine	.375	.191	.199
Aspartic acid	.628	.358	.272
Cystine	.145	.091	.050
Glutamic acid	.816	.467	.353
Glycine	.210	.123	.086
Histidine	.148	.079	.072
Isoleucine	.341	.199	.141
Leucine	.534	.296	.244
Lysine	.449	.239	.221
Methionine	.195	.121	.069
Phenylalanine	.332	.205	.119
Proline	.249	.137	.116
Serine	.465	.242	.238
Threonine	.300	.160	.148
Tryptophan	.076	.043	.033
Tyrosine	.255	.137	.124
Valine	.381	.224	.155

* U.S. Department of Agriculture, Agricultural Research Service. 1998. USDA Nutrient Database for Standard Reference, Release 12.

** 1979 Poultry Science 58:131-134

Eggs, A Natural Wonder

Egg Nutrition

Eggs are highest quality protein and are often used as a standard to measure protein in other foods. They also contain Vitamins A, D, E, K, and the B-complex and a variety of minerals, particularly iron. Plus, eggs contain the ideal balance of the essential amino acids the body can't manufacture. Because eggs are very easy to digest, they are frequently included in therapeutic diets.

The yolk makes up just over one third of an egg, provides three fourths of the calories, all of the fat and Vitamins A, D and E, most of the choline, phosphorus, iron and calcium, and almost half of the protein and riboflavin. The white (albumen) has more than half of the total protein and riboflavin.

Eggs And Cholesterol

Eggs & Cholesterol – Cholesterol is part of every cell and is essential to the body. In fact, the body manufactures 800 to 1,500 mg of cholesterol per day.

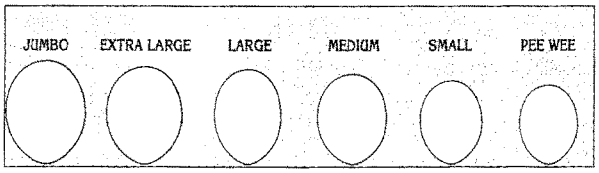
There are varying opinions as to the relationship of blood cholesterol and diet. Many respected scientists recommend that normal, healthy individuals should eat a varied diet, control weight, and exercise regularly. In their opinions, if this is done, it is not necessary to restrict dietary cholesterol or any individual food, since research has shown that dietary cholesterol has little effect on serum cholesterol in most healthy people. Other reputable scientists believe it is prudent to restrict dietary cholesterol. Those concerned about their blood cholesterol levels should consult with and follow the advice of their physician.

The most important contributing factor to high blood cholesterol level has been shown to be excess saturated fat in the diet. Eggs have always been relatively low in saturated fat. Overall, eggs contain a moderate amount of fat, composed mainly of unsaturated fatty acids.

Also quite significant, the latest data indicate that eggs contain less dietary cholesterol than previously thought. A large egg averages only 213 mg cholesterol rather than 274 mg as listed in some references. This represents a 22% reduction in cholesterol content. (See preceding 2 pages for complete nutritional analysis.)

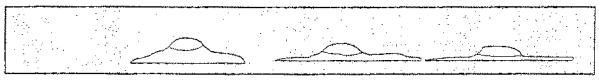
A Foodservice Guide To
Shell Eggs

Egg Size



	JUMBO	EXTRA LARGE	LARGE	MEDIUM	SMALL	PEE WEE
Minimum wt. per dozen	30 oz.	27 oz.	24 oz.	21 oz.	18 oz.	15 oz.
Minimum wt. per 30 dozen case	56 lbs.	50 1/2 lbs.	45 lbs.	39 1/2 lbs.	34 lbs.	28 lbs.

Egg Quality



	GRADE AA	GRADE A	GRADE B
Break Out Appearance	Covers a small area.	Covers a moderate area.	Covers a wide area.
Albumen Appearance	White is thick and stands high; chalaza prominent.	White is reasonably thick, stands fairly high, chalaza prominent.	Small amount of thick white; chalaza small or absent. Appears weak and watery.
Yolk Appearance	Yolk is firm, round, and high.	Yolk is firm and stands fairly high.	Yolk is somewhat flattened and enlarged.
Shell Appearance	Approximates usual shape; generally clean,* unbroken; ridges/rough spots that do not affect the shell strength permitted.		Abnormal shape; some slight stained areas permitted; unbroken; pronounced ridges/ thin spots permitted.
Usage	Ideal for any use, but are especially desirable for poaching, frying, and cooking in shell.		Good for scrambling, baking, and use as an ingredient in other foods.

*An egg may be considered clean if it has only very small specks, stains or cage marks. Source: USDA

Egg Size Substitutions

JUMBO	X-LARGE	LARGE	MEDIUM	SMALL
1	1	1	1	1
2	2	2	2	3
5	5	6	7	8
9	10	12	13	15
18	21	24	27	28
37	44	50	56	62

Grading

The quality of an egg is determined by the grade of the egg and is not related to size. Each egg is classified according to the U.S. Standards for interior and exterior quality factors. This determines the grade of the egg as AA, A, or B. Only eggs packed in official USDA plants and sampled by official USDA graders can be packed in cartons bearing the USDA grade shield. USDA grading is a voluntary service offered to processing plants that meet minimum USDA equipment, facility, sanitary, and processing requirements. All other plants grade and identify their cartons according to state egg standards.

Specifications

Shell egg specifications can be tailored to meet specific needs of buyers and can vary in complexity and detail. At a minimum, specifications should include grade, size, and type of packing and packaging. An example might be:

Eggs, Shell, fresh shell protected U.S. Consumer Grade AA, Large, 30 dozen per shipping case. Cartons labeled with an expiration date not to exceed 28 days from date of packaging. Deliveries to be made within 5 days of official grading.

Purchasing

When purchasing shell eggs, follow these guidelines:

1. Accept only clean, sound, and odor-free eggs.
2. Purchase eggs according to grade and size desired and only in the quantity needed for one to two weeks.
3. Accept only eggs delivered under refrigeration. Transfer to refrigerated storage promptly.
4. Accept only eggs packed in snug-fitting fiberboard boxes to reduce breakage. Eggs are generally packed and purchased in 30 dozen cases or half cases of 15 dozen.
5. Consider size and grade in relation to use and price. Also, compare prices for different sizes of eggs of the same grade.
6. Check the grade of eggs delivered to you. Inspect the shells and then randomly break a few. These eggs should meet the guidelines for their given grade. (Refer to Egg Quality Chart, page 7.)

Storage, Handling & Refrigeration

Shell eggs should be delivered in refrigerated trucks and not allowed to stand at room temperature for any length of time. Proper storage and handling are important in maintaining quality. Grade AA can rapidly lose quality to become Grade B. Eggs kept at room temperature (or above 68°F) may lose more quality in one day than in one week under refrigeration.

Kept under proper refrigeration (45°F or below; do not freeze) eggs will retain their quality for several weeks. Cool temperatures retard the growth of bacteria should they be present. Eggs should be kept in their case to prevent loss of moisture. Store eggs away from food such as onions, apples, and cabbage as eggs can pick up strong odors.

Assuring Food Safety

Any food, particularly protein-rich animal foods, can carry microorganisms that cause disease or spoil the food. An intact shell egg has many chemical and physical properties (e.g., iron-binding complexes and membrane barriers) that deter bacterial growth. But eggs are susceptible to bacterial growth once the shell and membranes are broken, oxygen is added and the nutrients from the yolk and the white are mixed together. The microorganism of particular importance to eggs and egg products is a bacterium called *Salmonella* (Sal'-mo'nell'a). This bacterium is typically found in the gastrointestinal tract of warm-blooded animals. Although *Salmonella* may not make the carrier animal ill, if it gets in the human food supply it can make people ill.

The safety of shell eggs is first ensured by diverting any eggs with cracks, chips or breaks (which encourage bacteria to pass through the shell) away from the human food supply. Additionally, intact eggs are washed and sanitized shortly after they are laid to remove any microorganisms that might be present. A continuation of sanitary practices (with particular emphasis on hand-washing during food preparation) is necessary to ensure that food is not re-contaminated with bacteria, viruses or parasites.

In recent years, *Salmonella* Enteritidis (which is abbreviated as SE) has adapted itself to survive in an unusual location - the reproductive tract of the hen. In rare instances (estimated to be 1 in 20,000 eggs in the U.S.), this bacterium can be deposited inside the shell in the egg white. Although the number of bacteria per egg is likely to be very low (because the egg white discourages bacterial growth), once the shell is cracked and the iron-rich yolk mixed with the white, bacteria grow with great ease. Likewise, if the yolk membrane deteriorates (which it will in several weeks or at temperatures over about 60°F) bacteria can grow inside the intact shell egg. Even though SE in eggs is rare, eggs must be treated in a way to block the transmission of disease.

Food safety control measures include keeping eggs cool and using eggs less than 28 days old. Since bacteria can grow readily once the shell is broken, pooled eggs need to be prepared in small batches and cooked promptly. The use of a thermometer when preparing sauces and casseroles will ensure that the food has reached appropriate temperatures. Reaching a temperature of 160°F or holding food at 145°F for 3.5 minutes will destroy SE if it is present. Additionally, containers that have held raw egg must be washed and sanitized before being used again, even for the same recipe. Vulnerable populations, such as the very young or the aged, can be protected by using pasteurized egg products.

Egg Handling and Preparation Tips

Storage

- Refrigerate at 45°F or below. Do not freeze.
- Store shell eggs in their case.
- Store away from foods with strong odors (foods such as fish, apples, cabbage or onions).
- Rotate - First in/First out.

Handling

- Always wash hands.
- Take out only as many eggs as needed for immediate use. Do not stack egg trays (flats) near the grill.
- Use only clean, uncracked eggs.
- Eggs should not be washed before using; they are washed and sanitized before they are packed.
- Use clean, sanitized utensils and equipment.
- Never mix the shell with internal contents of the egg.
- Do not reuse a container (blender, bowl, mixer, etc.) after it has had raw egg mixture in it. Clean and sanitize the container thoroughly before using again.

Preparation

Whole eggs cooked until the white is set (completely coagulated and firm) and the yolk is beginning to thicken (no longer runny but not hard) are considered to have met necessary time and temperature requirements for safety. Scrambled eggs need to be cooked until firm throughout with no visible liquid egg remaining. Egg white coagulates between 144°F and 149°F and the yolk between 149°F and 158°F. Therefore, it is not necessary to cook eggs until hard or rubbery in order to kill any bacteria that may be present.

- A good rule of thumb is that whole eggs should be cooked until the white is completely coagulated (set) and the yolk begins to thicken.
- Cook scrambled eggs in small batches no larger than 3 quarts according to rate of service, until firm throughout and there is no visible liquid egg remaining.
- Pooling eggs, the practice of breaking large quantities of eggs together and holding before or after cooking greatly increases the risk of bacterial growth and contamination.
- Never leave egg or egg-containing dishes at room temperature more than one hour (including preparation and service).
- Egg dishes for those who are pregnant, elderly, very young or ill should be thoroughly cooked. These groups at highest risk should avoid consuming raw or undercooked eggs. Pasteurized egg products are a low-risk alternative for these groups.
- Hold cold egg dishes below 40°F.
- Hold hot egg dishes above 140°F. Do not hold hot foods on buffet line for longer than 1 hour.
- Do not combine eggs that have been held in a steamtable pan with a fresh batch of eggs. Always use a fresh steamtable pan.
- Do not add raw egg mixture to a batch of cooked scrambled eggs held on a steamtable.
- When refrigerating a large quantity of a hot egg-rich dish or leftover, divide into several shallow containers so it will cool quickly.

A Foodservice Guide To
Egg Products

The term "Egg Products" refers to processed or convenience forms of eggs obtained by breaking and processing shell eggs. Egg products include whole eggs, egg whites, and egg yolks in frozen, refrigerated liquid, and dried forms, available in a number of different product formulations, as well as specialty egg products. Specialty egg products include: prepeeled hard-cooked eggs, egg rolls or "long eggs," omelets, egg patties, quiches, quiche mixes, scrambled eggs, fried eggs, and others.

Egg products are becoming increasingly popular in foodservice operations. That's because they're convenient to use and also provide a cost savings with regards to labor, storage, and portion control.

Frozen, refrigerated liquid, and dried egg products are similar to shell eggs in nutritional value and most functional properties.

Food Safety

By law, all egg products are processed in sanitary facilities under supervision of the USDA and bear the USDA inspection mark. They must be pasteurized (which removes all harmful bacteria) and are routinely sampled and analyzed for *Salmonella*. If a product was contaminated with *Salmonella*, it would be barred from consumer channels. Keep in mind that even though egg products are pasteurized, proper handling and storage is still vital.

Pasteurized egg products are being used more often to help ensure food safety. They may be used to protect high-risk populations or when preparing lightly cooked foods (such as sauces, salad dressings, French toast or Monte Cristo Sandwiches).

Large Shell Egg Equivalency

Frozen Or Refrigerated Liquid

	WEIGHTS	MEASURES
Whole Eggs:		
1	1 3/4 oz.	3 Tbsp.
10	1 lb. 1 3/4 oz.	2 Cups
12	1 lb. 5 1/2 oz.	2 1/2 Cups
25	2 lbs. 13 oz.	1 qt. 1 1/4 Cups
50	5 lbs. 8 oz.	2 qts. 2 1/2 Cups
Yolks:		
10	7 1/4 oz.	3/4 Cup
12	8 1/2 oz.	3/4 Cup 2 Tbsp.
22	1 lb.	2 Cups less 2 Tbsp.
Whites:		
10	11 1/2 oz.	1 1/4 Cups 2 Tbsp.
12	14 oz.	1 1/2 Cups 2 Tbsp.
14	1 lb.	2 Cups less 2 Tbsp.

Shell Egg Equivalency

Dried Whole Eggs

SHELL EGG (Large Size)	DRIED WHOLE SIFTED	WATER
6	3 oz. (1 Cup)	1 Cup
12	6 oz. (2 Cups)	2 Cups
24	12 oz. (1 Qt.)	1 Qt.
50	1 lb. 9 oz. (2 Qt. & 1/3 Cup)	2 Qt. & 1/3 Cup
100	3 lb. 2 oz. (1 Gal. & 2/3 Cup)	1 Gal. & 2/3 Cup
150	4 lb. 11 oz. (6 Qt. & 1 Cup)	6 Qt. & 1 Cup
200	6 lb. 4 oz. (2 Gal. & 1 1/3 Cups)	2 Gal. & 1 1/3 Cups

Purchasing

Follow these basic guidelines when purchasing egg products.

1. Purchase only pasteurized egg products.
2. Specify egg products bearing the USDA inspection mark.
3. Specify exact type of egg products desired: (such as frozen salted whole eggs, refrigerated egg whites, dried scrambled egg mix, etc.).
4. Accept only egg products that are in tightly sealed containers. Frozen products must show no signs of thawing.

Specifications

For egg products, specifications may include:

1. Type of product
2. Packaging
3. USDA Inspection
4. Various lab analysis for physical, nutritional, chemical information, etc.

Storage And Handling

Frozen-Egg Products – Frozen egg products should be transferred to freezer immediately upon delivery. Store frozen eggs at 0°F or below.

Containers should remain tightly sealed during storage.

To defrost, leave container in refrigerator or set in cold running water. Container should remain tightly sealed.

Never thaw at room temperature. Thaw only the amount of product needed for required use. Use defrosted eggs promptly.

Cover and refrigerate any leftover thawed portions and use within one to three days.

Refrigerated Liquid Egg Products should be transferred to refrigerators immediately upon delivery. Always store in refrigerator, keeping seal intact.
Check the label of the liquid egg product you are using as shelf life may vary. Once opened, use immediately.

Dried Egg Products should be stored in a cool, dry place away from light, and preferably in refrigerator. (Never above 70°F.)

After opening, seal tightly for restorage and refrigerate.

If combined with dry ingredients and held for storage, seal tightly in a closed container and store in the refrigerator.

Reconstitute only that amount of dried eggs which will be used immediately.

Specialty Egg Products should be kept refrigerated or frozen according to their requirements.

The Solution Is Simple

Practically any problem you have with eggs can be solved quickly and easily. Here are a few examples:

Problem:
Greening

Cooked eggs may turn green (a natural chemical reaction) if held over heat for an extended period of time. Here's how to avoid it:

Solutions:
Omelets And Scrambled Eggs

- Use fresh eggs (Grade AA or A). Greening is more likely in older eggs.
- Cook eggs in small batches, no larger than three quarts.
- Substitute a medium white sauce for the liquid in the egg mixture. (One part white sauce to five parts egg.)
- Use temperatures of 140°F and above for steamtable holding.
- Do not hold hot foods on buffet line for longer than 1 hour.
- Use only stainless steel equipment and utensils.
- Try a liquid egg product if greening is frequent. (Many of these contain citric acid which retards greening.)
- Beat in 1/4 teaspoon lemon juice for every 18 large eggs, or 1/4 teaspoon citric acid crystals for every dozen large eggs.

Hard-Cooked Eggs

- Simmer eggs (185-190°F) in water. *Don't boil.*
- Cool immediately in cold water. Peel when cool.

Problem:
Weeping

Water separating from cooked eggs is caused by over-cooking or by cooking and holding at high heat or from the addition of watery ingredients. Here's how to avoid it:

Solutions:
Scrambled Eggs

- Prepare eggs in small batches, no larger than three quarts.
- Substitute a medium white sauce for the liquid in the egg mixture. (One part white sauce to five parts egg.)
- Use temperatures 140°F and above for steamtable holding.
- Use egg products with stabilizers (i.e. gums) added.
- Limit the amount of added ingredients and make sure they are well-drained.

Meringues

(Due to undercoagulation of the foam during beating or cooking)

- Beat whites until frothy before adding sugar.
- Add sugar slowly.
- Stop frequently and lift whites from bottom of bowl to ensure thorough and even beating.
- Use clean metal or glass – not plastic – bowl.
- Beat until sugar is dissolved, the peaks barely fold over and whites do not slip from sides when bowl is tilted.
- If the meringue is to be used on a pie, place it on a hot 160°F or above filling, and brown immediately at 350°F, for approximately 15 minutes. (3 egg white meringue).

For pie meringues containing a larger number of egg whites, reduce baking temperature and increase baking time to achieve temperature of 160° F in center of meringue.

Baked Custards
(includes quiches, custard pies, timbales)

- Blend egg and milk mixture thoroughly so that no strands of white remain.
- Cook only until custard tests done.
- Use a water bath for even cooking. Place baking pan in larger container and fill larger container with hot water to within one inch of top of custard.
- Baked custards, quiches, custard pies, and timbales should be baked to an internal temperature of 160°F and mixture tests done (knife inserted near center removes cleanly).

Problem:
Rubbery and Dry

The problem is the result of overcooking and high heat. It generally follows weeping. Here's how to avoid it:

Solutions:
Omelets And Scrambled Eggs

- Cook at medium heat until no visible liquid egg remains.
- Cook in small batches, no larger than three quarts.
- Use a medium white sauce as liquid in egg mixture. (One part white sauce to five parts egg.)
- Use temperatures 140°F and above for steamtable holding.

Fried

- Cook over medium heat on preheated grill or in preheated pan.
- Use the right amount of fat to avoid toughening, about one teaspoon per egg.
- Baste with fat or steam-baste by adding small amounts of water and covering.

Eggs Turn On A Menu, Instantly

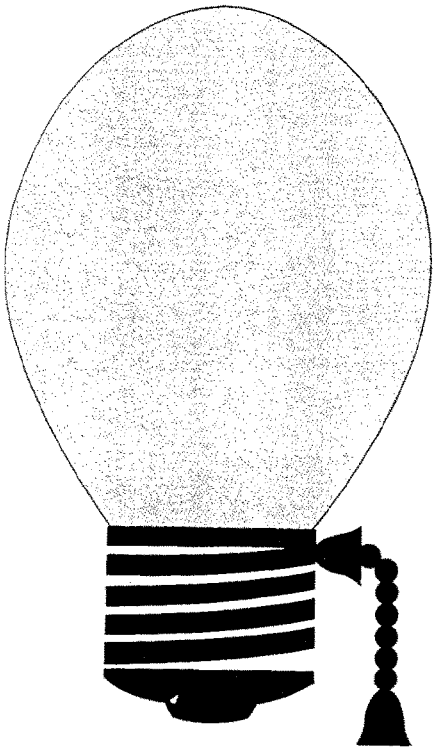
Lighter, Brighter Ideas

It's incredible what eggs can do for any menu. Including yours!

Souffles, Frittatas, Omelets, Quiches, Egg Salads...every one is a dramatic and delicious dish that'll give your menu a new and elegant look for breakfast, lunch, brunch or dinner. And there are hundreds more egg dishes waiting for you to discover them.

Each is a breeze to prepare. And you already have many of the ingredients in stock.

So add egg dishes to your menu today. You'll wonder why you didn't do it sooner.



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 F-0490

Statement Before the
Senate Subcommittee on Oversight of Government, Management, Restructuring, and the District of Columbia

Hearing On

Egg Safety

July 1, 1999

Testimony presented on behalf of the United Egg Producers

by

Keith Mussman
Mussman's Back Acres
Grant Park, Illinois

Good morning. My name is Keith Mussman and I am a farmer producing eggs in Illinois. I have been in this business all my life, having followed in the footsteps of my father who produced eggs and sold them in the Chicago area more than twenty-five years ago. I am testifying today on behalf of my industry organization, United Egg Producers (UEP), a national cooperative representing the interests of nearly 80% of all egg production nationwide. We appreciate the opportunity to present our views today on the safety of eggs and egg products in the nation's food supply.

Food Safety is Important to the Egg Industry

The egg industry considers food safety of paramount importance and is committed to enhancing the safety of shell eggs and egg products as is evidenced by the number of voluntary programs it has undertaken. For example, the egg industry through UEP has developed a national 5-Star quality assurance program. UEP has sponsored HACCP training workshops for egg producers and processors. The American Egg Board has published egg handling and preparation guidelines for food service employees and consumers, and partnered with the White House on President Clinton's food safety initiative with the FightBac program (the American Egg Board is a founding member). UEP has supported FDA in determining that eggs, like other protein-rich foods, should be classified "potentially hazardous."

A recent survey conducted by Dr. Kenton Kreager, Director of Technical Service, Hyline International, Dallas Center, Iowa (a leading primary breeder of Leghorn chickens) was entitled, "Egg Industry Initiatives to Control Salmonella." The report noted that data was collected from 41 egg producers with over one million or more laying hens and representing a total 125 million layers (approximately 50% of the nation's total). Of those responding, 93% reported to be participating in one of the industry's egg quality assurance programs such as UEP's "5 Star" program or comparable state programs. Biosecurity measures, rodent control, proper egg washing temperatures and pH are a part of every producer's program.

The egg industry has initiated and implemented voluntary programs in response to every concern raised about food safety, while providing a wholesome food at a price comparable to the time when my father was marketing eggs in Chicago. The nation's consumers enjoy the advantages of excellent prices for eggs along with the assurance that egg producers are working to enhance the food safety of their products.

Effectiveness of Industry Programs

In 1998 the FoodNet and PulseNet systems for surveillance reported a **44% decline** in Salmonellosis attributed to Salmonella *enterica* Serovar Enteriditis (S.E.) during the past three (3) years. Likewise, the record on outbreaks – where two or more people became ill – shows a decline in illness that began in 1990. The Salmonella Surveillance system shows a similar decrease in the number of people becoming ill. But even one sick person is one too many and industry efforts are continuing to enhance safety.

What is Currently In Place For Ensuring Food Safety?

Federal-State Shell Egg Grading Programs

The Egg Products Inspection Act of 1970 provides uniform standards of quality, grade, condition, weight, and labeling for shell eggs in interstate commerce. The U.S. Standards, Grades, and Weight Classes for Shell Eggs provide the basis for the Federal-State grading programs and have been incorporated into State egg laws and regulations affecting the marketing of eggs. All states in the U.S. have laws regulating the sale of eggs.

For egg products, egg further processors are operating under both a continuous inspection system and, in most cases, a HACCP system. HACCP is universally accepted in the scientific community, so the egg further processors look forward to the implementation of HACCP by regulation with the monitoring of critical control points to ensure the safe processing and handling of egg products.

Shell Egg Quality and Pathogen Control

Shell egg quality factors can be divided into those used to determine exterior quality and those factors used to determine interior quality. External quality factors include normal egg shape, texture, soundness of shell (no checks or cracks) and shell cleanliness. Interior quality is determined by candling, and some of the factors evaluated are albumen appearance/viscosity, intensity of the yolk shadow, shape of the yolk, normalcy of egg interior (no blood nor meat spots), size of air cell, and the absence or presence of any defects.

Eggs which fail to meet grading standards are either diverted to the breaking market for pasteurization, or deemed inedible for humans and processed for other uses such as pet foods.

The external quality factors of the shell play a role in the safety and wholesomeness of the product, as does the contents of the egg interior.

Pathogens can be controlled by preventing their entry into foods, by reducing the amount present, or by destroying when possible those that are present. A large part of ensuring that eggs are micro biologically safe involves preventing microbes from penetrating the egg shell. Refrigeration helps to prevent bacterial growth and thereby reduce any amount potentially present in the food. Preventing microbial contamination starts in the egg laying facility and continues through processing, grading, packing, storage, and preparation.

Washing, Sanitizing and Refrigeration of Eggs

Shell eggs are cleaned in wash water of approximately 110 degrees Fahrenheit, or 20 degrees higher than the egg temperature. A sanitizing solution is used in the washing process to enhance the cleaning process.

Soon after processing, eggs are packaged and stored at 45 degrees Fahrenheit. Proper cooling is of critical importance in maintaining egg quality throughout the production and processing chain, as well as at the retail and food service levels.

The Structure of Eggs and Its Effect on Bacteria

Although foods of animal origin most often are targeted as the vehicles of food borne disease outbreaks, a wide variety of foods are associated with food borne illness. Shell eggs are only rarely associated with bacteria, especially in comparison to other protein-rich foods. Even all food products of animal origin are not alike. The natural purpose of an egg was not for food, but the reproduction of the species. Every integral part of the egg has a purpose. One function is to provide the embryo a place that is relatively safe from harm, both physical and pathological.

Therefore, the egg has characteristics that provide for the protection against the growth of bacteria, unlike other animal products such as milk and meat. Because the egg's purpose was species renewal, the natural immune system built in the structure of the eggs is analogous to the same type of protections provided biologically from mothers to their newborn babies.

The protection defense is partly physical (the shell, its membranes and the albumen). Indeed, compartmentalization is an essential feature of an egg's antimicrobial defense. However, every part of the egg, physical or chemical, is assembled to maximize its particular function.

If intact, the egg shell and shell membranes protect the egg against invasion of bacteria. Most bacteria, including Salmonella, find it difficult to multiply in egg whites because of antibacterial substances present there. The white lacks the nutrients needed for bacterial growth. The thick white that surrounds the yolk and yolk membrane also prevent bacteria from entering the nutrient-rich yolk. The compartmentalized structure of the egg means that the largely defenseless yolk is located centrally in a freshly laid egg, and it is thereby protected from contamination from the shell by the albuminous sac and thin albumin, both of which are richly endowed with antimicrobial factors.

Thus, if handled properly, eggs have a natural protection against bacterial contamination.

Role of Food Handling in Egg S.e. Outbreaks and Educational Efforts

Most of the SE outbreaks associated with food have been a result of improper food handling and preparation; this has typically been at the institutional food service level. Holding raw egg batters at room temperature for extended times, using containers that go unwashed between uses, inadequate cooking, and inadequate cooling of leftovers have all contributed to foodborne outbreaks.

The egg industry has assumed responsibility for educating the public, particularly in the food service area, since it is the area most often associated with problems regarding foodborne illness.

Understanding the Uniqueness of the Egg and the Impossibility of Zero-Risk

It is a fact that a zero-risk or a sterile food supply is impossible. Federal food safety efforts and regulations must reflect this fact.

It is important that accurate information is communicated about risk and that sound food service educational information is provided to consumers, and particularly to the food service sector, so that everyone is well educated in safe food handling and understands their responsibility for ensuring food safety.

As we have pointed out in the discussions above, the egg is a unique food. All foods are not created equal. The unique properties of the egg (it's the only food we know that already comes packaged – in the shell), makes our product different from other food products. As such, those involved with regulating our product need to recognize these inherent distinctions that separate eggs from other food products and cause eggs to respond differently to pathogen control interventions from other foods.

Conclusion

Just as there is no single control method that will eliminate all pathogens and toxins from the food chain, there is no single method for providing a 100% guarantee that foods will be free of pathogens. In order for food safety policy to be science-based, accurate and successful, the individual characteristics of all foods must be fully understood and taken into account. A one-size-fits-all regulatory approach rarely works, and it will not work for shell eggs and egg products.

In March, the Committee on Appropriations of the U.S. House of Representatives and the United States Senate received the joint status report filed by the Secretaries of Agriculture and Health and Human Services on actions taken by the respective agencies to enhance the safety of shell eggs and egg products. This report revealed the close working relationship between USDA and HHS regarding shell eggs and egg products.

Egg producers and processors do have to deal with a variety of regulatory agencies. We do not always agree with the actions taken by these agencies. When we disagree with them, we have not been shy about saying so.

However, for the most part the agencies do a difficult job well. We have not seen the General Accounting Office's report and will read it with interest. Based upon what we know now, however, we are not convinced that the structure of our food safety agencies is a problem. They have different roles and different

areas of expertise. To us, the real issue is what our public policies should be, not who implements them.

Under the present system, we have already witnessed a significant decline in the number of cases of Salmonellosis since 1996. Coordination among agencies currently provides checks and balances as well as the opportunity for marshaling expertise from different disciplines and areas of expertise.

Congress, of course, should insist that this coordination be cooperative rather than competitive. Everyone's goal must be protecting food, not turf.

Thank you for providing this opportunity to present this testimony on the views of the nation's egg industry.

Senate Subcommittee on Oversight of Government Management, Restructuring, and the District of Columbia

Testimony Given by:

Harold DeVries
Mallquist Butter and Egg Company
Rockford, Illinois

July 1, 1999
342 Dirksen Senate Office Building
Washington, DC

Good morning. My name is Harold DeVries and I am Vice President and a principal stockholder at Mallquist Butter and Egg Company in Rockford, Illinois. My company is a small agricultural business packaging about 4 million eggs per week from its one-half million laying chickens. We also distribute liquid, frozen, and dried eggs. In addition, my company is involved in the distribution of butter and cheese. I am here today at the request of Senator Durbin's office.

I appreciate the opportunity to present my views today. Let me begin by saying that food safety is very important to me personally, to my company, and to my industry. The reputation of my company is dependent on quality and we operate quality assurance programs to ensure a safe food supply. Mallquist Butter and Egg Company has instituted procedures to identify those critical control points from farm through distribution for monitoring quality assurance, including cleaning and disinfecting the poultry house, rodent and pest control, proper egg washing, biosecurity, and refrigeration.

In addition to those measures my company performs to enhance the safety of our food products, I am active in my national association, United Egg Producers (UEP), which has taken the initiative in the development of programs and activities to be responsive to government and consumer concerns on food safety. Just to mention a few activities, UEP has been instrumental in:

1. Establishing a Salmonella *enterica* Serovar Enteritidis (S.E.) Task Force
2. Securing $3.4 million annually from Congress for S.E. Pilot Project
3. Calling for chicken breeder testing through the National Poultry Improvement Plan
4. Proposing and lobbying for passage of a National Refrigeration Law
5. Recommending that liquid pasteurized egg products be used in institutions serving immuno-suppressed persons who are at higher risk of severe illness, such as hospitals and nursing homes.

6. Developing a "5-Star" Total Quality Assurance Program for use at the farm level
7. Sponsoring Hazard Analysis Critical Control Points (HACCP) workshops for the egg production and processing industries
8. Publishing egg handling and preparation guidelines for food service establishments

The egg industry through UEP and the American Egg Board have been involved in many other activities as well. Today, I wanted to share information about food safety actions in the State of Illinois to demonstrate the degree of awareness of the problems in foodborne illnesses and the activities on the state and local levels.

Foodborne illnesses are a significant problem affecting the public's health. Everyone in the food distribution system – from producer to processor to transporter to preparer to consumer – has a significant role to play in the safety of the food supply. **Consumer confidence, both actual and perceived, in the safety of the final food product depends in large degree on knowledge.**

With the issue of food safety of such paramount importance, former Illinois Governor Jim Edgar charged the state's departments of Agriculture and Public Health to convene a task force to analyze food safety issues likely to confront Illinois in the 21st century and to recommend actions to resolve public concerns.

This task force was chaired by Becky Doyle, then the state's agriculture director and John Lumpkin, M.D., M.P.H., the state's public health director. I also served on the task force since eggs have become the "poster child" for food safety issues. Other members of the task force included academics, the legal profession, meat and poultry processors, restaurants, food retailers, local health departments and the public. The task force met five times between December 2, 1997 and October 2, 1998 to address its mission.

Purpose of Illinois Food Safety Task Force

The task force identified four areas for study:

1. Review the food safety chain from "farm to table," e.g., food production, transportation, processing, sales and service, and consumption.
2. Identify the problems and barriers to safer food in Illinois, addressing such issues as
   (1) effectiveness and efficiency
   (2) communication
   (3) duplication of services
   (4) statutory authority
   (5) adequacy of resources
   (6) regulatory structure
   (7) education and training requirements
   (8) federal and national food safety guidelines
3. Analyze the strengths and weaknesses of the current Illinois food safety system.

4. Define problems identified, develop creative solutions and make food safety recommendations to the directors of the departments of Agriculture and Public Health.

Foodborne Illness: A Public Health Problem

During fiscal 1998, local health departments in Illinois investigated almost 1,200 complaints about food and illness. The microorganism that caused the foodborne outbreaks could only be determined in one third of the incidents – two thirds of the outbreaks occurred because of unknown causes. Food service establishments – restaurants, cafeterias, and delis – accounted for 57% of the sites where outbreaks were reported. Proper handling and preparation of food, both in and out of the home, is a critical step in preventing disease.

While the causes and effects of foodborne diseases are better understood today, emerging risks need to be monitored. For example, consumers are changing; increasing numbers of elderly and immuno-suppressed persons are at higher risk of severe illness; consumers spend less time cooking than ever before, and may have received less instruction on food handling at home or school.

Current Illinois Food Safety System

Where the "rubber meets the road" is at the local level. More than 90 Illinois local health departments and 135 municipalities provide preventive food safety functions at the community level through inspections of restaurants, schools, caterers and food stores for adherence to food safety requirements. They promote safe food handling behaviors through educational efforts with schoolchildren, the general public and the retail

food industry. Public health agencies, both state and local, investigate complaints, monitor developments that emerge as potential threats to food safety for the population of Illinois and investigate foodborne illness outbreaks and recalls to identify the source and thereby prevent the spread of illness and injury.

The Illinois Department of Agriculture (IDA) exercises its food safety authority through preventing and eradicating animal disease, monitoring livestock slaughter, and inspecting meat and poultry wholesale processing. IDA also regulates refrigerated warehouses, oversees egg grading and quality, and verifies accuracy of weights and measures.

The Illinois Department of Public Health (IDPH) has the responsibility for inspecting food processing plants and warehouses for all the remaining non-meat and poultry products, defining rules for operating retail level food establishments, providing training and standardization of local health department food inspectors, and reviewing local food safety programs for compliance with state standards.

I noted these responsibilities by these agencies to demonstrate the wide range of activities that directly affect the food supply.

Challenges and Areas for Improvement

There are a number of areas that can be strengthened to enhance the safety of our food supply. Additional monetary resources are necessary at the state and local levels for regulatory activities and to provide educational opportunities addressing food safety issues. Food safety regulations are not uniformly applied or enforced through the system. In additional, basic and applied research into microbes that cause foodborne illnesses and into the mechanisms by which they contaminate our foods and cause outbreaks, as

well as emerging pathogens. The HACCP system is widely accepted by the scientific community as the best known approach to enhancing the safety of foods. If HACCP systems are fully implemented, the effectiveness of the food safety system can be enhanced significantly, but **absolute safety of potentially hazardous foods cannot be assured.**

Recommendations of the Task Force

Food safety is the responsibility of numerous and diverse stakeholders. Therefore, partnerships between industry, government and the public provide the links necessary to build a coordinated and cohesive framework for action. Partnerships can improve efficiency and provide a mechanism for the exchange of information and data. With partnerships come the interaction and communication necessary to promote cooperation and collaboration between government regulatory agencies and industry. Partnering among stakeholders also can serve to integrate regulated activities with important non-regulatory components such as education and training activities.

The first recommendation from the task force is to broaden coordination and cooperation between the Illinois agencies with the respective federal and local counterparts so that food safety programs are consistent and uniform. Partnerships between regulatory agencies can establish a framework to ensure that regulation and enforcement are effective and consistent, and that resources are adequate and appropriately allocated throughout the system.

The second recommendation is for the development of a mechanism to ensure that regulated industries, government agencies and the general public have a formal venue to advise the departments of Agriculture and Public Health on issues of mutual concern relative to the food supply.

Allowing partners a forum for sharing information and raising concerns has been recognized as an effective tool for raising awareness about regulatory developments and for developing and maintaining procedures for the industry.

The task force also recognizes the value of the U.S. Centers for Disease Control and Prevention's Foodborne Disease Active Surveillance Network (Foodnet). **In the last 3 years, as reported by FoodNet, the incidence of Salmonellosis associated with Salmonella enteriditis has decreased 44%. This is great news for the egg industry and the public. It suggests that efforts by the industry are having an effect.** In Illinois, the participation in the FoodNet system is seen as essential in the improvement of the foodborne illness surveillance system.

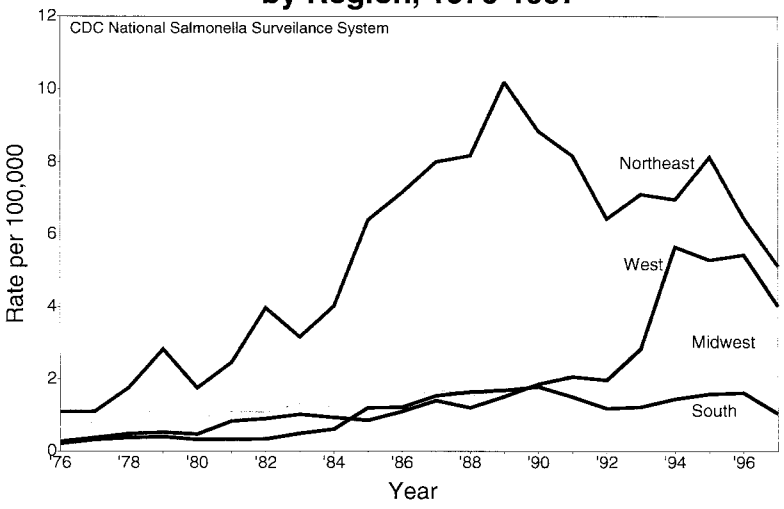
Conclusion

The egg industry has demonstrated responsiveness and cooperation with federal, state and local agencies in addressing the safety of shell eggs and egg products. A large number of agencies are involved in food safety. However, the expertise from these agencies address the issue of food safety from different and complementary perspectives. The egg industry has developed numerous programs and activities designed to enhance food safety and to educate the channel from "farm to table" in the proper production, transportation, processing, handling, and preparation of its products.

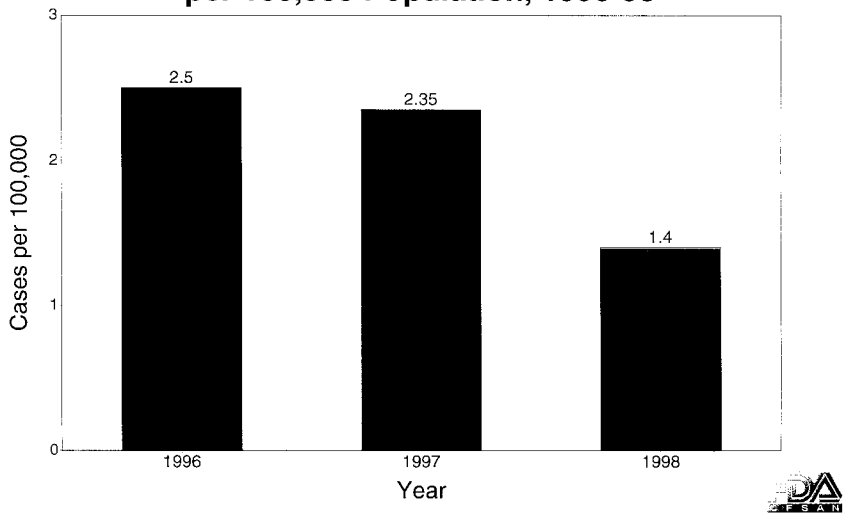
Education and training can be one of the least costly yet most effective means to protect consumers against foodborne illness. Increasing individual awareness of food safety matters all through the food chain and motivating consumers to adopt simple, yet important sanitation and food handling behaviors is effective in improving food safety.

I appreciate the opportunity to be here today and explain what is taking place on the state level relative to food safety and how the egg industry is taking the initiative in developing programs to enhance the safety of its shell eggs and egg products. Thank you.

Salmonella Enteritidis Isolation Rates by Region, 1976-1997



FoodNet *Salmonella Enteritidis* Cases per 100,000 Population, 1996-98



FACT FOOD ANIMAL CONCERNS TRUST
POST OFFICE BOX 14599, CHICAGO, ILLINOIS 60614

TESTIMONY TO THE SUBCOMMITTEE ON OVERSIGHT OF
GOVERNMENT MANAGEMENT, RESTRUCTURING
AND THE DISTRICT OF COLUMBIA

July 1, 1999

Food Animal Concerns Trust (FACT) is a non-profit organization that advocates for better farming practices that will protect human health, improve the safety of meat, milk, and eggs and promote the humane husbandry of food animals. In 1984, FACT launched its NEST EGGS® program, a model egg farming system, in which our Pennsylvania farms have included controls for Salmonella enteritidis (SE) since 1991. We market eggs in major grocery store chains on the East Coast and in the Midwest. FACT calls for the creation of a single federal agency that will have within it responsibility for shell egg safety.

In August 1998, FACT filed comments in response to the Advance Notice of Public Rulemaking on Salmonella Enteritidis in Eggs (SE ANPR)[1] as requested by the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA). The SE ANPR addressed egg safety across the entire continuum from farm to table including egg production as well as egg processing. To date no action whatsoever

[1] Advance Notice of Public Rulemaking on Salmonella Enteritidis in Eggs, Federal Register, Vol. 63, No. 96, at pp. 22502-27511, May 19, 1998.

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has been taken by either the USDA or the FDA based on the information it had received in response to the SE ANPR. The USDA Food Safety and Inspection Service (FSIS) did recently issue a rule regarding egg time and temperature, but that regulation was pending long before publication of the SE ANPR. FSIS was obliged to release a regulation on time and temperature or risk losing five million dollars in agency funding.

At the Chicago area Food and Drug Administration Modernization Act meeting, on April 28, 1999, Center for Food Safety and Applied Nutrition (CFSAN) Director Joseph Levitt informed the attendees that the only measures on CFSAN's "A" List regarding prevention measures for shell eggs were:

- Publishing a proposed rule on refrigeration of shell eggs at retail and safe handling practices by consumers
- "In conjunction with USDA, preparing a status report on actions taken to enhance the safety of shell eggs and egg products, in accordance with the Appropriations Conference Report."
- Educating consumers and retail handlers about safe storage and handling of shell eggs to reduce the incidence of illness from eggs contaminated with Salmonella enteritidis.[2]

Other than the above-referenced actions by CFSAN and FSIS, no other actions have been proposed with regard to the prevention of SE in shell eggs by any of the agencies with responsibility for eggs. This is despite the completion of the SE Risk

[2] 1999 CFSAN Program Priorities, January 1999.

Assessment Report[3], the issuance of the SE ANPR on SE in Eggs, and the receipt of many comments in response to the SE ANPR. In order for any new egg safety system to be feasible, the entire current egg system must be evaluated with a very critical eye. By their inaction, the relevant regulatory agencies have already illustrated that they cannot accomplish this step.

Since the regulatory agencies with responsibility for shell eggs have indicated their course of inaction with respect to protecting consumers from SE in shell eggs, FACT welcomes the intervention by Congress and the White House in this area. FACT calls for the creation of a single federal food safety agency that will have within it responsibility for the safety, inspection and enforcement of regulations relating to shell eggs.

A single agency for egg safety is essential for the prevention of SE in shell eggs.

The present food safety system is, for the most part, comprised of regulations that were enacted over 70 years ago. Obviously, great changes have occurred over the last 70 years in the way that food is produced, processed, marketed, imported and transported. Food is no longer produced solely on family farms. Rather, food is now more often produced on large concentrated animal feeding operations (CAFOs). Processing occurs at large facilities often far from where the food has been produced and where it will be sold. Food is now sold in large retail operations rather than small family markets. We are now at a crossroads where change in the current system is mandated, not only due to the rise of foodborne pathogens, but also because change is necessary to create a system

[3] Salmonella Enteritidis Risk Assessment Report, July 1998.

capable of handling and adapting to the challenges that will be presented in the twenty-first century.

At the federal level, the current food safety system has at least 12 agencies involved in the key functions of safety.[4] Over 50 memoranda of agreement exist between the various agencies related to food safety.[5] Finally, more than 35 federal statutes regulate food safety.[6] These figures do not even take into account the numerous state and local food safety related regulations. Clearly, the current federal food safety system is "complex, fragmented, and cumbersome."[7] This state of affairs is untenable and must be changed.

The regulatory response to shell eggs illustrates the need for change. To the extent that there are regulations governing shell eggs, no one agency oversees the safety of eggs. Instead, at least three agencies are involved: FDA-CFSAN; USDA-FSIS; and the USDA-Agricultural Marketing Service (AMS). This situation has resulted in inconsistent food safety policy decisions.

While the USDA has the authority to grade eggs, the FDA is the agency required to perform tracebacks of foodborne illness outbreaks. For producers, this situation results in confusion as it is unclear who creates the rules that must be followed with regard to egg production and processing. For consumers, the confusion lies in determining who is responsible for protecting them from unsafe eggs. It is clear that joint efforts between different regulatory agencies to regulate the safety of a particular

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[4] Committee to Ensure Safe Food from Production to Consumer, Institute of Medicine, National Research Council, Ensuring Safe Food From Production to Consumption, National Academy Press, 1998 at 3.
[5] Id.
[6] Id. at 7.

commodity are simply not effective. FACT wants a food safety system where it is clear who is responsible for regulating food production.

Another area of confusion has to do with often conflicting mandates existing within the same agency. For example, part of the USDA's purpose is to both promote egg sales and to regulate portions of the egg industry. When the USDA permits producers to affix the "USDA Grade A" stamp on egg cartons, which mandate is being fulfilled? Consumers may believe that the stamp certifies they are purchasing a safe product. In fact the stamp is a promotional tool signifying that the egg meets certain quality standards, not food safety criteria.[8] The USDA regulation regarding the stamp does not include any provision for the prevention of SE. In the final analysis the juxtaposition of these two purposes within one agency conceivably places the interests of the food industry over and against the food safety needs of consumers.

The new single egg safety agency should be empowered with regulatory authority as well as enforcement powers.

The current system for regulating shell eggs does not confer any enforcement powers upon the agencies entrusted with the authority to regulate eggs. For example, the FDA can conduct traceback investigations where a foodborne illness outbreak has occurred, but the FDA does not have the authority to force the company to recall the eggs and/or products that caused the outbreak. A new single egg safety agency should be

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[7] Id. at 23.

[8] Regulations Governing the Grading of Shell Eggs (7 CFR Part 56) and U.S. Standards, Grades, and Weight Classes for Shell Eggs (AMS 56).

empowered to not only regulate, but also to force compliance without having to resort to court action.

By implementing a new single egg safety agency, roles and responsibilities can be clearly established.

The creation of a single egg safety authority would allow for a complete reorganization of the regulation of shell eggs. The new authority would allow for the creation of departments and regulations that would eliminate duplication, allow for clear roles and responsibilities, create effective enforcement mechanisms, and ensure that departments are properly regulating the issues allocated to them.

The new single egg safety authority must have farm-to-table regulatory powers.

As previously discussed, the current food safety system is inadequate because it fails to sufficiently address food safety problems at all points along the food production continuum, particularly on the farm. Currently, the USDA has no authority to require producers to test for foodborne pathogens or to employ farm management practices that would reduce pathogen contamination. The new egg safety authority must be provided with the power to require on-farm food safety steps, especially microbial testing and pathogen controls. The new food safety system must begin inside the farm gate.

FACT calls for the creation of a mandatory federal program with uniform standards designed to eliminate the threat of SE in shell eggs.

The creation of a national program with uniform standards will address the food safety concerns of consumers and provide a level playing field for producers. This

program should include mandatory on-farm environmental testing, with the following on-farm steps:

1. Test laying houses for SE before and during the laying cycle.
2. Provide SE free chicks to pullet houses.
3. Test pullets prior to placement in the layer houses.
4. Divert eggs from the market when SE is found.
5. Process feed in a manner that kills SE.
6. Prohibit induced molting, or at a minimum establish SE controls when induced molting is used.
7. Establish rodent controls.
8. Establish and maintain a biosecurity program.
9. Keep records for at least one year.

The attached addendum describes the above steps.

In conclusion, a single agency for egg safety is essential for the prevention of SE in shell eggs. The agency should be empowered with regulatory authority as well as enforcement powers, with clearly established roles and regulatory responsibilities that move from farm to table. FACT believes that the centerpiece of any federal food safety response regarding shell eggs must be the creation of a mandatory on-farm testing program with uniform standards designed to eliminate the threat of SE in shell eggs. Thank you.

ADDENDUM

Establishing a Mandatory National Program

As recognized in the SE ANPR, a patchwork of state and industry quality assurance programs (QAPs) has arisen in response to the threat of SE.[9] However, the requirements of the various QAPs are far from uniform and participation in the QAPs is not mandatory. Some programs simply recommend biosecurity steps and rodent control programs, while other programs require testing for SE in the laying houses. In the United Egg Producers' "5-Star" Program, testing for verification is offered to participants, but not required. Moreover, there is no uniformity among the QAPs as to what should be done if SE is found on a farm.

A single mandatory national standard that would be applicable to all egg producers is necessary for the following reasons. First, despite the fact that a number of QAPs have been put into place, not all producers participate in such QAPs. In fact, there is no publicly available data as to the number of participants in most programs.[10] A national standard would provide the assurance that every producer is require to meet the same basic SE control steps believed to be critical for egg safety. Second, in states where there is a state QAP, consumer confusion may arise since some producers may claim to

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[9] The Pennsylvania Egg Quality Assurance Program, the California Egg Quality Assurance Plan, The New England Risk Reduction Program, the New York State Egg Quality Assurance Program, the South Carolina Egg Quality Assurance Plan and the United Egg Producers "Five Star" Program.

[10] The United Egg Producers claim that "100 producers have pledged to follow the program guideline. This many producers account for over 100 million laying hens." Food Safety Digest, March/April 1998 at p.1. However, this claim does not state that the producers have actually submitted documentation evidencing complete implementation of the Program, nor does it identify what percentage of egg producers this number represents.

be participants in the state program and others in the industry program. Further confusion may arise from lack of consumer awareness as to the components of each QAP and which QAP would provide the best safety protection. Finally, a national program would provide protection against interstate problems such as selling eggs from one state with a QAP without an environmental testing requirement in another state which maintains such a requirement.

This mandatory national program should be administered by a single federal agency. Prior to this rulemaking, issues involving shell eggs have been addressed by a several offices of the FDA and the USDA. For example, while the USDA has the authority to grade shell eggs, the FDA is the agency required to perform tracebacks of foodborne illness outbreaks. This lack of centralization and coordination has made it difficult for producers to understand their regulatory responsibilities and to know who to contact in the event of questions or problems. This rulemaking should be used as an opportunity to eliminate both producer and consumer confusion regarding shell eggs.

Mandatory environmental testing

The necessity of incorporating testing into any QAP has been recognized by a variety of groups and individuals.[11] Simply from a common sense perspective, testing is

[11] Dr. John Mason, Food Safety Consultant, has said that absent some type of testing for SE (at least of the environment), there cannot be any objective indication that QAP measures are effective. Food Safety Digest, May/June 1997 at page 5 (citing a presentation made by Dr. Mason at the Conference on Animal Production Food Safety held in conjunction with the Livestock Conservation Institute's 1997 annual meeting.) Petition for Regulatory Action to Require That (1) Warning Labels About the Risks of Salmonella enteritidis (SE) Be Placed on shell egg Cartons and (2) SE Control HACCP Programs Be Implemented on All Egg-Producing Farms, Submitted by the Center for Science in the Public Interest to the U.S. Department of Health and Human Services, Food and Drug Administration, 5/14/97, at p. 12, Richard D., and Gary D. Butcher, Special Report: Salmonella: Controlling it in the broiler, egg industries, FEEDSTUFFS, 10/11/93,

necessary. Absent such testing, how does a producer know whether the layers are infected since infected layers are generally asymptomatic?[12]

Even the United Egg Producers have, to some degree, recognized the importance of environmental testing by including environmental testing of the facility as a validation that the 5-Star Program is working.[13] Unfortunately, the testing in the UEP 5-Star Program is recommended to occur two to three weeks prior to depopulation. By this time, thousands of contaminated eggs could already have been produced and marketed.

The Salmonella Enteritidis Risk Assessment Report (SERA), recently released by the Food Safety and Inspection Service (FSIS), also demonstrates the need for testing, especially on large farms. The SERA found that by flock size strata, the largest stratum, flock sizes of 100,000 per flock, contributed almost two-thirds of SE positive eggs.[14] At a time when large egg production operations are becoming the norm, this SERA data in and of itself should be sufficient justification for required testing on all egg farms.

In terms of the test itself, FACT supports environmental testing over testing batches of eggs. Environmental tests provide a more accurate picture of whether or not the flock is contaminated. Infected hens do not produce contaminated eggs all of the time. Furthermore, not all hens in a flock house are infected by SE at the same time. Therefore, testing batches of eggs will not provide sufficient evidence to determine

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Vol. 65, Number 42, at pp. 22-34, 45; Recommendations contained in the Salmonella Enteritidis Review Team Report prepared by Review Team 1/18/97 at pp. 10, 12.

[12] "Salmonella enteritidis silently infects the ovaries of healthy appearing hens and contaminates the eggs before the shells are formed." Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control Salmonella enteritidis Infection Web page, June 28, 1996; International Increase in Salmonella enteritidis, A New Pandemic, Epidemiologic Infection, 3/26/90 at p. 25.

[13] UEP "5-Star" Total Quality Assurance Program.

[14] Salmonella Enteritidis Risk Assessment Report, July 1998 at p.63.

whether the flock house is contaminated by SE. On the other hand, since infected hens will shed SE, environmental samples provide greater certainty as to whether SE is present in the hens.

Finally, in implementing a mandatory national program, the responsible federal agency should certify laboratories conducting SE testing so that the issue of the testing competency of the laboratory is removed as a factor in evaluating a producer's compliance with the program.

Provide SE free chicks to pullet houses.

The importance of chicks being free of SE at the time of placement in the pullet house has long been recognized. Since July, 1989, the National Poultry Improvement Plan (NPIP) has included a program intended to reduce the incidence of SE in hatching eggs and chicks. This program recognizes the importance of environmental testing and requires environmental samples to be collected from the flocks when the flocks are two to four weeks of age. Samples are also collected every 30 days after the first sample has been collected.[15] Unfortunately, the requirements of the NPIP apply only to those hatching and newly hatched chicks that may be moved interstate and, therefore, many breeders and hatcheries are not required to follow the NPIP requirements. Several QAPs do require participants to purchase chicks and pullets from hatcheries participating in the NPIP "U.S. Salmonella Enteritis Monitored Program," and/or to require testing of a

[15] 9 CFR Section 145.33 (l) (vi) and (vii).

certain number of chick papers at time of delivery.[16] However, none of the QAPs have released information as to the names of participants or, in the case of state QAPs, the percentage of producer participation. In addition, the QAP which claims to have the largest number of participants, the UEP 5-Star Program, does not include either a requirement that the chicks and pullets be purchased from hatcheries participating in the NPIP nor does it require testing of a certain number of chick papers at time of delivery.[17] The NEST EGGS® program requires that chick box liners be tested prior to placement in the pullet house.

We believe that the requirement that only SE free chicks be placed in the pullet house is crucial because even if a "small percentage of Salmonella-positive eggs enter the hatching cabinet, the spread of Salmonella from these eggs can be extensive."[18] Chicks are extremely susceptible to Salmonella contamination because they do not develop immune systems until they are 10 days old. In addition, hatchery contamination can limit the effectiveness of competitive exclusion.[19] Further, a recent study found that Salmonella could be found inside the beak of chicks which were still in the egg but ready to hatch.[20] Here also competitive exclusion would be ineffective since colonization had already occurred. Since it is not possible to totally prevent SE contamination in the chicks, testing of chicks is a necessary component of any SE elimination program.

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[16] South Carolina Egg Quality Assurance Plan; Pennsylvania Egg Quality assurance Plan; California Egg Quality Assurance Plan; New England Salmonella enteritidis Risk Reduction Program and New York Salmonella enteritidis Quality Assurance Program.
[17] UEP "5-Star" Program.
[18] Bailey, J.S., Cason, JA and NA Cox, Effect of Salmonella in Young Chicks on Competitive Exclusion Treatment. 1998 Poultry Science 77: 394-399.
[19] Id.

Test pullets prior to placement in layer houses

Generally, producers place pullets, rather than chicks, in layer houses. Chicks are generally transported from the hatchery to the pullet house and from the pullet house to the layer house. Since contamination can occur at any point in this continuum, it is essential that pullets be tested prior to placement in the layer house. Programs that follow the NPIP "U.S. Salmonella Enteritidis Monitored Program" require testing every 30 days following the initial test. Other programs also address the need for SE free pullets. For example, the California Egg Quality Assurance Program states that "chicks and pullets should always be transported in coops and trucks that are decontaminated between flocks." Testing of pullets is essential as part of any SE elimination program because if SE contaminated pullets enter the layer house, they can cause contamination to the layer house through a variety of methods including airborne transmission[21], ingestion of fecal material[22], and through contaminated water[23].

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[20] Nelson Cox, Incidence and Impact of Salmonellae in Broiler Hatcheries, International Symposium on Food-borne Salmonella in Poultry, July 25-26, 1998.

[21] Baskerville, A., Humphrey, TJ, Fitzgeorge, RB, Cook RW, Chart, H., Rowe, B., and A. Whitehead, Airborne infection of laying hens with Salmonella enteritidis phage type 4, Veterinary Record (1992) 130, 395-398; Holt, PS, Mitchell BW, and Richard K. Garst, Airborne Horizontal Transmission of Salmonella enteritidis in Molted Laying Hens, Avian Diseases (1998) 42: 45-52; Wray C. and R. Davies, Big Fleas Have Little Fleas on Their Back to Bite Them: Environmental Problems in Poultry Production, International Symposium on Food-Borne Salmonella in Poultry, July 25-26, 1998 (Salmonella can survive for long periods in dusts in poultry houses despite cleaning and disinfection)..

[22] Mice are carriers of SE. At night, mice come out of hiding, eat from the feed trough and deposit an average of 100 pellets per mouse in the feed trough in a 24 hour period. Those pellets are the first items consumed by chickens when the lights are turned on. Charles Beard & Richard Gast, Where are we with SE, Egg Industry, July/August, 1992; Henzler, DJ, and HM Opitz, The role of mice in the epizootiology of Salmonella enteritidis infection on chicken layer farms. Avian Diseases 36:625-631 (1995).

[23] Nakamura, M., Nagamine, N., Takahashi, T., Suzuki, S., Kijima, M., Tamura, Y., and Shizuo, S., Horizontal Transmission of Salmonella enteritidis and effect of stress on shedding in laying hens (1993) Avian Diseases 38:282-288

Divert eggs from the market where SE is found

When SE tests are positive, the eggs must be diverted to pasteurization. When there is a positive result, current tests are not able to determine which or how many hens are infected. Also, there is no way to determine which eggs are contaminated absent testing each egg.[24] Therefore, when tests find SE, all of the eggs must be diverted to pasteurization. FACT believes that to market eggs from known SE positive flocks is to violate consumer confidence in producers providing them with a safe food product. Only two QAPs[25] follow testing with diversion of eggs once SE is found in the flock. NEST EGGS® incorporates this step into its SE elimination program.

Process feed in a manner that kills SE

Researchers have found Salmonella in feed[26] both in animal and plant protein. Thus, feed is an additional source of transmission of the infection. In order to eliminate SE, producers must include a program for achieving effective control of Salmonella contamination of poultry feed.[27] One effective method of reducing Salmonella contamination in poultry feed is pelleting feed through a heat process.[28] NEST EGGS®

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[24] Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control Salmonella enteritidis Infection Web page, June 28, 1996

[25] Pennsylvania egg Quality Assurance Program and New York State Egg Quality Assurance Program. Both programs require eggs to be tested if an environmental test is positive and if any egg pools are positive, the eggs must be diverted to pasteurization.

[26] McChesney, DG, Kaplan, G., and Patsy Gardner, Special Report: FDA survey determines salmonella contamination, FEEDSTUFFS, 2/13/95 at 20-23; H. Riemann, Bacteria in Feed, In: Proceedings of a Symposium on Feed Quality Assurance-A Systemwide Approach. September 18-19, 1990.

[27] SG McIlory, Control of Salmonella Contamination of Poultry Feeds, International Symposium on Food-Borne Salmonella in Poultry, July 25-26, 1998; Feed contamination an important factor in salmonella control, Poultry Times, 4/6/98 at p. 11.

[28] [28] McCapes, R.H., H.E. Ekperigin, W.J. Cameron, W.L. Ritchie, J. Slagter, V. Stangeland, and K.V. Nagaraja, Effect of a New Pelleting Process on the Level of Contamination of Poultry Mash by Escherichia coli and Salmonella, Avian Diseases 33:103-111, 1989.

has found this method to be very effective. Other methods include a combination of heat and propionic acid[29] and yeast added to poultry feed.[30] Finally, in order to ensure that feed is salmonella free, it must be regularly tested.

Prohibit induced molting, or at a minimum establish SE controls when induced molting is used.

Researchers have demonstrated that where molting is induced, there is a decrease in the resistance of hens to SE and an increase in the incidence of SE shedding.[31] As a result, SE can readily be transmitted among hens (both molted and not molted). The combined effect of acutely susceptible hens exposed to SE results in increased transmission of SE.[32] In addition, every hen must eat every four hours.[33] Thus, after four hours of feed withdrawal the hens will begin to eat feces[34], which would include SE organisms if any of the hens have SE and are shedding. FACT recommends that the practice of induced molting should be discontinued as part of the program to eliminate SE in shell eggs.

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[29] Matlho, G., Himathongkham, S., Riemann H., and Philip Kass, Destruction of Salmonella enteritidis in Poultry Feed by Combination of Heat and Propionic Acid, Avian diseases 41: 58-61, 1997.

[30] The Report of the 100th Annual Meeting of the United States Animal Health Association, Presentation by Dr. Stan Bailey in the Report of the Committee on feed Safety, October 12-18, 1996, at p. 169.

[31] Holt, PS and RE Porter, Jr., Effect of Induced Molting on the Course of Infection and Transmission of Salmonella enteritidis in White Leghorn Hens of Different Ages, Poultry Science 71: 1842-1848 (1992); Holt, PS, and RE Porter, Jr., Effect of Induced Molting on the Recurrence of a Previous Salmonella enteritidis Infection, Poultry Science 72:2069-2078 (1993); PS Holt Horizontal Transmission of Salmonella enteritidis in Molted and Unmolted Laying Chickens, Avian Diseases 39:239-249 (1994).

[32] Holt, PS, et al. Microbiological Analysis of the earliest Salmonella enteritidis Infection in Molted and Unmolted Hens. Avian Diseases 39:55-63 (1995); PS Holt, Predisposing Factors, International Symposium of Food-Borne Salmonella in Poultry, July 25-26, 1998.

[33] S. Russell, Effect of Poultry Processing on Populations of Bacteria on Fresh Broiler Chicken Carcasses, International Symposium on Food-Borne Salmonella in Poultry, July 25-26, 1998.

[34] Id.

The SERA found that molting is associated with an increased rate of SE positive eggs within SE positive flocks and, therefore, used molting as a factor in its assessment. On the other hand, the SERA at several points appeared to minimize the potential impact of molting as a factor in the incidence of SE. First, the SERA estimates that 22% of flocks producing eggs on any given day are flocks that were previously molted.[35] While this may be true, this percentage fails to represent the full molting picture. In fact, the use of induced molting is estimated to be 60% nationwide and 90% in California.[36] While these two statistics represent different measures of the use of induced molting, they clearly indicate that the practice is widely used in the United States.

Second, the SERA states that SE positive flocks that are molted do not perpetually produce SE positive eggs more frequently than flocks that are not molted. Instead, according to the SERA, there appears to be a period immediately after molt when molted flocks are at higher risk of producing more positive eggs.[37] On the other hand, the Schlosser study found that molted flocks not only produced SE positive eggs twice as frequently as non-molted flocks, and also molted flocks produced SE contaminated eggs for a period of up to 140 days post-molt.[38] Still, the SERA concluded that SE positive flocks will produce more positive eggs during the first 70 days post-molt. Their conclusion is intended to minimize the impact of the molting factor.

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[35] SERA at p. 40.
[36] Peter S. Holt, Effect of Induced Molting on the Susceptibility of White Leghorn Hens to a Salmonella enteritidis Infection, Avian Diseases 37:412-417 (1993).
[37] SERA at p. 42.
[38] Schlosser, W., Henzler, D., Mason, J., Hurd, S., Trock, S., Sischo, W., Kradel, D., and Hogue, A., Salmonella enteritidis Pilot Project Progress Report. Washington DC (1995).

Third, the SERA stated that infected hens typically produce SE positive eggs only during the first week of their four week infection.[39] Also, the SERA estimated that a positive hen in her first week of infection only produces SE positive eggs 8% of the time during that week. Thus, the SERA estimated an SE positive egg frequency of six SE positive eggs per 100,000 eggs produced in flocks detected through environmental testing or spent hen survey methods.[40] From this statistic, the SERA proceeds to make other conclusions.

However, these statistics fail to recognize other factors which may increase the importance of molting as a factor in the spread of SE. First, as discussed above, once the SE organism is in the layer house, it can live for long periods in dust in the flock house and can even survive cleaning and disinfection.[41] Thus, even assuming the hens recover after four weeks, recurrence of infection, through retransmission via rodents and pests[42], is entirely possible due to the continued existence of the organism in the house. Second, unless there is environmental testing of the house and/or testing of the eggs, the producer cannot be certain whether the flock is SE free once the flock returns to production. For these reasons, if the practice of induced molting is to be permitted then controls need to be put in place to lessen the incidence of SE among molted hens.

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[39] SERA at p. 51.
[40] Id.
[41] Wray C. and R. Davies, Big Fleas Have Little Fleas on Their Back to Bite Them: Environmental Problems in Poultry Production, International Symposium on Food-Borne Salmonella in Poultry, July 25-26, 1998 (Salmonella can survive for long periods in dusts in poultry houses despite cleaning and disinfection).
[42] Id.

Three control measures are recommended. First, mandatory post-molt environmental tested should be implemented.[43] Second, rather than a complete withdrawal of feed, a modified diet should be utilized.[44] Such a diet would lessen the impact of the molt, in part, because the hens would have less incentive to eat feces since they would be getting some food. Finally, the use of a competitive exclusion product at the inception of the molt should be considered since this may prevent SE colonization in the gut.[45]

Establish rodent controls.

There now appears to be a consensus among industry and consumer groups concerning the importance of rodent control..[46] A recent study by the Agricultural Research Service of the USDA found, after two years of sampling more than 1000 mice from commercial poultry houses, that SE was in the spleen of one out of five of the mice.[47] It is believed that contaminated mice can survive usual cleaning and disinfectant procedures and could cause some clean houses to become SE positive even though no

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[43] The Pennsylvania Egg Quality Assurance Program requires that manure be tested in molted flocks at five to seven weeks following return to feed and that eggs must be tested as well.

[44] Holt, PS, Buhr, RJ, Cunningham, DL and RE Porter, Jr., Effect of Two Different Molting Procedures on a Salmonella enteritidis Infection, Poultry Science 73:1267-1275 (1994).

[45] Fsnet 4/9/98 European veterinarians prescribe Enrofloxacin as a treatment for SE prior to molt and it is reinforced by Aviguard, a competitive exclusion product. Currently, Dr. Peter Holt is testing the effectiveness and safety of Enrofloxacin and Aviguard under a cooperative research agreement with Bayer Corporation. GC Mead, Prospects for "Competitive Exclusion" Treatment in Controlling Salmonellas and Other Foodborne Pathogens in Poultry, International Symposium in Food-Borne Salmonella in Poultry, July 25-26, 1998. Dr. Mead stated that competitive exclusion should be used any time an antibiotic treatment has been done to repair the flora, even in adult hens. Thus, if antibiotics are used to treat a SE infection that occurs during the molt, competitive exclusion may be useful to establish a protective environment against recurrence in the hen.

[46] See, e.g., United Egg Producers' "5-STAR" Top Quality Assurance Program (A HACCP type food safety program with validation.).

[47] Fsnet 4/28/97

chickens are introduced. At night, mice eat from the feed trough and deposit an average of 100 pellets per mouse in the feed trough in a 24 hour period. Those pellets are the first items consumed by the chickens when the lights are turned on.[48] Research has found that mice may excrete Salmonella intermittently for at least 18 weeks.[49] Therefore, mice can recontaminate hens after an SE infection has occurred during a molt. Also, they can move out of the buildings during cleaning and disinfection and return thereafter to contaminate the house.[50] Thus, rodent control is a crucial part of any SE elimination program and most of the QAPs have included this as a step in their programs.

Establish and maintain a biosecurity program.

The implementation and maintenance of an on-farm biosecurity program been included as a step in all QAPs and must be included in the mandatory national program. The goal is to make the facility rodent and pest proof. "A biosecurity program comprises a series of regulations for the location and design of farms, movement of personnel and equipment; manufacturing and distribution of feed; rodent and pest control; cleaning and disinfection procedures; disease surveillance and risk assessment."[51] All employees must be trained concerning the program and must participate in the program. The biosecurity program is ongoing and must be constantly monitored and maintained.

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[48] Charles Beard & Richard Gast, Where are we with SE, Egg Industry, July/August 1992; Clifford Wray, Big Fleas Have Little fleas on Their Back to Bite Them: Environmental Problems in Poultry Production, International Symposium on Food-Borne Salmonella in Poultry, July 25-26, 1998 ("Chickens find mice feces very palatable.").

[49] Clifford Wray, Big Fleas Have Little fleas on Their Back to Bite Them: Environmental Problems in Poultry Production, International Symposium on Food-Borne Salmonella in Poultry, July 25-26, 1998

[50] Id.

[51] Rosales. AG, and Eric L. Jensen, Biosecurity and disinfection for Salmonella Control, International Symposium on Food-Borne Salmonella in Poultry, July 25-26, 1998.

Keep records for at least one year.

Finally, records must be created and maintained to demonstrate compliance with the requirements of the program to assist the federal agencies in the event of a traceback. In addition, recordkeeping might shield the producer from some adverse consequences[52] and proof of compliance may provide the producer with reduced insurance premiums.[53] Many of the QAPs have recognized the importance of this element by incorporating recordkeeping as a requirement of their program.[54] Thus, in the creation of a mandatory national SE elimination program, recordkeeping for at least one year must be included.

Conclusion

For over ten years, the egg industry has hoped that the problem of SE in shell eggs would just go away. It is clear that the problem of SE has not been eliminated either by ignoring it or by establishing voluntary QAPs. In fact, the organism has mutated into an even more virulent form and has persisted as a consumer health problem. It is essential that the FDA and USDA use this rulemaking opportunity to establish a mandatory federal program with uniform standards designed to eliminate the threat of SE in shell eggs. Such a program will provide assurances to the consumer and a level playing field for producers. The cornerstone of the mandatory national program must be the inclusion of mandatory environmental testing for SE. Only through testing can a producer verify that

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[52] In the event of a traceback, participants in good standing with the New York State Egg Quality Assurance Program with no previous positive environmental samples are not placed under restriction.

[53] Pennsylvania Egg Quality Assurance Program.

[54] United Egg Producer's "5-Star" Program, New England Salmonella enteritidis Risk Reduction Program, New York State Egg Quality Program; and the South Carolina Egg Quality Assurance Program. In all likelihood, it is also a part of the Pennsylvania Egg Quality Assurance Program; however, it was not specifically included as a requirement in their brochure.

the other elements of its SE elimination program are working. One-time testing two to three weeks prior to depopulation cannot serve this purpose. Testing must be conducted at specified intervals throughout the life of the flock including upon placement in the pullet house, placement in the layer house, post-molt and after depopulation of the flock house. Testing is also necessary to ensure the provision of SE free feed to flocks. Most egg producers agree that rodent and pest control programs and complete biosecurity programs are integral parts to the elimination of the organism from the farm. Finally, the national mandatory program must include a requirement that eggs be diverted to pasteurization where SE has been found in the flock house. While these steps are focused only on farm controls, FACT believes that if the on-farm component of the SE threat is controlled, a significant step towards the elimination of the threat of SE will have been accomplished.

TESTIMONY

To be Included in the Hearing Record on July 1, 1999

HEARING BEFORE THE SENATE SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT, RESTRUCTURING, AND THE DISTRICT OF COLUMBIA

SUBJECT: Egg Safety: Are There Cracks in the Federal Food Safety System?

I am L. John Davidson of Pasteurized Eggs, L.P. located in Laconia, New Hampshire and submit this written testimony to be part of the Hearing Record. The Company has developed an all-natural process to pasteurize shell eggs to FDA standards established at a 5-log reduction of a known count of salmonella consisting of all strains commonly associated with shell eggs. The process employs tightly controlled warm water baths. The technology is patented. The processing machinery is available to egg producers and costs about the same as other equipment commonly used by the egg industry. Each machine has a capacity of 13 million dozen per annum for each 8-hour shift. The added cost to the consumer for a safe egg is projected at 4.5¢ per week. The eggs will be Certified as Pasteurized by a resident USDA inspector subject to the pasteurization achieving the FDA standard. The egg safety results for the public will equate to the 29 year successful experience achieved by the liquid egg industry which employs only a 4.5-log reduction using product which predominantly includes eggs that are older, rejected because of shell condition, cracked or from hens infected with avian influenza. According to the CDC no trace back of a salmonella outbreak from eggs has even been attributed to a pasteurized liquid egg source.

The Company's pasteurization technology not only produces the safest egg at low cost but also includes a protective FDA approved sealant which reduces risk of recontamination and preserves the characteristics of freshness for an extended time. Additionally, in anticipation of further food safety considerations in process, the eggs exit from the pasteurizer with an internal temperature of 41°F.

The reason for this testimony being submitted for the record is that the Subcommittee may benefit from the knowledge that a solution to the public health problem caused by contaminated shell eggs exists. Historical information concerning pasteurization and questions are provided. A compelling argument for pasteurization of shell eggs should be made. U.S. citizens should be provided with full information and mandated warning labels concerning the risk associated with eating unpasteurized shell eggs.

It is inconceivable that the excellent track record of food safety achieved from mandated pasteurization of milk, liquid eggs and now juices ever would be considered unnecessary and replaceable through hygiene and husbandry practices. The same opportunity for the complete elimination of the public health risk caused by salmonella in shell eggs is available through pasteurization. The agencies of jurisdiction should be required to take appropriate action.

BACKGROUND INFORMATION:

1960's: The technology to pasteurize liquid eggs was developed.

1970: Congress mandated pasteurization of all liquid eggs resulting in providing the public with a safe product just like pasteurized milk.

1985: A new strain of salmonella in shell eggs was discovered (Salmonella enteritidis – Se), determined to be internal to the egg when it is laid. Numerous disease outbreaks occurred with many associated deaths resulting from contaminated shell eggs.

1994: The FDA set a standard for pasteurization of shell eggs having learned that a commercial scale pasteurization technology for shell eggs had been developed which inexpensively processes eggs without noticeably altering either their aesthetics or their functionality.

1997: The USDA Poultry and Egg Grading Division officially adopted a new shield certifying pasteurization of shell eggs with the condition that they be USDA graded eggs and have been processed to meet the FDA standard of a 5-logarithmic reduction of a known count of salmonella.

1997: The FDA published its revised edition of the Model Food Code which included a requirement that facilities serving highly susceptible populations (nursing homes, hospitals, etc.) utilize only pasteurized eggs in their menus. The Code also required that facilities servicing mixed groups either serve hard-cooked eggs or provide warning labels, clearly visible to the consumer, which state that under-cooked eggs may be harmful to one's health.

1997: The shell egg producers, through its organization (the United Egg Producers), rejected the positions of both the food safety inspection (FSIS) and the Centers for Disease Control (CDC) that salmonella in shell eggs is prevalent, a growing health problem, kills people, makes in excess of 1,000,000 Americans sick and costs the public in excess of $1.0 billion annually.

1998: The U.S. Poultry and Egg Association recommended that hospitals and nursing homes serve only pasteurized egg products.

1998: The National Restaurant Association (NRA) recommended the Model Food Code to its membership subject to compromise being reached primarily on 2 issues: 1) Whether or not food refrigeration be at 41°F or 45°F. 2) Whether gloves be required in the preparation and handling of food. According to a June 1999 Report, the NRA states that it expects the rate of State adoption of the Code to be doubled once the open issues have been resolved. They expect resolution in the near term.

Since 1994 sixteen (16) States have adopted the Code along with the U.S. Air Force and Army. Twenty-two (22) additional States are near adopting the Code.

Enforcement has been left to the adopting jurisdictions. A 1997 study showed that 90% of nursing homes still served unpasteurized shell eggs.

1998: Dr. Catherine Woteki, Under Secretary of Agriculture-Food Safety, stated that the frequency of Salmonella enteriditis, according to a computer model, has been reduced to 1 egg in 20,000 and causes [only] 662,000 cases of illness annually using solely Salmonella enteritidis in its statistical projections. The average cost of an illness is $1,500. (FDA) for each patient. None of the projections for contaminated eggs were based on actual field tests. No new science has been offered. The customary recommendations for washing of hands, refrigeration and better hen house management were recommended. No reference to the benefits of shell egg pasteurization has been made even though an excellent

record for pasteurization has been clearly established for milk, liquid eggs and now juices.

1999: Shell egg pasteurization equipment will be available to Egg producers. The equipment specifications include processing of pasteurized shell eggs to the established 5-log FDA standard and qualification for certification by the USDA to use its new shield displaying 'Certified Pasteurized'. The machine will produce 13 million dozen annually per shift. The fully loaded added cost for the producer will be 15¢ per dozen (1-1/4¢ per egg) above the cost for one dozen raw eggs. The new safe egg, produced and distributed within the current system, will be introduced from Boston to Washington, DC in 1999 and across the U.S. next year.

An inexpensive smaller machine to satisfy small producer needs also has been developed.

Costs and Consumption: Statistics indicate that the average per capita U.S. consumption is 15.5 dozen. The extra cost to the consumer for a safe egg would be 4-1/2¢ per week subject to retail and producer adjustments.

QUESTIONS:

1. **Is there a crack in the Federal Food Safety System for Eggs when the FDA has taken action to mandate pasteurization of fruit juices and has not mandated either warning labels or pasteurization of shell eggs when the preponderance of evidence shows shell eggs to be a far greater public health threat?**

2. **Is there a crack in the Federal Food Safety System for Eggs when the track record for pasteurized liquid eggs (30% of egg production) shows no incidence of a foodborne illness outbreak traced back to a liquid egg source in 29 years of mandatory pasteurization and a similar solution for raw shell eggs has not been initiated although the FDA standard has been set and the technology to achieve it is available?**

3. **Is there a crack in the Federal Food Safety System for Eggs when the CDC recognizes that shell eggs are the number one source of food poisoning caused by salmonella; the FDA supports mandated pasteurization for risk groups through its Model Food Code and has set a standard for shell egg pasteurization; the CDC considers illness**

caused by salmonella in shell eggs as epidemic; pasteurization has long provided safety in milk and liquid eggs, and no federal agency has yet accepted the responsibility to resolve the obvious health risk through mandating warning labels on menus and egg cartons or mandating pasteurization?

4. **Is it possible that the crack in the Federal Food Safety System for Eggs is the result of uncoordinated management conducted by several agencies whose staff gathers, interprets and publicizes data without the benefit of comparative analysis and direction delivered by one party at the top who is responsible for disseminating to the public and Congress information that is expert, current and reliable?**

   Example #1: 1998 – Dr. Catherine Woteki, Under Secretary of Agriculture-Food Safety, stated that, based on a computer model (not confirmed by field testing), the frequency of Salmonella enteritidis in shell eggs has been reduced to 1 egg in 20,000. She cites that this one strain causes 662,000 cases of illness annually. The conversion of that statistic would indicate that approximately 1 egg in 6,500 causes illness without inclusion of the additional illnesses caused by commingling of eggs. Each illness costs an average of $1,500. (FDA). She fails to mention that pasteurization would save in excess of $1.0 billion annually at an increased cost of product to the consumer of less than half that amount.

   Example #2: All current statistical references used by Dr. Woteki and other agencies are limited to Salmonella enteritidis. Nothing has changed on the risk of illness caused from other strains of salmonella that justified the mandating of liquid eggs in 1970. The result is that the threat from contaminated shell eggs is grossly understated.

   Example #3: No Agency, exposed to the new pasteurization technology available, approved and ready for market, has acknowledged the full complement of safety benefits provided by the current technology developed:

   i. A higher kill of all strains of salmonella (5-logs) than the liquid egg requirement (4.5-logs).

ii. The eggs exit the shell egg pasteurizer at an internal temperature of 41°F.

iii. The eggs are sealed with an FDA approved sealant which provides protection from recontamination and extends the retention of the characteristics of freshness.

Example #4: In 1999, Dr. Robert V. Tauxe, Chief, Foodborne and Diarrheal Diseases Branch, CDC, probably the most knowing and respected expert in government concerning foodborne illnesses, published an article stating that the problem of salmonella in shell eggs is growing (not declining) and has caused a worldwide epidemic.

Example #5: Reports claiming a reduction in the frequency of outbreaks fly in the face of information provided by the scientific community which reports new and more resilient strains of salmonella (Phage types) are here, increasing the frequency of outbreaks 5-fold (CDC) and spreading across the U.S. The only proven safe ways available to combat it is by not eating eggs at all, hard-cooking them thoroughly or pasteurizing them.

Respectfully Submitted By:

L. John Davidson
President

7/1/99
Date:

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GAO

United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

July 22, 1999

The Honorable George V. Voinovich
Chairman, Subcommittee on Oversight of Government Management,
Restructuring, and the District of Columbia,
Committee on Governmental Affairs
United States Senate

Dear Mr. Chairman

I am pleased to respond to your letter of July 14, 1999 asking for further information on our recommendation that the Congress consider consolidating responsibility for egg safety responsibilities in a single federal department. (See Food Safety: U. S. Lacks a Consistent Farm-to-Table Approach to Egg Safety, GAO/RCED-99-184, July 1, 1999.) Specifically, you asked whether egg safety responsibilities should be consolidated within the Department of Agriculture or the Department of Health and Human Services and why.

As you know, for many years GAO has reported on the need for a single agency to administer a unified, risk-based food safety inspection system. If such an agency is established, egg safety would become one of its responsibilities

Alternatively, assigning egg safety responsibilities to either of the Departments that currently share egg safety responsibilities would have both advantages and disadvantages. However, on balance, we believe that consolidation in the Department of Agriculture would be preferable. This is because Agriculture (1) currently operates the only active federal safety inspection programs for eggs and egg products, (2) has the necessary technical expertise for effective oversight of farms as well as shell egg and egg products processing facilities, and (3) has significantly more inspection resources assigned to egg safety. As a result of these factors, transferring egg safety responsibilities to Agriculture would also prove simpler logistically.

If you have any further questions, please contact me at 202-512-5138.

Sincerely yours,

Lawrence J. Dyckman
Director, Food and Agriculture Issues

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 30 1999

The Honorable George V. Voinovich
Chairman, Subcommittee on Oversight of Government Management,
Restructuring, and the District of Columbia
Committee of Governmental Affairs
United States Senate
Washington, DC 20510-6250

Dear Mr. Chairman:

Thank you for your letter of July 14, 1999, with additional questions from your hearing on egg safety. Below are our responses to those questions.

1. Please respond to the GAO's recommendation that Federal egg safety responsibility be consolidated into a single department.

It is important to note that it was Congress who has established the current statutory framework for egg safety under five different laws and several agencies, as outlined in the report from the General Accounting Office (GAO). The Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA), however, have worked well together to address the problem of *Salmonella* Enteritidis (SE) in eggs. As both agencies stated during the recent hearing on eggs before this Committee, we agree it has taken too long to control this public health problem, however, by November 1 1999 a report will be submitted to the President's Council on Food Safety, outlining a coordinated strategic plan for egg safety. When the strategic plan for egg safety is completed, copies will be forwarded to the Committee on Governmental Affairs.

Consideration of any changes in food safety jurisdiction, including egg safety jurisdiction, will be a part of the overall deliberations of the President's Food Safety Council's strategic planning effort. Therefore, we believe it is premature to respond on whether consolidation is the best answer.

2. How many personnel are assigned full-time and part-time to egg safety?

FDA's general approach to food safety is to have personnel devoted to the safety of multiple foods, including eggs. Depending upon the particular issue, responsibilities for egg safety are divided among persons whose expertise is in food labeling, preventive controls, regulation development, traceback of egg-related illness, legal issues, research and analysis, inspections, economics, and consumer and industry education. The agency, therefore, does not have specific staff assigned solely to egg safety. In addition, FDA augments its personnel assigned to this issue through partnerships related to egg safety with federal, state and local agencies, including inspections of egg packing plants by state agencies, and Agricultural Marketing Service (AMS) through an agreement with FDA, and on-farm investigations and inspections by state agencies.

FDA's egg safety program includes:

- regulation development (policy developers, regulation writers, economists, and research scientists),
- traceback of egg-related illness, including microbiological assessment of implicated farms (veterinarians, microbiologists, field investigators, and laboratory technicians),
- research on *Salmonella* Enteritidis in eggs (risk assessment developers, research scientists, and laboratory analysts/technicians), and
- consumer/industry education (consumer educators, writers, retail model code (Food Code) policy developers and writers).

Although it is difficult to assess the numbers of people working on egg safety on a daily basis, the time spent on certain projects can be estimated. It is estimated that the proposed rule to require refrigeration of eggs at retail and safe handling labeling on eggs required 4200 hours of FDA time to complete. The average traceback of egg-related illnesses, of which FDA does approximately 6 per year, averages approximately 460 hours of FDA time per outbreak. We estimate that in FY 98 the Agency expended approximately 15 FTEs on egg safety.

3. Should there be a uniform national code for egg safety?

Yes, there should be uniform national standards for egg safety. As we indicated at the July 1 hearing before your subcommittee, the President's Food Safety Council is developing a farm-to-table action plan that will provide a comprehensive, coordinated national approach to ensure egg safety. The action plan will be completed by November 1999. The overall objective of the action plan is to control and reduce pathogens through identifying and developing research and technology measures and improved enforcement and through a comprehensive set of preventive controls, testing, guidance and training. In pursuing such a plan, the agencies may consider intrastate as well as interstate implementation of control measures, which FDA has authority to do under the Public Health Service Act.

4. Should there be more resources directed to checking chicken flocks for SE? If there were comprehensive checks of chicken flocks for SE, and such checks were successful at preventing contaminated eggs from continuing on in the food process where they could be a health threat, would that make most other elements of the egg safety system unnecessary?

Additional resources are needed for a comprehensive on-farm SE control program. Resources from FDA's proposed FY 2000 budget, together with recent increases in staff at FDA's Center for Food Safety and Applied Nutrition from FY 98-99 funding are sufficient for development of standards for a national system of preventive controls for egg production. However, FDA will need additional resources to implement the comprehensive farm-to-table SE control program that is currently being developed by the President's Council on Food Safety.

Epidemiological evidence suggests that on-farm controls can reduce the incidence of SE-contaminated eggs. However, evidence indicates that these controls are not 100 percent effective in preventing human infection. In addition, SE is not the only potential egg-associated pathogen. Therefore, a farm-to-table strategy for egg safety with multiple barriers is necessary to fully protect American consumers.

5. Has FDA developed performance standards and goals for egg safety as required for all Federal activities by the Results Act? How is FDA coordinating its egg safety activities with other agencies in the context of the Results Act?

Yes, FDA's Results Act goals for egg safety include plans to publish the retail refrigeration and safe handling labeling proposed rule in FY 1999, which has been accomplished. It is estimated that implementation of this rule, when finalized in FY 2000, will reduce annual egg-related illness by 15 percent. In addition, FDA has egg safety objectives in the Healthy People 2010 goals. Egg safety measures already in place plus efforts that will be outlined in the egg action plan will aid the agency in meeting its objectives to reduce the number of *Salmonella*-related infections and the number of *Salmonella* Enteritidis outbreaks by 50 percent by 2010.

FDA is coordinating its egg safety activities with other agencies by developing an egg safety action plan through the President's Food Safety Council, which will pull together all of the separate actions, whether FDA, USDA or state, needed to provide a comprehensive, coordinated approach to egg safety. After the plan is developed and implemented, continued cooperation among agencies will be necessary to ensure that eggs are safe from farm to table.

6. The GAO report noted numerous times that FDA safety inspections are limited by lack of resources. Is FDA's budget adequate to execute its egg safety responsibilities? If not, what is the budget shortfall? Is FDA addressing this?

FDA's egg safety responsibilities include coverage of the production and processing of shell eggs. FDA seeks to accomplish this through federal, state and industry partnerships. GAO is correct, we do not have enough resources to adequately cover all egg safety responsibilities. FDA, through the egg safety action plan mentioned above, will develop resource estimates for FY 2001-2004 for FDA needs.

If you have any questions, please call Michael Eck of my staff at (301) 827-0102.

Sincerely,

for Melinda K. Plaisier
Interim Associate Commissioner
for Legislation

cc: The Honorable Richard Durbin
Ranking Minority Member
Subcommittee on Oversight of Government
Management, Restructuring, and the
District of Columbia
Committee of Governmental Affairs
United States Senate
Washington, D.C. 20510

United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

AUG 3 1999

The Honorable George V. Voinovich
Chairman, Subcommittee on Oversight of Government Management
Restructuring, and the District of Columbia
601 Hart Senate Office Building
Washington, DC 20510

Dear Senator Voinovich:

Thank you for providing Margaret Glavin, Associate Administrator of the Food Safety and Inspection Service (FSIS), with the opportunity to testify before your Subcommittee at the July 1,1999 hearing on egg safety. I know Ms. Glavin enjoyed meeting you and the other Members of the Subcommittee and appreciated the invitation to discuss this very important issue.

First, allow me to clarify that FSIS is responsible for ensuring that meat, poultry, and egg products are safe, wholesome, and accurately labeled. FSIS enforces the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, which require Federal inspection and regulation of meat, poultry and egg products prepared for distribution in interstate commerce for use as human food.

FSIS shares your concerns about food safety and is committed to ensuring that our food supply remains the safest in the world. We appreciate the opportunity to answer the questions laid out in your letter of July 14, 1999.

1. Please respond to the GAO's recommendation that Federal egg safety responsibilities be consolidated into a single department.

The Strategic Planning Task Force of the President's Food Safety Council is co-chaired by the leaders of the two Agencies with jurisdiction over egg safety – USDA Under Secretary for Food Safety Catherine Woteki and FDA Commissioner Jane Henney.

The Task Force is in the process of developing a comprehensive national strategic food safety plan. Recognizing the significance of the egg safety issue, the Task Force has named a work group to make progress in this area quickly. The Task Force and Work Group are sponsoring a public meeting on egg safety to be held in Washington, DC on August 26, 1999.

2. How many USDA personnel are assigned full-time and part-time to egg safety?

We currently have 99 inspectors assigned to continuous egg product inspection jobs. In addition, other individuals are being cross-utilized in egg product inspection jobs, when necessary.

3. Should there be a uniform national code for egg safety?

The President's Council on Food Safety, established in August 1998 under Executive Order 13100 and represented, in part, by FSIS and the Food and Drug Administration (FDA), is developing a comprehensive national egg safety strategic plan that will consider a national code for egg safety. This plan is expected to address *Salmonella* Enteritidis (SE) through a farm-to-table approach. A public meeting, to be held in Washington, DC, is being planned for August 26, 1999. The meeting is intended to be a working meeting in order to discuss goals and objectives to significantly reduce the number of foodborne illnesses associated with SE in shell eggs and egg products. A uniform national code for food safety would provide public health and regulatory agencies at all levels with practical, science-based, manageable, and enforceable provisions for mitigating risk factors related to shell eggs known to contribute to foodborne disease. A national code for egg safety would establish a foundation for uniform, effective standards for egg safety.

4. Given the implementation of HACCP systems, should FSIS reconsider its continuous inspection policy at egg processing plants?

As you know, FSIS does not yet have HACCP systems in place for processed egg products. FSIS expects to publish a proposed rule on processed eggs by spring 2000. The proposal is expected to address a number of issues, including industry HACCP systems and Sanitation Standard Operating Procedures (SSOPs) pathogen reduction performance standards to update and replace the current command-and-control pasteurization requirements, and the elimination of prior approval requirements for egg product facility drawings, specifications, and equipment. Currently, our inspection program personnel are present at all times during operations at egg processing establishments under Federal inspection, as required in the statute and the current regulations. However, FSIS does believe inspection activities should be based on risk and that it is appropriate to examine the merits of continuous inspection at egg products establishment.

5. Has USDA developed performance standards and goals for egg safety as required for all Federal activities by the Results Act? How is USDA coordinating its egg safety activities with other agencies in the context of the Results Act?

FSIS is developing performance indicators for egg products as required by the Results Act. They are based upon egg product inspection Sanitation Standard Operating Procedures (SSOPs) and Pathogen Reduction/Hazard Analysis and Critical Control Point (HACCP) requirements. These performance indicators will form the basis of the HAACP requirement in the rule when it is promulgated. This is one of the first major steps to enhance the safety of egg products, which is within the FSIS mission. When

completed, they will augment other farm-to-table egg safety activities. The very nature of these farm-to-table egg safety activities and the rulemaking process will include all interested parties. FSIS is also in the process of looking into potential solutions to the July 1999 GAO review entitled, "Food Safety: U.S. Lacks a Consistent Farm-To-Table Approach to Coordinate Egg Safety."

6a. Should there be more resources directed to checking chicken flocks for SE?

Yes, and a portion of these resources could be directed to establishing the reasons why some flocks are SE-positive and other flocks are SE-negative. Our analysis of the data shows that more than 50% of the laying flocks could be positive for SE. Identifying risk factors for these SE-positive flocks could provide tools for producers to reduce the risk of producing SE-positive eggs, which occur about once in every 20,000 eggs, on average.

Furthermore, some of these resources could be directed toward monitoring egg-laying flocks and eggs for new strains of SE, which could cause human illness. It is important to remember that SE in eggs was not a recognized problem fifteen years ago. Monitoring egg-laying flocks for emerging diseases could allow for rapid identification and control of public health problems.

Within USDA, the Agricultural Research Service (ARS) is conducing research to develop methods to prevent the transmission of SE in layer flocks and the Animal and Plant Health Inspection Service (APHIS) is conducting a National Animal Health Monitoring Service study of laying flocks for SE.

6b. If there were comprehensive checks of chicken flocks for SE, and such checks were successful at preventing contaminated eggs from continuing on in the food process where they could be a health threat, would that make most other elements of the egg safety system unnecessary?

No. "Other components of the egg safety system" consist of requirements for cleaning of the shells of eggs, refrigerated storage, proper cooking, and use of pasteurized egg products for high risk groups (i.e. elderly in nursing homes, persons with weakened immune systems, and infants). These are part of a comprehensive food safety system. It is always a good idea to refrigerate potentially hazardous products in clean packages to prevent cross-contamination and to help prevent pathogens from multiplying. In addition to SE contamination inside shell eggs, SE and other salmonella can contaminate the external shells of eggs. Although this is a problem that is easy to control, proper food handling throughout the farm-to-table continuum is required to prevent additional foodborne illnesses. It is critical to cook potentially hazardous products to temperatures that will kill pathogenic microorganisms. Pasteurization of eggs is an important method for providing safe raw egg products to consumers.

Improvement in one area of the farm to table continuum does not make other elements of the egg safety system unnecessary, because there are so many other things that can and do go wrong in the complex process of food production on an industrial scale. Scientists believe that SE cannot be entirely eliminated from the environment and, therefore, will always be a threat. Testing does not ensure that every organism has been found and false negatives are always a possibility. Also, egg-laying hens do not consistently shed SE. Sometimes a flock will be SE negative and sometimes the same flock will be SE positive for this organism. The best approach is to employ multiple means of preventing the SE organism from entering the egg-laying hen and, subsequently, the egg. Proper refrigeration, egg handling, and storage practices further reduce the chances that contaminated eggs will reach the food supply. Thus all these elements of the egg safety system combine to achieve a multiple burdens approach, a widely recognized food safety strategy.

I hope this information is helpful to you and your staff. If I can be of further assistance, please let me know.

Sincerely,

Thomas J. Billy
Administrator
Food Safety and Inspection Service