

Scrambled Eggs

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

PHOTOCOPY
PRESERVATION

CSPI CENTER
FOR SCIENCE
IN THE
PUBLIC INTEREST

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CSPI was founded in 1971 by three scientists who believed that consumers need knowledgeable experts representing their interests, just as industry has scientists representing its point of view. CSPI accepts no government or corporate funds. Our support comes from more than 750,000 members, the sale of educational publications, individual donors, and foundation grants. CSPI's co-founder and executive director, Michael F. Jacobson, holds a Ph.D. in microbiology from the Massachusetts Institute of Technology. He has worked as a full-time consumer advocate since 1970.

A Consumer's Voice

CSPI, one of the few national consumer organizations focusing on health and nutrition issues, often stands alone in identifying problems and alerting the public to dangers. CSPI routinely discloses deceptive marketing practices, dangerous food additives or contaminants, or flawed science propagated by industries concerned primarily with profits. Our scientists and lawyers work together closely to map strategies for research, education, regulatory action, and legislation to promote the public interest.

CSPI's work, though often controversial, is highly regarded. The *Boston Globe* has called CSPI "the nation's most respected nutrition advocacy group based on science." FDA Commissioner David Kessler called CSPI "a tireless advocate. They deserve enormous credit and our appreciation."

Health Through Diet

Beginning in the 1970s, CSPI publicized the links between a diet high in fat, saturated fat, cholesterol, sodium, and sugar and such diseases as heart disease, diabetes, and cancer. The federal government now estimates that about 400,000 Americans die prematurely each year from the effects of poor diet and lack of exercise.

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 **Building a
Healthier America**

CSPI's national Food Day celebrations in the mid-1970s brought nutrition messages to hundreds of communities around the country and even into the White House. In 1980, the federal government finally adopted a national nutrition policy — the *Dietary Guidelines for Americans* — that recommended the kind of diet CSPI had been advocating for nearly a decade.

More recently, CSPI's landmark series of restaurant-nutrition studies has generated enormous public attention, and spurred many restaurants to improve the nutritional quality of their dishes.

Because milk is a major source of saturated fat, CSPI created the "1% Or Less" campaign. This uniquely effective media-education campaign urges people to switch from whole or 2% milk to "1% or less." The first six-week campaign *doubled* the consumption of skim and 1% milk in a West Virginia community.

- CSPI gets results. Because of our initiatives:
- A new federal law sets standards for health claims on food labels and provides clear comprehensive nutrition information on nearly all packaged foods.
 - Thousands of restaurants have added healthier options to their menus, and the movie-theater industry has largely switched to less harmful oils for popping popcorn.
 - Major fast-food chains stopped frying with beef fat and many have introduced more healthful foods.
 - Deceptive ads sponsored by companies such as McDonald's, Kraft, and Campbell Soup have been stopped.

Food Safety Project

Meat and poultry are all-too-often contaminated with deadly bacteria that cause a majority of the 9,000 food-poisoning deaths each year. CSPI is encouraging industry and government to develop a much more effective system of food-safety practices. Staffed by scientists and lawyers, CSPI's

Food Safety Project focuses on a number of crucial issues, including meat, poultry, and seafood inspection; monitoring the safety of food additives; and reducing the use of chemical fertilizers and pesticides.

Because of CSPI's work, the Food and Drug Administration banned many uses of sulfites, a food preservative responsible for numerous deaths. FDA responded to another CSPI request by warning pregnant women to minimize or avoid consumption of caffeine. In 1996, CSPI led the opposition to the approval of olestra, an unsafe fat substitute.

CSPI helped win passage in 1990 of a law that sets the first national definition of "organic food." That law is encouraging more farmers and processors to provide pesticide-free fresh and processed foods. CSPI also promotes state policies that would decrease the use of pesticides and fertilizers and increase aid to farmers using sustainable or organic methods.

Alcohol Policies Project

Alcoholic beverages cause over 100,000 deaths each year. Despite that awesome toll, efforts to combat alcohol problems have focused principally on treating alcoholics... ignoring the \$2 billion that companies spend each year encouraging people to drink more.

CSPI has spearheaded an aggressive prevention-oriented program that concentrates on stricter controls on advertising, better labeling, and higher excise taxes. CSPI's coalitions on those issues have encouraged many health and civic groups to mount educational programs and advocate new laws. CSPI played a critical role in the passage of a federal law requiring warning notices on beverage containers. CSPI's many reports on alcohol include *Marketing Booze to Blacks* and *Tainted Booze*.

Oprah Winfrey:
"They're on a mission for America...the mastermind critics that sounded the food alarm."

Informing the Public

Informing the public is an important part of CSPI's mission. CSPI produces a steady stream of reports, press releases, speeches, and media appearances. Staff members appear regularly on such shows as "Donahue," "Oprah," "NBC Dateline," and "Today," and on dozens of other national and local television and radio shows. Our activities are covered by hundreds of newspapers and magazines.

CSPI's award-winning *Nutrition Action Healthletter*, the largest-circulation health newsletter, provides CSPI members and journalists with timely information about personal health, CSPI's advocacy activities, and important nutrition research. The *New York Times* has called the *Healthletter* "the best known of the newsletters...the information is accurate, well written, and up to the minute." The *Times*' Jane Brody calls it "my personal favorite."

Nutrition Action Healthletter gets readers involved in influencing food policies by encouraging them to send cards, letters, and coupons to government and corporate officials.

CSPI's colorful, fact-packed posters — such as "Chemical Cuisine" and "Nutrition Scoreboard" — can be found in tens of thousands of homes and classrooms across the country, as are our books, videos, and nutrition curriculum.

Looking Ahead

Future new technologies and corporate activities will generate new health threats, as well as offer new opportunities to improve the public's health. CSPI's expert staff will continue to evaluate new products, marketing activities, and government policies to help ensure that science is truly being used in the public interest.

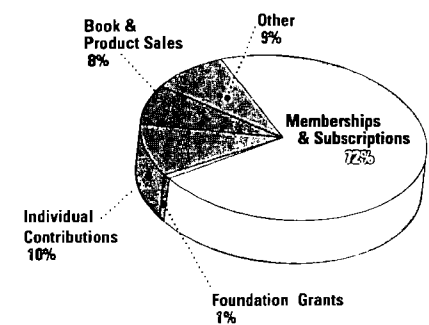
With the public's support, the Center for Science in the Public Interest will increase its

efforts to help Americans improve their health through education and by influencing government policies and corporate practices.

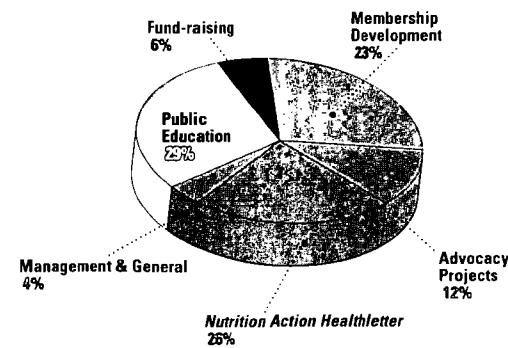
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Contact: Bill Bryant at (202) 332-9110 ext. 370 or
Caroline Smith DeWaal at (202) 332-9110 ext. 366

Threat of Contaminated Eggs Grows as Agencies Scramble

**CSPI: Nationwide spread of food poisoning bacteria in eggs
causes sickness or death in thousands of Americans a year**

Over the past 15 years, food poisoning from eggs has grown from a rare occurrence to the most common cause of outbreaks. According to a report released today by the Center for Science in the Public Interest (CSPI), "*Salmonella enteritidis* (SE) bacteria in eggs are causing hundreds, and possibly thousands, of food-poisoning deaths each year."

The nonprofit, health-advocacy group also filed a formal petition calling on the Food and Drug Administration (FDA) to require a warning notice on egg cartons. The notice would state: "Caution: Eggs may contain illness-causing bacteria. Do not eat raw. Cook eggs until the yolk is firm."

CSPI announced the petition and released a 22-page report, *Scrambled Eggs*, at a press conference Wednesday morning in Washington. The report documents the woeful governmental response in the ten years since SE was first identified in eggs. The group also outlined how the disease can best be brought under control.

"Eggs used to be safe," Caroline Smith DeWaal, director of CSPI's Food Safety Program, said, "but now they are the leading cause of food poisoning outbreaks in the country. This is the consequence of a decade of government neglect and Congressional cave-ins to industry pressure."

"It is time to label egg cartons," she said, "to warn consumers that the eggs may be contaminated with harmful bacteria. Until new programs assure that shell eggs are safe, consumers need to be reminded of the risk every time they bring home a carton of eggs."

--MORE--

According to government data cited by CSPI, SE infection causes up to a million illnesses each year. Sufferers experience flu-like symptoms, such as diarrhea, abdominal pain, nausea, and fever and chills. Some people can have more serious complications, such as rheumatoid arthritis, meningitis, kidney or heart disease, and death. Elderly residents of nursing homes are especially at risk.

In April 1992, USDA began a voluntary pilot program to control SE in Pennsylvania. The program, which had requirements ranging from regular on-farm testing to effective refrigeration, proved successful. But in 1995, Congress cut all funding for the program, thereby preventing USDA from expanding it nationwide.

According to Elizabeth Dahl, staff attorney for CSPI's Food Safety Program, "Egg industry lobbyists were responsible for killing federal support for the program. Now, with nearly half the nation's egg-laying flocks contaminated with *Salmonella*, Congress must act on behalf of consumers, not producers."

"Thousands of Americans have paid a terrible price for government's failure to ensure safe eggs," said CSPI Executive Director Michael Jacobson. "We hope that our petition -- together with the Clinton Administration's new food-safety initiative -- will enable Americans to trust that eggs are once again safe."

CSPI, besides calling for the warning labels on egg cartons and creation of control programs modeled after the successful Pennsylvania Egg Quality Assurance Program, offered the following advice to consumers:

- Refrigerate eggs promptly.
- Cook eggs until the yolks are firm.
- Thoroughly cook egg dishes like french toast and omelets.
- Don't let kids eat cookie dough or cake batter that contains raw eggs.
- Use only pasteurized eggs for Caesar salad, homemade mayonnaise, eggnog, and meringue.

--END--

The Center for Science in the Public Interest (CSPI), based in Washington, D.C., is a nonprofit health-advocacy organization with nearly one million members. CSPI focuses on nutrition, food safety, and alcohol policy. It was a major proponent of last year's improvements in meat and poultry inspection. It fought for -- and won -- the law that requires "Nutrition Facts" labels on all food packages. CSPI publishes the Nutrition Action Healthletter and accepts no government or industry funding. (Find CSPI on the Internet at www.cspinet.org.)

**Press Conference on *Scrambled Eggs*
Statement of Caroline Smith DeWaal
Director of the Food Safety Program
Center for Science in the Public Interest**

**May 14, 1997
Washington, DC**

Eggs used to be safe. Without worrying, parents could let their children lick the bowl while preparing cakes and cookies. Without concern, consumers could eat raw or undercooked eggs in salad dressing, 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*. Eggs have become the number one contributor to food poisoning outbreaks, with hundreds of thousands of Americans getting sick or dying every year.

Sometime in the last two decades, 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 Northeast and with quick action, the problem might have been 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. But more about that from our next speaker.

In the absence of effective government action, *Salmonella enteritidis* (SE) in eggs has reached epidemic proportions. Up to one million illnesses and hundreds or even thousands of deaths each year may be caused by SE-contaminated eggs. Internally contaminated eggs are showing up from coast to coast.

There is no way to tell which eggs contain *Salmonella* and which ones are contamination-free. Consumers are generally unaware of the hazard and continue to eat raw and undercooked eggs, without realizing that such practices are risky.

Here are some tips that consumers can follow to protect themselves:

- Refrigerate eggs promptly.
- Cook eggs until the yolks are firm. This doesn't mean rock hard, just firm.
- Thoroughly cook egg dishes like french toast and omelettes.
- Don't let kids eat raw cookie dough or cake batter that contains raw eggs.
- Use only pasteurized eggs for Caesar salad, homemade mayonnaise, eggnog, and meringue.

Today, CSPI is calling on FDA to mandate a label on egg cartons.

The simple label we are proposing says:

**Caution: Eggs may contain illness-causing bacteria.
Do not eat raw. Cook until yolk is firm.**

It also utilizes an international symbol for warning, with the message “Cook until firm”.

Although preventing the risk to consumers is a better solution than labeling a potentially hazardous product, a label is the quickest and easiest way to reach consumers. It could be a temporary measure until proven control programs are put in place. Until new programs assure that shell eggs are safe, consumers need to be reminded of the risk every time they bring home a carton of eggs.

Press Conference on *Scrambled Eggs*
Statement of Elizabeth Dahl
Staff Attorney, Food Safety Program
Center for Science in the Public Interest

May 14, 1997
Washington, D.C.

Many 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 national public health epidemic.

The federal Centers for Disease Control and Prevention first identified SE as a problem in eggs in 1986, when a food poisoning outbreak in seven states sickened over 3,000 people. Today, 11 years later, the federal government has *no* programs in place to prevent food poisoning from *Salmonella enteritidis* in eggs, while more people than ever are getting sick from eating contaminated eggs.

What happened during the last 11 years? Four government agencies each have some responsibility for regulating eggs and the egg industry, including the Food and Drug Administration and three different agencies under the U.S. Department of Agriculture. None of these agencies took the necessary steps to keep eggs safe. Any one of these steps would have helped:

- Requiring egg producers to test their hens for *Salmonella*
- Preventing eggs from *Salmonella*-positive flocks from being sold in supermarkets
- Requiring eggs to be refrigerated
- Requiring warning labels on egg cartons

This chart highlights just some of the ways that a tiny foodborne bacteria outsmarted the federal government.

- In 1986, *Salmonella enteritidis* caused almost 6,000 reported cases of food poisoning. These reported cases represent just a tiny fraction of all cases.
- In 1987, the U.S. Department of Agriculture decided not to establish a mandatory *Salmonella* control program for egg producers. Instead, USDA opted for a voluntary program.
- In 1989, 8,500 cases of food poisoning from *Salmonella* were reported. Clearly, the voluntary program was not working. But instead of working together, USDA and FDA failed to communicate with each other and actually wasted time developing competing control programs.

- By 1991, USDA had a mandatory control program in place. Unfortunately, the program didn't require on-farm testing for the SE bacteria by all egg producers. Egg producers only had to clean up their farms if a traceback investigation proved that their flock had already caused food poisonings. However, the traceback investigations were time-consuming and only about 20 a year were completed.
- Also in 1991, Congress passed a law requiring eggs to be refrigerated during transportation and storage. Refrigeration can prevent the SE bacteria from multiplying inside eggs, but USDA has never enforced this law.
- In 1992, USDA, the Pennsylvania government, and Pennsylvania egg producers began a voluntary pilot program. The program required that all participating producers test their flocks several times for the SE bacteria.
- In 1995, over 10,000 cases of food poisoning from SE were reported nationwide. But the news from Pennsylvania was better. The pilot program apparently reduced the number of SE-infected flocks. Despite those encouraging results, Congress bowed to egg industry trade groups and eliminated USDA's funding for the pilot program and the traceback program. Congress prevented USDA from possibly expanding the program nationally.

What we have seen is blatant disregard for the public health. It's time for the egg industry and federal government to face up to the problem and protect the public.

Even without USDA support, the Pennsylvania pilot program evolved into the successful Pennsylvania Egg Quality Assurance Program, which egg producer and marketer Paul Sauder will tell you about in a minute. A team of 15 scientists recommended that the requirements of this program, including on-farm testing, be implemented nationwide.

That's why CSPI is calling on FDA today to exercise its authority to require the egg industry across the country to adopt *Salmonella* control programs modeled after the Pennsylvania program. It's a step that the federal government should have taken long ago to protect consumers from contaminated eggs.

**Press Conference on Scrambled Eggs
Statement of Don Schaffner, Ph.D.
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**May 14, 1997
Washington, DC**

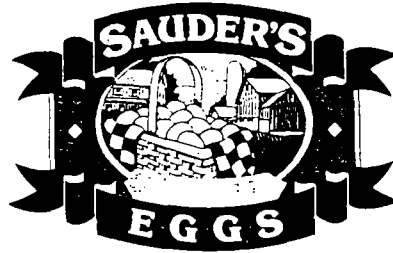
The best system we have for ensuring the safety of the food supply today is called "HACCP", which stands for the Hazard Analysis and Critical Control Point system. Virtually all academic scientists, government officials, industry or consumer groups agree on this point.

One of the fundamental concepts in HACCP is that our food safety system must extend from "farm to fork". This means that everyone from the largest commercial farm to the individual family member has a role to play. The CSPI petition helps expand the HACCP system in this way.

By encouraging egg producers to implement *Salmonella enteritidis* (SE) control HACCP programs, this should reduce the incidence of SE in raw eggs. Eventually, over time, the levels of SE in eggs produced from all egg farms should drop, just as it has in Pennsylvania. The Pennsylvania program has produced a 65 percent drop in the number of laying houses testing positive for SE, in just 3 short years!

Just as the egg producers have a role to play, so do average people like you and me. We need to be sure that when we cook eggs at home we cook them thoroughly, especially when they are to be eaten by the very young, the very old, and the immuno-compromised. The warning label that CSPI is suggesting should help to inform the average person of the risks associated with consuming raw or undercooked eggs. Consumers have become familiar with such labels, which are now required, on raw meat and poultry purchased at the supermarket. A similar label on eggs will help to remind them that eggs are also a potentially hazardous food, and should be handled accordingly.

It is estimated that foodborne disease causes millions of cases and thousands of deaths every year. *Salmonella* is the most commonly reported cause of foodborne outbreaks. The suggestions CSPI is making in their petition can help reduce disease and improve the health of the U.S. consumer.



The best to you from Sauder's

Pennsylvania Egg Quality Assurance Program PEQAP

- 1) I was delighted to hear Vice President Gore announce the White House Food Safety Initiative on Monday. The five-point plan has all the points we have in the PEQAP: 1) Research, 2) Testing, 3) Early Warning System, 4) Government Coordination, and 5) Education.
- 2) In 1990 one of my producers was the first to be involved in a trace back, this started our Company's involvement in finding a way to keep S.E. out of fresh eggs and keep the consumer from losing confidence in fresh eggs.
- 3) We worked together with U.S.D.A., Pennsylvania Department of Agriculture, Penn State University, Pennsylvania Department of Health and the egg industry in opening up our flocks for testing.
- 4) At the start of the Pilot Project in 1992, 38 percent of layer houses were positive for S.E., today in the PEQAP we have reduced this to 8 percent. This is a reduction of 80 percent in number of **"Positive" houses.**
- 5) In the PEQAP Egg Quality Assurance Program there are 250 flocks covering over 18 million layers. (Pennsylvania is the fourth largest egg producing state in the United States.)
- 6) The Pennsylvania Egg Quality Assurance Program is a voluntary industry program intended to minimize Salmonella enteritidis contamination of shell eggs. Although this program does not guarantee shell eggs to be free of S.E., the program does assure commitment of the producers to implementation of those policies most likely to prevent S.E.

This risk reduction program is an extensive H.A.C.C.P. Program which includes testing at the five critical control points, diverting eggs if positive and third party monitoring by the Pennsylvania Department of Agriculture.

- 6) Why are we involved in this program that adds cost to operations?
 - a) We are committed to produce, process and market eggs under the highest standards for food safety.
 - b) We can not lose the confidence of the consumer in fresh eggs.
 - c) We are looking for ways to add value:
 - New cartons - Different ways to package
 - Vitamin enriched eggs
 - Sharing responsibilities from farm to table
- 7) We also have a refrigeration law in Pennsylvania that covers eggs from farm to consumer that helps keep eggs safe.

Scrambled Eggs

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

Elizabeth Dahl
Staff Attorney, Food Safety Program

Caroline Smith DeWaal
Director, Food Safety Program

May 1997

Center for Science in the Public Interest

\$5

We gratefully acknowledge the assistance of Michael F. Jacobson, Lucy Alderton, Kimberly Loui, and Grace Ko in preparing this report. We also thank the experts in government and industry who reviewed drafts of the report.

The Center for Science in the Public Interest is a non-profit organization that focuses on food and nutrition policies. It is supported largely by the nearly one million subscribers to its *Nutrition Action Healthletter*.

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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 all 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

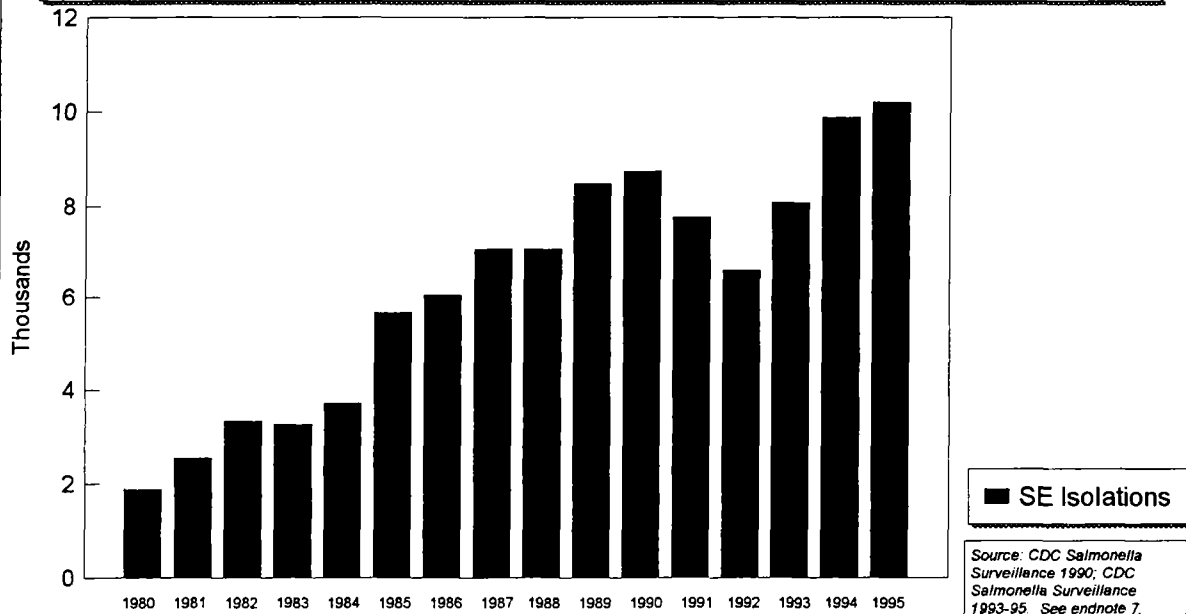


Figure 2. Percent of Food Poisoning Outbreaks Caused by SE, 1988 - 1992

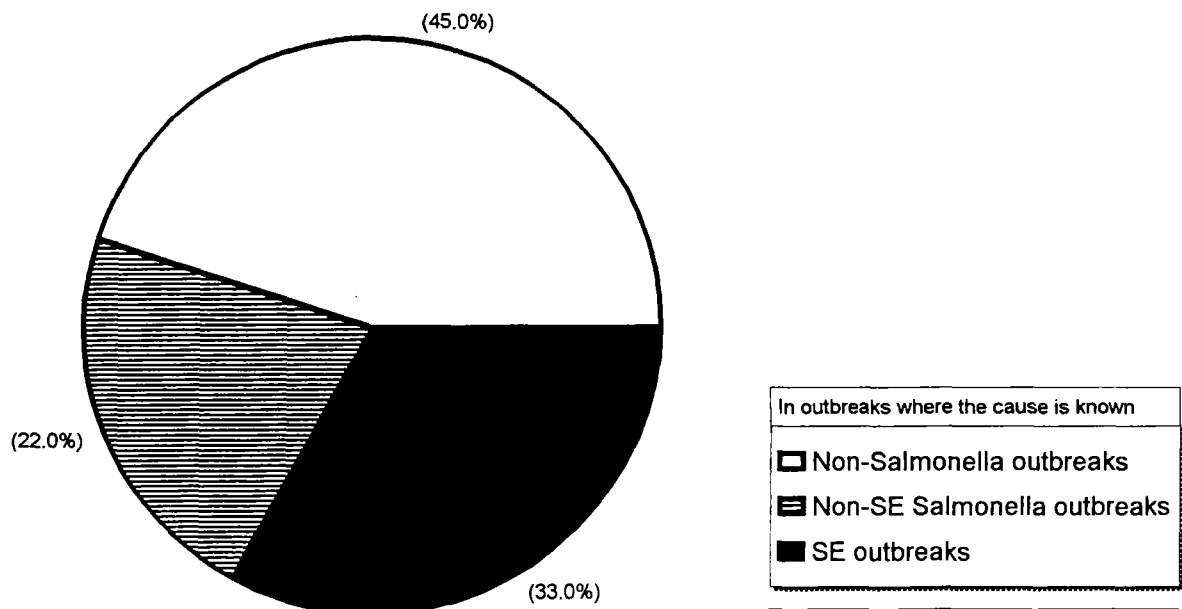


Figure 3. Number of Confirmed SE Cases, 1995

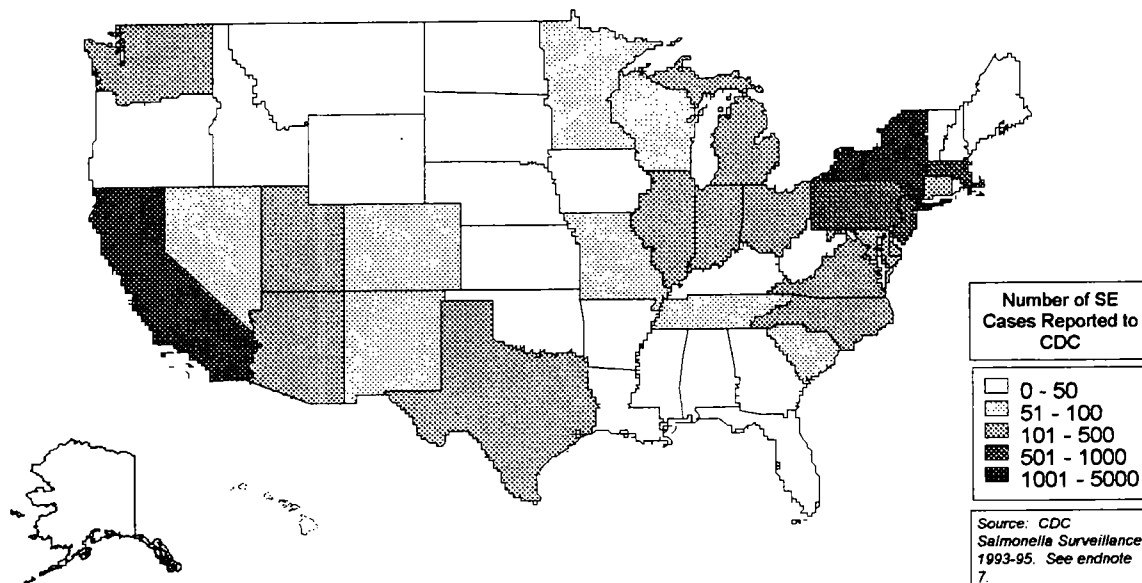
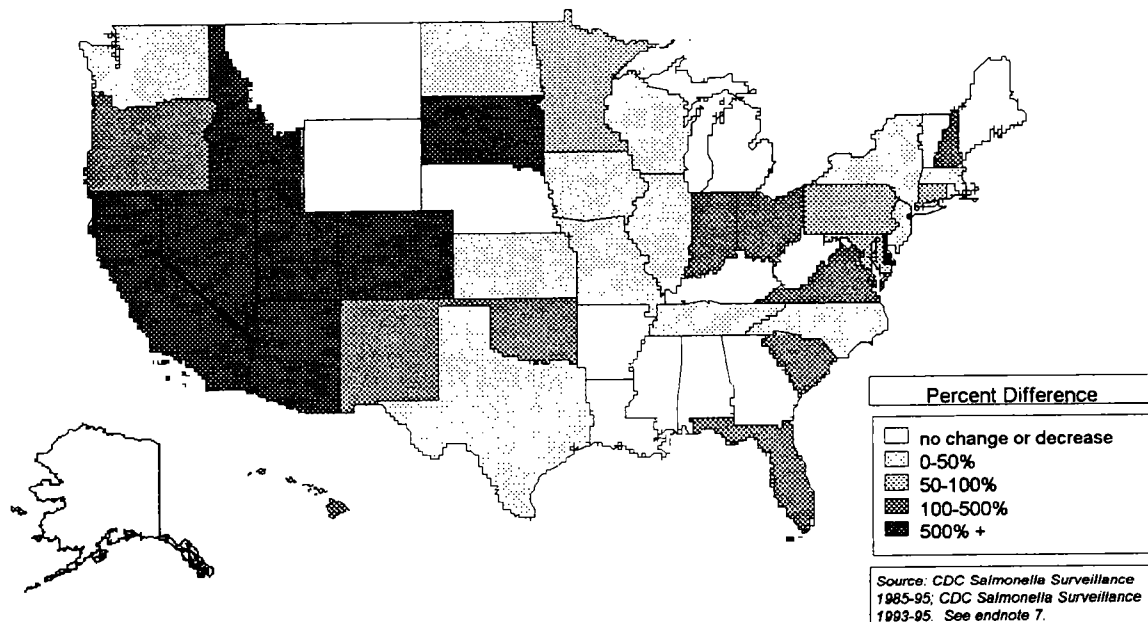


Figure 4. Increase in SE Cases, 1985-1995



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

**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
Over 10,000 reported SE food poisonings for the year	1992	USDA, Pennsylvania government, and industry begin voluntary pilot program
	1995	Congress cuts funding for successful pilot program and for traceback program, at egg industry request

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.

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 market³⁸ 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.

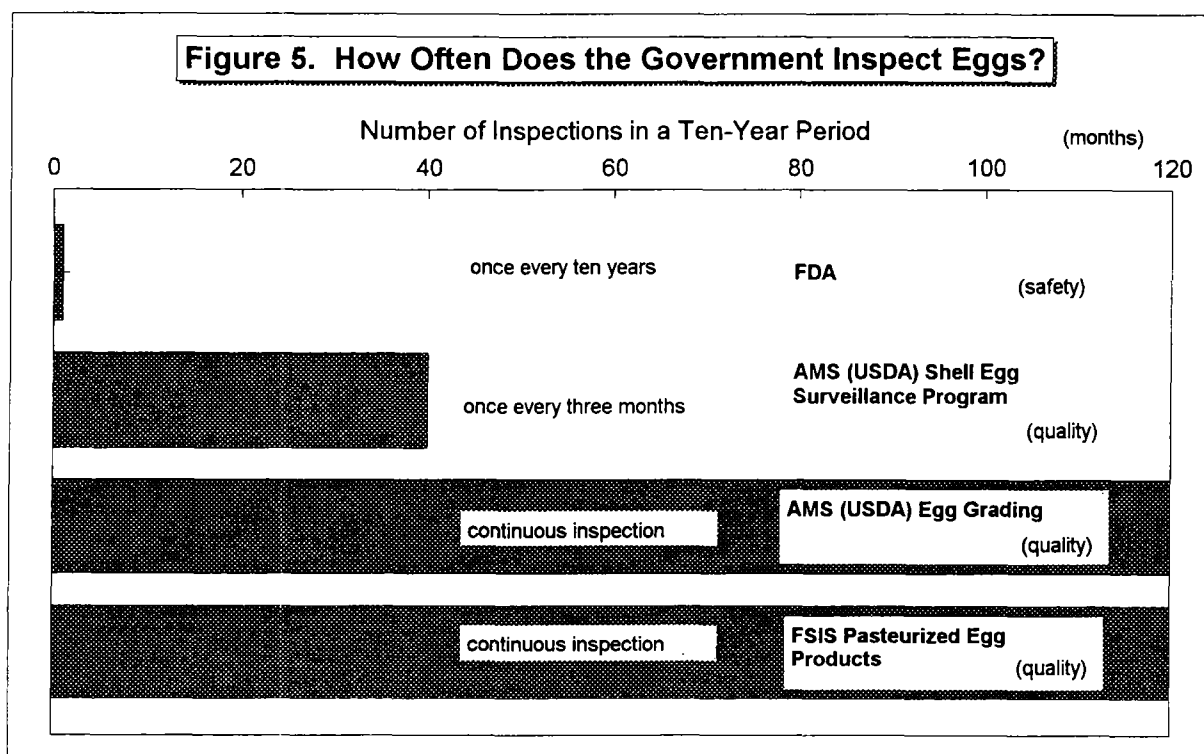
FDA occasionally inspects shell egg-packing plants and is responsible for monitoring whether eggs are contaminated with SE. However, FDA's inspection resources are so limited that it inspects most food manufacturing plants under its jurisdiction an average of only once every ten years.⁴⁹ (See Figure 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.



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 recommendation 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 several times per year. These inspections should include verification that a testing program is in place to assure 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

1. U.S. General Accounting Office, *Food Safety and Quality: Salmonella Control Efforts Show Need for More Coordination*, (Washington, D.C.: U.S. General Accounting Office, April 1992), p. 10 [hereinafter cited as *Salmonella Control Efforts*].
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 5B, "Salmonella Reported from Human Sources by Geographic Region and Serotype, 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).
17. Telephone conversation with David Kradel, Coordinator of Food Safety Activities, Pennsylvania Poultry Federation, Harrisburg, PA, April 23, 1997. Although a vaccine against SE exists, it has not been widely used because it is not 100% effective and can cause a reaction in some birds.
18. Thomas L. Schwarz, Center for Food Safety and Nutrition, Food and Drug Administration, quoted in "BSE Threat to Humans Cannot Be Ignored: European Researcher," *Food Chemical News*, August 15, 1994, p. 40.
19. A.C. Baird-Parker, "Foodborne Illness," *The Lancet*, Vol. 336, November 17, 1990, p. 1232.
20. *CDC Surveillance Summaries 1988-92*, p. 11.
21. 1995 Food Safety Module of the Behavioral Risk Factor Surveillance System, reported in "Survey Data Show Regional Differences in High-Risk Food Consumption Behaviors," *Food Chemical News*, January 13, 1997, p. 24.
22. Allan Hogue and Eric Ebel, "1995 Spent Hen Survey of *Salmonella Enteritidis*," *APHIS Report of Accomplishments in Animal Production Food Safety FY 1995*, March 1996, p. 2.2-1.
23. M. Wierup, et al., "Control of *Salmonella enteritidis* in Sweden," *International Journal of Food Microbiology*, Vol. 25, 1995, p. 219-226.

24. *Salmonella Control Efforts*, p. 16.
25. 21 U.S.C. § 111, *et seq.*
26. 42 U.S.C. § 264(a).
27. 21 U.S.C. §§ 331(a-c); 342(a).
28. Bruce Ingersoll, "U.S. to Mandate Testing of Poultry for Salmonella," *Wall Street Journal*, February 20, 1990, p. B5.
29. Telephone conversation with Dawn Kent, Public Affairs, APHIS, Washington, D.C., April 29, 1997; 9 C.F.R. § 53.2.
30. Telephone conversation on April 23, 1997 with Rebecca Irwin, D.V.M., M.S.C., Health Canada, Guelph, Ontario.
31. *Salmonella Control Efforts*, p. 40.
32. *Salmonella Control Efforts*, p. 18.
33. *Salmonella Control Efforts*, pp. 18-19.
34. *Salmonella Control Efforts*, p. 41.
35. 9 CFR Parts 71 and 82.
36. "SE Traceback Program Decreased in Effectiveness, USDA Office of Inspector General Reports," *Food Chemical News*, January 15, 1996, p. 23 [hereinafter cited as *SE Traceback Program*].
37. An additional reason for the slow tracebacks was that the program's automation system was inadequate.
38. *Salmonella Control Efforts*, p. 4.
39. 7 U.S.C. §§ 6911(a), 6912(a), 6981(a-b).
40. *SE Traceback Program*, p. 23; Citizens for Sensible Safeguards, *Back Door Extremism: Misusing the Appropriations Process to Gut Public Protections*, September 1995, p. 46.
41. Remarks of Thomas L. Schwarz, FDA, at the State-Federal Food Safety Conference, Washington, D.C., October 30, 1996.
42. Pennsylvania Poultry Producers, et al., "Salmonella Enteritidis Pilot Project Progress Report," May 22, 1995, p. 1.
43. Pennsylvania Poultry Federation, "Pennsylvania Egg Quality Assurance Program," May 1994.
44. *SE Traceback Program*, p. 23.
45. "A New Layer of Food Safety Assurance?," *Food Safety Digest*, March/April 1996, p. 5; Telephone conversation with David HENZLER, Pennsylvania Department of Agriculture, Harrisburg, PA, April 18, 1997.
46. Allan Hogue, et al., *Salmonella Enteritidis Review Team Report*, Final, January 18, 1997, pp. 3, 9-10.

47. *Ibid.*, pp. 1-3, 9-10.
48. Conversation with Robert Tauxe, CDC, in Washington, D.C., Oct. 30, 1996; "FSIS Budget Set by House, Senate 'Not Encouraging,' Official Says," *Food Chemical News*, October 2, 1995, p. 43.
49. Food and Drug Administration, U.S. Department of Agriculture, Centers for Disease Control and Prevention, "Food Safety from Farm to Table: A New Strategy for the 21st Century, Discussion Draft and Current Thinking: A National Food Safety Initiative, A New Interagency Strategy to Prevent Foodborne Disease," February 20, 1997, p. 23.
50. Telephone conversation with Michael Holbrook, Agricultural Marketing Service, USDA, Washington, D.C., March 4, 1996.
51. *Ibid.*
52. 21 U.S.C. § 1031 *et seq.*
53. *Salmonella Control Efforts*, p. 11
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.
55. 21 U.S.C. §1034(e).
56. Letter to Rep. Joe Skeen, Chairman of Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies from Michael R. Taylor, Acting Undersecretary for Food Safety, USDA, September 5, 1996.
57. 21 U.S.C. § 1034(e)(3).
58. See note 18.
59. American Meat Institute, "Americans Underestimate Their Role in Preventing Foodborne Illness, New National Survey Shows," (Washington, DC: American Meat Institute, August 30, 1996).
60. Food Marketing Institute, *Trends in the United States: Consumer Attitudes and the Supermarket 1996*, (Washington, D.C., Food Marketing Institute, 1996), p. 30.
61. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, *Food Code*, (Springfield, VA: U.S. Department of Commerce, 1993), § 3-501.16 [hereinafter cited as *Food Code*].
62. *Food Code*, §§ 3-401.11, 3-401.12, 3-302.13.

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.

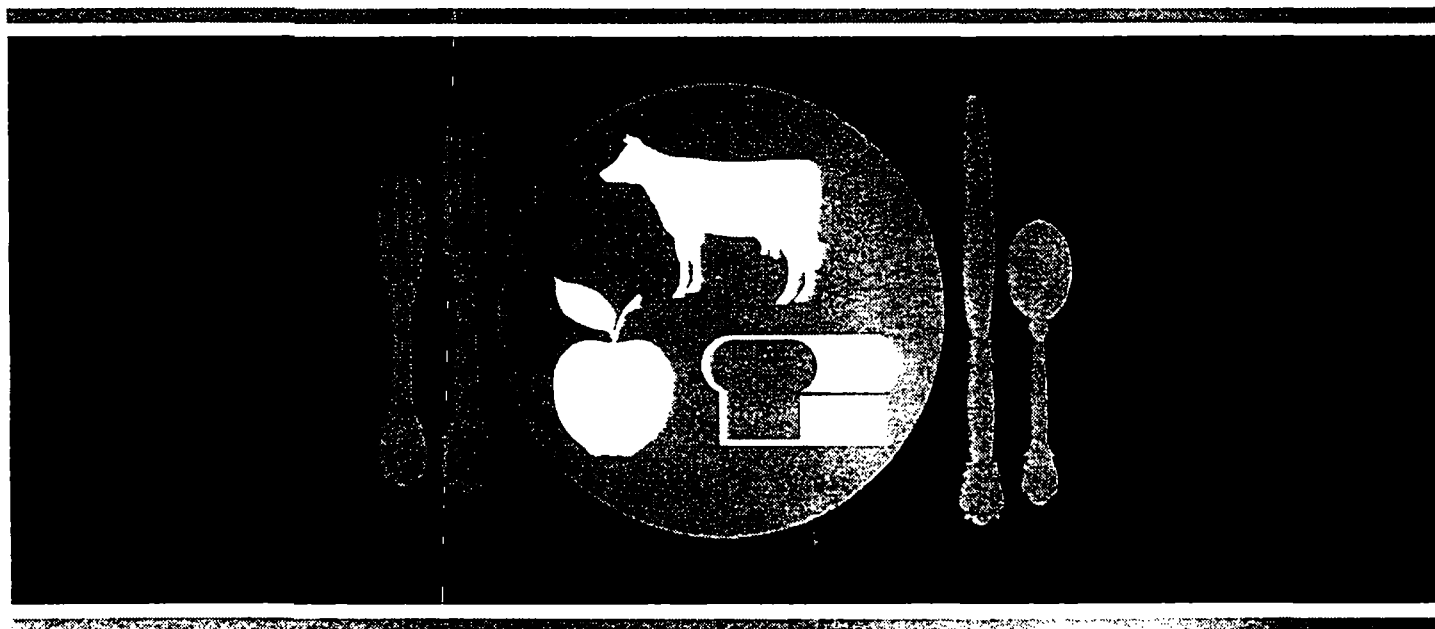
** No data from 1985 is available. This figure is from 1987. Percent difference is between the number of cases reported in 1987 and 1995.

*** Total includes data from states with no available 1985 data.

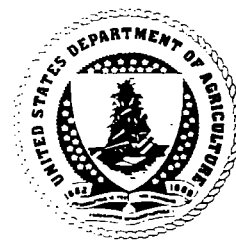
Source: CDC Salmonella Surveillance 1985-1995; CDC Salmonella Surveillance 1990; CDC Salmonella Surveillance 1993-95. See endnote 7.

FOOD SAFETY FROM FARM TO TABLE

A National Food-Safety Initiative



A Report to the President
May 1997



IMPROVING INSPECTIONS AND COMPLIANCE

Background

Inspection of commercial food processors is an integral part of the food-safety assurance system. Inspections are carried out by federal, state and local authorities. In addition to other food-inspection responsibilities, state and local officials also have primary responsibility for inspecting restaurants, supermarkets, and other retail establishments. At the federal level, FSIS has responsibility for meat and poultry inspection in slaughter and processing plants and egg-product-processing plants, and for all imported meat, poultry, and egg products. FDA conducts periodic, random inspections of all other food-processing plants; that entails fewer than 700 inspectors and laboratory personnel for 53,000 U.S. plants and for all other imported foods.

Problem

The number of inspections conducted by FDA has decreased steadily since 1981, when 21,000 inspections were conducted, so that today resources exist to carry out only about 5,000 inspections per year. An FDA-regulated plant is inspected by FDA, on average, only once every 10 years. FDA also relies upon the states to conduct some inspections under contract, but that number has dropped from 12,000 in 1985 to 5,000 now. Moreover, because the number of imports has doubled over 5 years, with no real increase in inspectors, a smaller percentage of imports are inspected at entry.

Given the limited inspection coverage, FDA is finding an increasing number of problems--the number of products recalled for life-threatening microbial contamination has increased almost five-fold since 1988. Federal budget constraints will likely prohibit significant funding increases in the future, so FDA must find new ways to provide adequate inspection coverage.

Recommendations

Scientists and other food-safety experts have concluded that the most effective and efficient mechanism to ensure that food processors identify and control hazards that could threaten food is the application of HACCP principles. FDA's seafood HACCP regulations go into effect in December 1997. FSIS began to implement its HACCP and Pathogen Reduction Requirements for the meat and poultry industries in 1997 with phase-in to be completed in 2000. HACCP programs allow government and industry resources to be used more appropriately, allowing the government and industry to focus on the greatest risks. To ensure that HACCP is properly implemented, and to ensure more efficient and effective monitoring of the safety of the food supply, recommendations are being made in the following areas.

Enhance Development of HACCP Procedures

FY97 Activities:

- Based on the best science available, FDA will propose appropriate regulatory and non-regulatory options, including HACCP, for the manufacture of fruit and vegetable juice products.
- Based on the best science available, FSIS will propose appropriate regulatory and non-regulatory options, including HACCP, for egg products
- FDA and USDA will immediately identify preventive measures to address public-health problems, such as those recently associated with fruits and vegetables, e.g., hepatitis A virus associated with frozen strawberries. This will be accomplished through a comprehensive review of current production and food-safety programs including inspection, sampling, and analytical methods.
- FSIS and FDA will jointly publish an ANPR in which they will evaluate the public-health, food-technology, and regulatory issues involved in reducing the risk of human illness from *Salmonella* Enteritidis in shell eggs. The ANPR will solicit information and comment on all elements of risk in the farm-to-table chain to ensure any resulting regulatory actions will be both reasonable and effective in reducing risk.
- FDA will evaluate whether and how to propose to require the use of HACCP in other appropriate food commodities and animal feeds.
- FDA will provide additional training in seafood HACCP and FSIS will complete HACCP training of inspectors in large meat and poultry plants.
- FSIS and FDA will evaluate expanding existing cooperative agreements so that plants producing meat and nonmeat foods are inspected by FSIS inspectors trained in FDA inspection standards. FSIS inspectors are already in these plants, and their presence could be better used to maximize use of federal resources without loss of inspection coverage for FSIS-regulated foods.
- FSIS will conduct a series of public meetings to discuss:
 - How HACCP requirements will be implemented in slaughter plants and how the roles and responsibilities of inspection personnel will change with that implementation.

- The design and testing of new inspection concepts consistent with HACCP principles to achieve food-safety and other consumer-protection objectives through distribution and retail channels to consumers.
- FSIS and state associations will complete development of HACCP-based control measures for meat and poultry processing at the retail level.

FY98 Activities with Food-Safety Initiative Funds

- FDA and USDA will cooperate in evaluating the feasibility of HACCP for commodities such as fresh fruit and vegetables. The process could also consider whether it is appropriate to use USDA inspectors to inspect plants that manufacture products regulated by both agencies or even products that must meet different regulatory requirements from the two agencies, such as fresh produce used in the school lunch program.
- FDA will implement seafood HACCP by hiring approximately 80 investigators to conduct inspections to ensure proper implementation of seafood HACCP.
- A performance-based organization (PBO), will be created, with Congressional approval, as the organizational structure for the voluntary fee-for-service seafood program currently located at the Department of Commerce's National Marine Fisheries Service. The Departments of Commerce and Health and Human Services will consider whether to locate the PBO at FDA, which would consolidate voluntary and mandatory seafood programs within one agency and provide limited additional resources for implementation of seafood HACCP, while continuing the voluntary fee-for-service program.
- FSIS will continue to propose changes to current regulations to harmonize with HACCP.

Long-term Activities

- FDA should further the use of HACCP principles, as appropriate, for other foods, including animal feeds, and use risk-assessment techniques where possible.

Enhance the Safety of Foods in Retail Food Establishments Particularly at State and Local Levels

More than 3,000 state and local regulatory agencies have primary responsibility for monitoring retail food establishments to ensure that consumers are protected. U.S. retail establishments include approximately 785,000 commercial and institutional food establishments, 128,000 grocery and convenience stores, and 1.5 million vending operations. Workers in these establishments have highly diverse backgrounds and training.

Key Facts from *Scrambled Eggs*

Eggs Contaminated with *Salmonella* Have Put Consumers At Risk Across the Nation.

- A type of *Salmonella* known as *enteritidis* causes an estimated 200,000 to one million human cases of salmonellosis each year. Contaminated eggs cause at least 80 percent of these illnesses.
- Between 1980 and 1995, the number of reported illnesses in the U.S. from *Salmonella enteritidis* (SE) increased by more than five times.
- SE causes a third of all food poisoning outbreaks for which the food source is known.
- SE caused more reported deaths between 1988 and 1992 than any other foodborne pathogen. Hundred or even thousands of people die from eating SE-tainted eggs each year.
- 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. Children, the elderly, and the immuno-compromised are more vulnerable.

Raw or Undercooked Eggs Can Contain Harmful SE Bacteria

Proper cooking of eggs kills the SE bacteria that may be inside the eggs. However, too many consumers don't know that common-egg preparation practices could make them sick. Some high-risk practices include:

- serving eggs "sunny side up," lightly poached, soft-boiled, or any other style where the yolk is still runny;
- eating cookie dough or cake batter that contains raw eggs;
- using raw eggs in salad dressing, such as Caesar salad or homemade mayonnaise.

The Federal Government Has Failed to Protect Consumers from the Risk of SE.

- Four government agencies are responsible for regulating eggs and the egg industry, including the Food and Drug Administration (FDA) and three different agencies under the U.S. Department of Agriculture (USDA). None of these agencies have taken the necessary steps to keep eggs safe. Any one of these steps would help:



- Requiring egg producers to test their flocks for SE
 - Preventing eggs from SE-positive flocks from being sold without pasteurization
 - Requiring eggs to be refrigerated
 - Requiring warning labels on egg cartons
- While shell eggs are continuously inspected for quality, they are inspected for safety *only once every ten years*, on average.
 - USDA finally began an SE control program in 1991. However, the program didn't require all egg producers to test their farms for the SE bacteria. Egg producers only had to clean up their farms if a traceback investigation proved that their flocks had already caused food poisonings. The traceback investigations were time-consuming and difficult. Only about 20 a year were completed.
 - In 1992, USDA, the Pennsylvania government, and Pennsylvania egg producers began a voluntary pilot program that included regular on-farm testing of flocks for SE. Even though the program showed progress in reducing SE contamination, Congress cut federal funding for that program and prohibited USDA employees from working on it.

All Egg Producers Should Be Required to Implement On-farm SE Control Programs Like the Pennsylvania Egg Quality Assurance Program

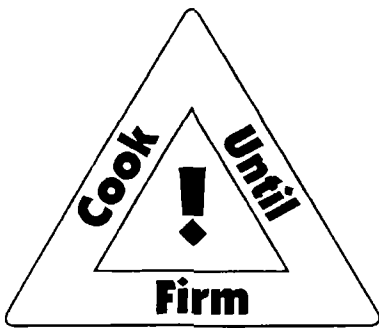
The pilot program in Pennsylvania survived despite the cut in federal funding and is now known as the Pennsylvania Egg Quality Assurance Program. The program reduced the number of contaminated flocks from 38 percent to 8 percent in five years. The number of human illnesses from SE in the market area for Pennsylvania eggs also showed a decrease. FDA should require all egg producers to implement control programs that include these features of the Pennsylvania program:

- Chicks for layer flocks should be obtained from SE-negative breeder flocks.
- Regular testing of manure and eggs for SE should be required.
- Testing should be subject to monitoring by FDA.
- When samples are positive, eggs from those flocks should be diverted to pasteurization plants and should not be sold in supermarkets.
- Eggs should be kept refrigerated at all times.

CSPI's Additional Recommendations:

- 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." This label will help consumers protect themselves from SE.
- Shell egg plants should be inspected for safety at least several times per year.
- 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.

Proposed Label for Egg Cartons



Caution: Eggs may contain illness-causing bacteria. Do not eat raw. Cook until yolk is firm.

WHAT 15 SCIENTISTS HAVE TO SAY ABOUT THE PENNSYLVANIA EGG QUALITY ASSURANCE PROGRAM

A team of 15 scientists from federal and state government agencies has been studying the problem of *Salmonella enteritidis* in eggs. The team released a final report on January 18, 1997, praising effectiveness of the Pennsylvania Egg Quality Assurance Program (PEQAP), originally known as the SE Pilot Project.

- **Preventing human illnesses from SE:**

“In the same time period that the SE Pilot Project and PEQAP have been in operation (1992-1995) there has been a reduction in human SE isolation rates in the Mid Atlantic region (New York, New Jersey, and Pennsylvania), the market for Pennsylvania eggs. We believe that the combined efforts of egg producers, retail marketers and food handlers have had a positive impact on public health in the Mid Atlantic region.”

- **Reducing the number of SE-infected hens:**

“PEQAP has shown progress in reducing SE infections in flocks. . . . Nationwide industry adoption of standardized quality assurance programs based on the interventions used in PEQAP should be encouraged.”

Members of the *Salmonella enteritidis* Review Team:

Chairperson: Allan Hogue, USDA, FSIS, APFS

Eric Ebel, USDA, APHIS, VS

Jeff Farrar, California Dept. Of Health Services

Richard Gast, USDA, ARS, SE Poultry Research Lab

Tom Gomez, USDA, APHIS, VS

Jean Guard-Petter, ARS, SE Poultry Research Lab

Joe Madden, FDA, CFSAN

Milton Madison, USDA, ERS, Animal Products Branch

Ann-Marie McNamara, USDA, FSIS, S&T

Robert Morales, NC State University

Delila Parham, USDA, FSIS, EERP

Phyllis Sparling, USDA, FSIS, EERP

William Sutherlin, USDA, FSIS, EPID

David Swerdlow, CDC,

Division of Bacterial & Mycotic Diseases

Patricia White, USDA, FSIS, APFS

Source: Allan Hogue, et al., *Salmonella Review Team Report*, Final, January 18, 1997, pp. 2-3, 9-10.

CONSUMER INFORMATION FROM USDA

Food Safety and Inspection Service, Food Safety & Consumer Education Office
(202) 690-0351; Fax (202) 720-9063

October 1996

Egg and Egg Product Safety

Eggs can be part of a healthy diet. However, they are perishable just like raw meat, poultry and fish. To be safe, they must be properly refrigerated and cooked.

Concern for Egg Safety

Today some unbroken fresh shell eggs may contain certain bacteria that can cause foodborne illness. The bacteria are *Salmonella enteritidis*. While the number of eggs affected is quite small, there have been some scattered outbreaks in the last few years. Currently the government, the egg industry and the scientific community are working together to solve the problem.

What Part Carries Bacteria?

Researchers say that if present, the salmonella bacteria are usually in the yolk or "yellow." But they can't rule out the bacteria being in egg whites. So everyone is advised against eating raw or undercooked egg yolks, whites or products containing them.

Who Should Be Extra Careful?

People with health problems, the very young, the elderly and pregnant women (the risk is to the unborn child) are particularly vulnerable to *Salmonella enteritidis* infections. A chronic illness weakens the immune system making the person vulnerable to foodborne illnesses.

Taking Steps at Home

Proper refrigeration, cooking and handling should prevent most egg-safety problems. Persons can enjoy eggs and dishes containing eggs if these safe handling guidelines are followed.

1. Don't Eat Raw Eggs

This includes "health-food" milk shakes with raw eggs, Caesar salad, Hollandaise sauce and any other foods like homemade mayonnaise, ice cream or eggnog made from recipes in which the raw egg ingredients are not cooked.

2. Buy Clean Eggs

At the store, choose Grade A or AA eggs with clean, uncracked shells. Make sure they've been refrigerated in the store. Any bacteria present in an egg can multiply quickly at room temperature.

3. Refrigerate Eggs

Take eggs straight home and store them immediately in the refrigerator set at 40° F or slightly below. Store them in the grocery carton in the coldest part of the refrigerator, not in the door. Don't wash eggs. That could increase the potential for bacteria on the shell to enter the egg.

Call Toll-free For More Information:

USDA Meat and Poultry Hotline
1(800) 535-4555
Washington DC (202) 720-3333

4. Use Eggs Promptly

Use raw shell eggs within 3 to 5 weeks. Hard-cooked eggs will keep refrigerated one week. Use leftover yolks and whites within 4 days.

If eggs crack on the way home from the store, break them into a clean container, cover it tightly, and keep refrigerated for use within 2 days.

5. Freeze Eggs for Longer Storage

Eggs should not be frozen in their shells. To freeze whole eggs, beat yolks and whites together. Egg whites can be frozen by themselves. Use frozen eggs within a year.

If eggs freeze accidentally in their shells, keep them frozen until needed. Defrost them in the refrigerator. Discard any with cracked shells.

Unopened cartons of egg substitutes can be kept frozen for 1 year.

6. Handle Eggs Safely

Wash hands, utensils, equipment and work areas with warm, soapy water before and after contact with eggs and egg-rich foods.

Don't keep eggs -- including **Easter eggs** -- out of the refrigerator more than 2 hours. Serve cooked eggs and egg-rich foods immediately after cooking, or place in shallow containers for quick cooling and refrigerate at once for later use. Use within 3 to 4 days.

7. Cook Eggs

Hard cooked eggs should be safe for everyone to eat. Those "at risk" for foodborne illness should avoid eating soft-cooked or "runny" eggs.

However, healthy persons may choose to eat eggs that are less than totally firm. Use the following cooking times:

- Fried eggs - cook 2 to 3 minutes on each side; 4 minutes in a covered pan
- Scrambled eggs should be cooked until firm throughout
- Poached eggs - 5 minutes over boiling water
- Soft-cooked eggs - 7 minutes in the shell in boiling water.

8. Use Safe Egg Recipes

Egg mixtures are safe if they reach 160° F, so homemade ice cream and eggnog can be made safely from a cooked base. Heat the egg-milk mixture gently. Use a thermometer or be sure the mixture coats a metal spoon.

Dry meringue shells are safe. So are divinity candy and 7-minute frosting, made by combining hot sugar syrup with beaten egg whites.

Meringue-topped pies should be safe if baked at 350° F for about 15 minutes. Chiffon pies and fruit whips made with raw, beaten egg whites cannot be guaranteed safe. Substitute whipped cream or whipped topping.

To make key lime pie safely, heat the lime (or lemon) juice with the raw egg yolks in a pan on the stove, stirring constantly, until the mixture reaches 160° F. Then combine it with the sweetened condensed milk and pour it into a baked pie crust. For meringue topping, bake as above.

For egg dishes such as quiche and casseroles, insert a knife in the center. It should come out clean.

Egg Product Safety

The term "egg products" refers to eggs that have been removed from their shells for processing. Basic egg products include whole eggs, whites, yolks and various blends, with or without non-egg ingredients, that are processed and pasteurized. They may be available in liquid, frozen and dried forms.

What Are Some Buying Tips?

- Containers should be tightly sealed.
- Frozen products should show no sign of thawing.
- Purchase refrigerated products kept at 40° F or below.
- Avoid hardened dried egg products.

Are Egg Products Pasteurized?

Yes. The 1970 Egg Products Inspection Act requires that all egg products distributed for consumption be pasteurized. They are rapidly heated and held at a minimum required temperature for a specified time. This destroys *Salmonella* but it does not cook the eggs or affect their color, flavor, nutritional value or use. Dried whites are pasteurized by heating in the dried form.

Can Egg Products Be Used in Uncooked Foods?

Egg products can be used in baking or cooking (scrambled eggs, for example). They have been pasteurized but are best used in a cooked product. Consumers should be sure that the internal temperature of the cooked dish reaches 160° F.

Egg products can be substituted in recipes typically made with raw eggs that won't be cooked to 160° F, such as Caesar salad and homemade mayonnaise. Although pasteurized,

for optimal safety, it is best to start with a cooked base, especially if serving high-risk persons.

Storage Times for Egg Products

- Frozen egg products - 1 year
- If the container for liquid products bears a "use by" date, observe it.
- For liquid products without an expiration date, store unopened cartons at 40° F or below for up to 7 days (not over 3 days after opening).
- Don't freeze opened cartons.
- Unopened dried egg products can be stored at room temperature as long as they are kept cool and dry. After opening, keep refrigerated.
- Use reconstituted products immediately or refrigerate and use that day.

Other Egg-type Items

Certain egg-type items are not presently considered egg products. These items, which are under FDA jurisdiction, include freeze-dried products, imitation egg products, and egg substitutes. Inspected, pasteurized egg products are used to make these items.

No-cholesterol egg substitutes consist of egg whites, artificial color and other non-egg additives. Direct questions about egg substitutes to the manufacturer or to the FDA.

USDA Dried Egg Mix

is a dried blend of whole eggs, nonfat dry milk, soybean oil and a small amount of salt. (This is a government commodity product, not usually available commercially.) To reconstitute, blend 1/4 cup with 1/4 cup water to make one "egg." The reconstituted mix requires cooking.

- Store USDA Dried Egg Mix below 50° F, preferably refrigerated. After opening, use within 7 to 10 days.
- Use reconstituted egg mix immediately or refrigerate; use within 1 hour.



DEC 21 1988

TO: State and Territorial Epidemiologists
State and Territorial Public Health Laboratory Directors
Through: Director, Center for Infectious Diseases 

Subject: Precautions to reduce the risk of institutional outbreaks of
Salmonella enteritidis.

In 1987, 6,950 isolates of Salmonella enteritidis (SE) were reported to the National Salmonella Surveillance System, representing 16% of all Salmonella isolates reported in that year. As summarized in the August 18, 1988, issue of MMWR, isolation rates of SE remain high in the northeastern part of the United States and are beginning to increase in Mid-Atlantic and East North Central regions as well. Reports of documented SE infection in egg-laying flocks in the Midwest, West, and South suggest that further spread of the SE epidemic to the rest of the United States could occur. Attempts to reduce the amount of infection by voluntary serologic screening of multiplier and layer flocks have begun, but it is too early to tell whether they will be successful. In the interim the importance of preventing outbreaks in nursing homes and hospitals, with the population at highest risk for severe outcome, cannot be overemphasized.

We reviewed reported outbreaks of SE infections from 1985 to 1988. During this time, eighteen outbreaks occurring in nursing homes and hospitals were reported, affecting 658 persons with 24 deaths (3.6% case fatality rate). A vehicle was determined for eight of the 18 outbreaks, accounting for 477 cases. Two outbreaks were associated with raw eggs (which were used in a mayonnaise substitute in one outbreak, and added to hot cereal in the other), three outbreaks were associated with undercooked scrambled eggs and three outbreaks were associated with pureed foods in settings where cross-contamination in the blender with raw egg was likely.

In most parts of the country where SE has emerged in epidemic form, the safest alternative for nursing homes and hospitals is to use pasteurized liquid egg products for all recipes calling for bulk pooled egg. Pasteurized egg is commercially available in 10 pound containers.

In all parts of the country, we recommend that menus, recipes, and food handling practices in nursing homes, hospitals, and food services for the home-bound elderly be reviewed and modified to prevent exposure to undercooked eggs. The following specific points merit special emphasis to reduce the risk of institutional outbreaks:

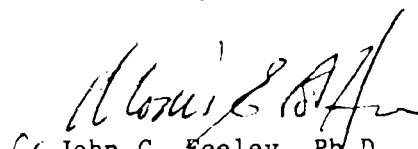
1) Recipes and practices which expose the consumer directly to raw egg are particularly hazardous. This includes home-made eggnog, home-made mayonnaise or home-made ice-cream, hollandaise sauce, and Caesar salads as well as the addition of raw egg to a food which has already been cooked.

2) Any recipe that calls for a large pool of eggs that are cracked ahead of time and held in a large container before cooking is of particular concern. A single infected egg can contaminate the whole pool. Rapid bacterial growth may then occur if the pooled egg mass is held above refrigerator temperature. Pooled separated egg yolk is likely to be more hazardous than pooled white or mixed egg, because of the lack of the bacteriostatic effects of albumin. Careful attention to holding times and temperatures and to thorough cooking are warranted.

3) Routine disassembly and sanitization of blenders after blending raw egg is a critical step that warrants special attention. The use of separate blenders to scramble raw eggs and to puree cooked foods would reduce the risk of cross-contamination.

Responsibilities for the inspection and certification of food service facilities in hospitals and nursing homes vary by State and may be diffuse. Accreditation by the Joint Commission on the Accreditation of Health Care Organizations does not guarantee regular food service inspections nor food-handler training to reduce the risk of nosocomial food-borne disease. Collaborative efforts by several State agencies may be necessary to ensure the continued safety of food service in hospitals and nursing homes.

The enclosed table summarizes the national SE surveillance data by state. The expansion of the SE epidemic into areas in the country that have been previously unaffected will require continuous collaborative efforts to identify the sources of outbreaks and to control them. Intensive investigation of foodborne outbreaks of salmonellosis and laboratory-based serotype surveillance of salmonellosis remain the foundation of our efforts to control this problem. The Enteric Diseases Branch (404-639-3753) would appreciate learning of any outbreaks of salmonellosis traced to shell eggs regardless of the serotype, and of any SE outbreaks regardless of the vehicle.


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Salmonella enteritidis isolates as a percentage of all Salmonella isolates reported to the National Salmonella Surveillance System by State, 1986 and 1987, in ranked order.

<u>1986</u> <u>State</u>	<u>#SE</u> <u>isolates</u>	<u>% of all</u> <u>isolates</u>	<u>1987</u> <u>State</u>	<u>#SE</u> <u>isolates</u>	<u>% of all</u> <u>isolates</u>
New Jersey	635	37.0	Delaware	19	43.2
Pennsylvania	948	31.4	Connecticut	567	39.6
Maryland	401	29.4	New York	1390	38.6
New York	1124	29.3*	New Jersey	616	38.2
Connecticut	252	24.2	Utah	41	35.0
Massachussetts	551	22.5	Pennsylvania	880	32.5
Vermont	26	19.8	Maryland	602	26.5
Ohio	208	17.8	Mississippi	29	23.6
Maine	28	16.7	Maine	46	22.6
Indiana	84	14.5	Massachussetts	470	22.1
North Dakota	11	14.1	Vermont	26	22.0
Montana	9	13.2*	South Dakota	18	19.1
Washington	101	12.8	Florida	3	16.7
Minnesota	53	12.8	Oregon	39	14.8
South Dakota	11	12.5	North Dakota	12	14.8
Utah	15	12.3	Ohio	196	14.5
West Virginia	23	12.2	Iowa	23	12.3
Delaware	7	11.3	Virginia	193	12.3
Oregon	20	10.7	Michigan	190	12.1
Wisconsin	89	9.7	Colorado	67	11.6*
Kentucky	23	9.4	Washington, DC	32	11.2
Tennessee	85	9.0	Illinois	320	11.1
Virginia	106	8.9	Indiana	64	10.3
Iowa	24	8.9	Minnesota	58	10.2
South Carolina	49	8.5	West Virginia	25	10.2
Michigan	120	8.1	Washington	61	9.6
Illinois	238	7.8	Wisconsin	79	8.4
North Carolina	117	7.3	Rhode Island	21	8.1
Arizona	26	7.2	Missouri	48	7.6
Colorado	23	7.0	Tennessee	72	7.1
Missouri	47	6.9	Kansas	25	7.0
Alabama	47	6.6	Alaska	7	6.6
Rhode Island	15	5.7*	California	361	6.2
Georgia	72	4.7*	North Carolina	87	5.2
Alaska	8	4.5	New Mexico	22	5.1
California	261	4.5	Kentucky	12	4.6
Arkansas	16	4.3	South Carolina	30	4.5
New Mexico	13	3.9	Oklahoma	13	4.2
Louisiana	16	3.3	New Hampshire	9	3.6*
Hawaii	15	3.2	Texas	59	3.5
Texas	54	3.2	Alabama	28	3.4*
Kansas	6	1.8	Arizona	12	3.0
Oklahoma	2	0.6	Montana	2	2.8*
Washington, DC	1	0.5	Louisiana	27	2.6
New Hampshire	0	0.0*	Hawaii	12	2.3
Nebraska	0	0.0	Georgia	35	2.2*
Nevada	0	0.0	Arkansas	2	0.6
Mississippi	0	0.0*	Nevada	0	0
			Nebraska	0	0
			Idaho	0	0
			Wyoming	0	0

*Greater than 20% (up to 100%) of reported isolates included in the denominator for this calculation were not serotyped, so that the proportional contribution of SE could be substantially greater than indicated here.