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Food Safety

Eggs

Scrambled Eggs

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

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EXECUTIVE SUMMARY

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

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

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

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

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

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

Key Conclusions and Recommendations

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

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

- FDA should mandate that egg producers implement on-farm Hazard Analysis and Critical Control Point (HACCP) programs to control SE. The SE control programs should be modeled after the successful Pennsylvania Egg Quality Assurance Program. The programs should include testing of manure and eggs. That testing should be monitored by FDA.
- Shell egg plants should be inspected for safety at least several times per year. These inspections should verify that plants only accept eggs from farms with SE testing programs in place and should ensure that eggs from infected flocks are diverted to pasteurization plants.
- FDA and FSIS should act quickly to implement science-based regulations mandating egg refrigeration at 41 degrees F during transportation and storage. Temperature requirements should be standardized across all the government agencies that regulate food, including the state and local governments responsible for enforcing temperatures at the retail level. Retailers and consumers should be informed that eggs should be kept refrigerated.
- Until the egg industry has effective programs in place to control SE, consumers must be warned that they risk illness from eating raw or undercooked eggs. FDA should mandate that the following label be placed on the tops of egg cartons: "Caution: Eggs may contain illness-causing bacteria. Do not eat raw. Cook until yolk is firm."
- FDA's Food Code should recommend that restaurants and other establishments not pool unpasteurized eggs unless they are cooked immediately.
- Food safety responsibility for eggs should be consolidated under the clearly defined authority of one of the two food safety agencies, either FSIS or FDA. Clear jurisdiction is needed to avoid agency competition and miscommunication.

- Congress should significantly increase funding for FDA's food safety functions and should fully fund FSIS's and FDA's efforts to address SE in eggs. President Clinton's

request for additional funding for food safety is an important step in ensuring that these agencies can adequately protect the public health.

INTRODUCTION

Eggs, once considered a safe food, have become increasingly contaminated over the last 15 years by a strain of *Salmonella* bacteria known as *Salmonella enteritidis*, or SE. While *Salmonella* sometimes is present on the outside of egg shells, no one ever thought the *inside* of eggs could be contaminated by bacteria. It was a surprise when government scientists first linked human illness from SE to internally contaminated eggs in 1986.¹

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

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

SE is responsible for the lion's share of food poisoning illnesses, about a third of all food poisoning outbreaks where the cause is known. (See Figure 2.) The estimated annual cost of illness from SE ranges from \$118 million to \$767 million.⁶ The magnitude of the current SE crisis was not inevitable. Before 1984, SE outbreaks were

largely confined to one geographical area, the northeastern United States. The problem spread to the mid-Atlantic states in the late 1980s. In 1992, a government-supported control program began in Pennsylvania that required testing of hens and cleaning of poultry houses. This program showed promise in reducing the number of food poisonings from SE. However, federal support for that program was discontinued in 1995, and no nationwide program has ever been implemented.

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

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

Figure 1. Number of SE Cases Reported to the CDC, 1980 - 1995

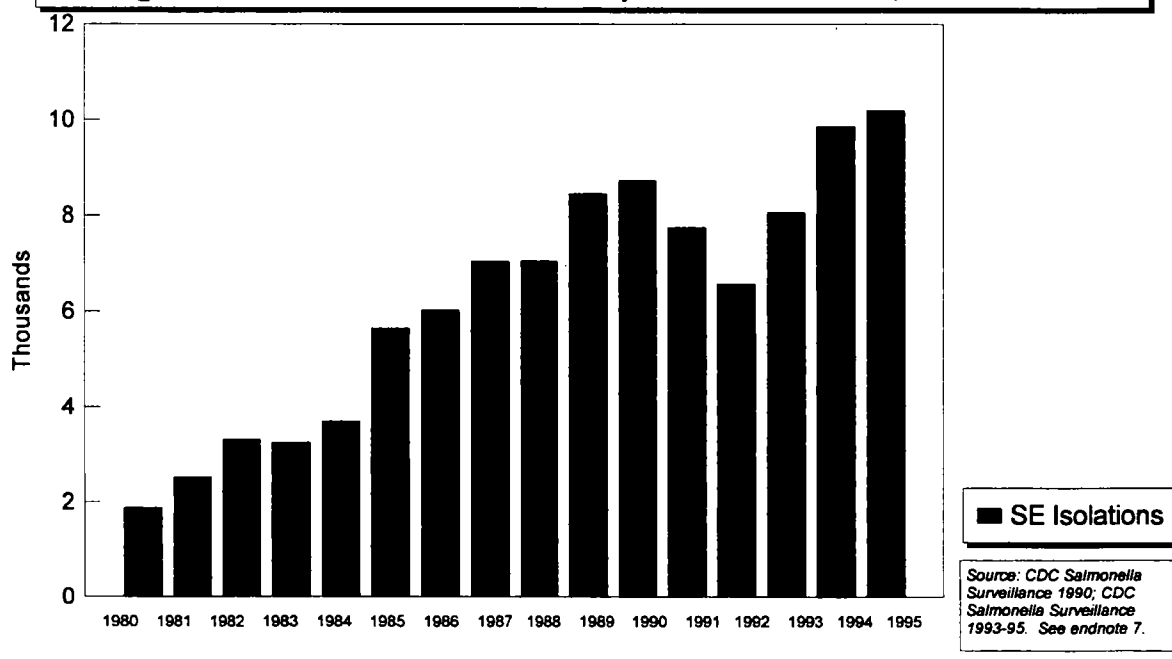
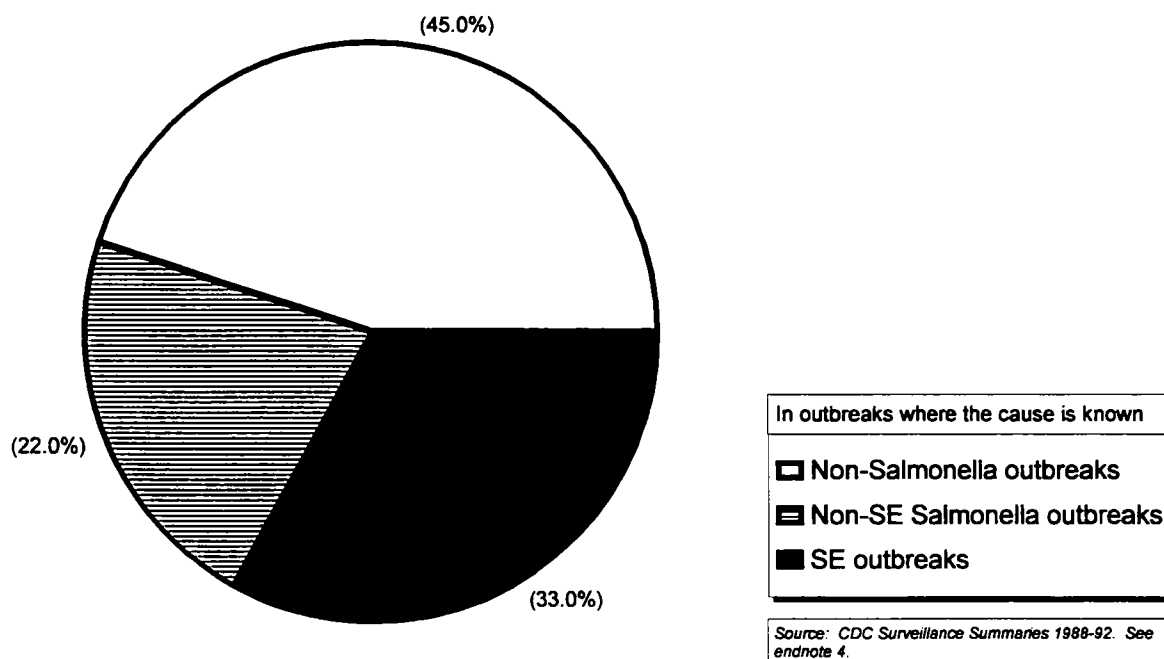


Figure 2. Percent of Food Poisoning Outbreaks Caused by SE, 1988 - 199



SE Has Increased Throughout the Nation

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

By 1984, SE began appearing in larger numbers outside the Northeast.⁸ (See Figures 3 and 4 and Appendix.) By 1986, the year CDC first linked SE to consumption of raw and undercooked eggs that were internally contaminated, the incidence of SE in the Northeast had increased more than sixfold over 1976 levels.⁹ While the number of cases of illness leveled off in the Northeast between 1990 and 1994, cases in the Rocky Mountain region doubled and cases in the Pacific region quadrupled during that same time period.¹⁰ In 1994, California accounted for about a quarter of the nation's laboratory-confirmed cases of SE.¹¹ A USDA survey showed that the frequency of SE isolates in unpasteurized liquid eggs nearly doubled in the northeastern and western U.S. between 1991 and 1995.¹²

To make matters worse, a more virulent form of SE, known as SE phage

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

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

Figure 3. Number of Confirmed SE Cases, 1995

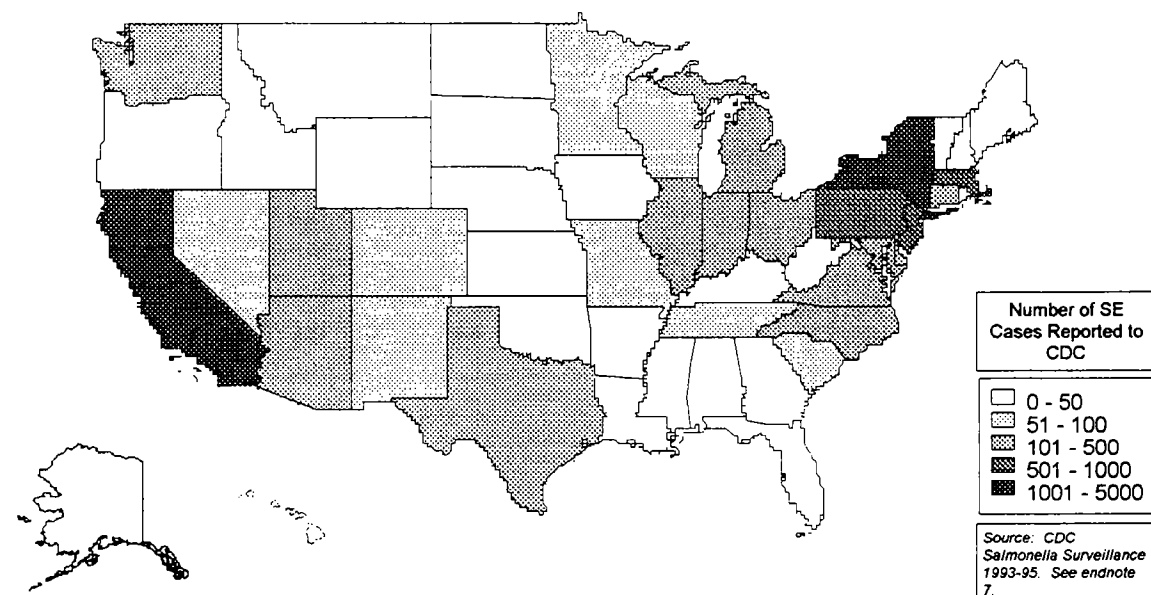
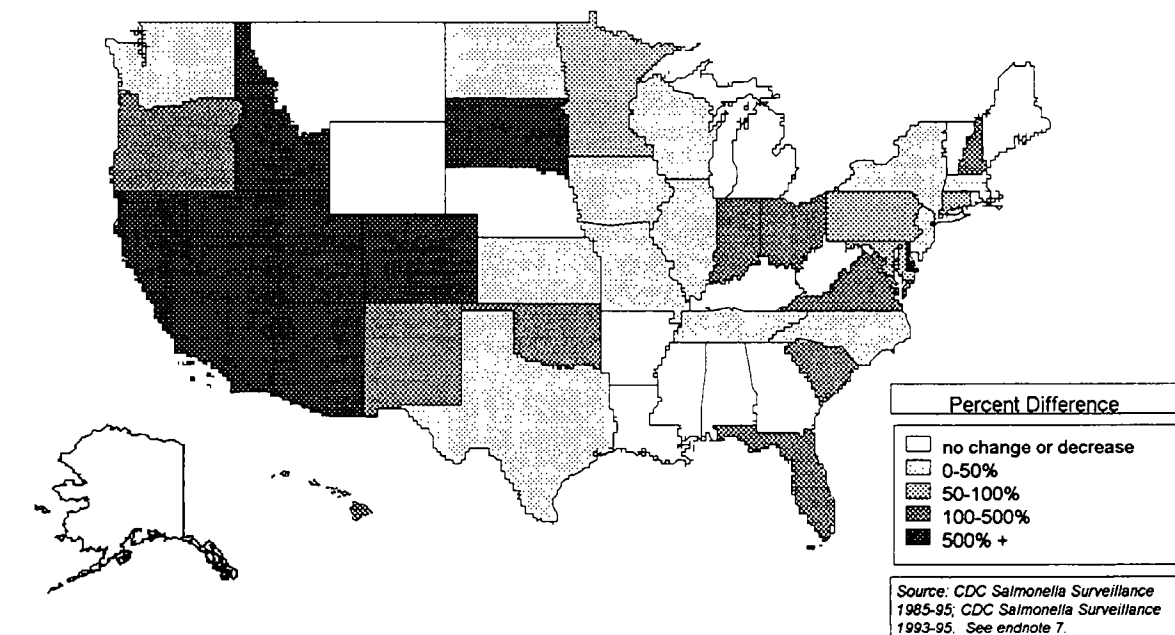


Figure 4. Increase in SE Cases, 1985-1995



Consumers Are at Risk of Illness from SE in Eggs

SE is found inside eggs laid by otherwise healthy hens that are infected by the bacteria.¹⁷ It is estimated that one out of every 10,000 eggs, or about 4.5 million eggs each year, are infected with SE.¹⁸

Consumers have no way of knowing which eggs are infected. The SE bacteria multiply inside eggs that are not properly refrigerated (to an internal temperature of 45 degrees F.) As few as 10 to 100 SE organisms may be enough to cause illness in elderly people, children, and the immuno-compromised.¹⁹

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

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

- serving eggs “sunny side up,” lightly poached, soft-boiled, or any other style where the yolk is still runny
- preparing French toast with an egg coating that is not thoroughly cooked

- using raw eggs in cookie dough or cake batter which is eaten before cooking
- using raw eggs in salad dressing, such as Caesar salad or homemade mayonnaise
- using raw eggs in eggnog
- using lightly cooked eggs in desserts, such as meringue and tiramisu

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

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

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

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

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.

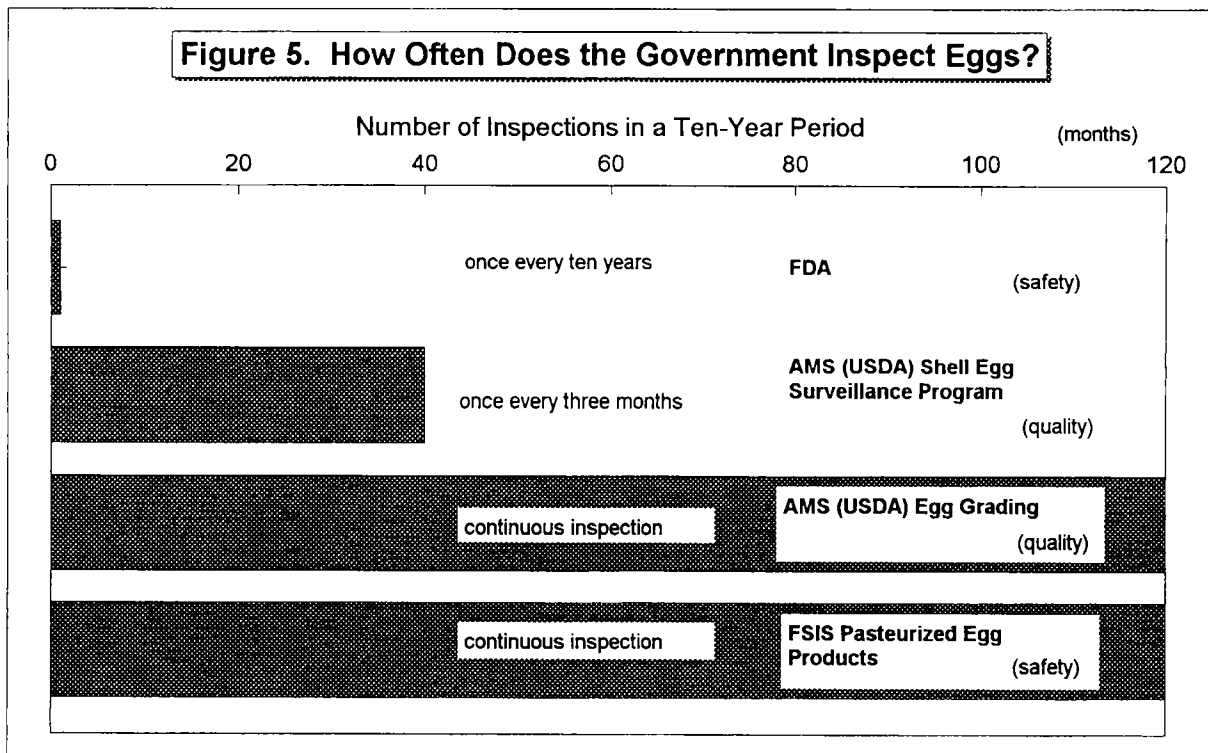
FDA occasionally inspects shell egg-packing plants and is responsible for monitoring whether eggs are contaminated with SE. However, FDA's inspection resources are so limited that it inspects most food manufacturing plants under its jurisdiction an average of only once every ten years.⁴⁹ (See Figure 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 at least several times per year. These inspections should check that plants accept eggs only from farms with SE testing programs in place. They should ensure that eggs from infected flocks are diverted to pasteurization plants.
- FDA and FSIS should act quickly to implement science-based regulations mandating egg refrigeration at 41 degrees F during transportation and storage. Temperature requirements should be standardized across the government agencies that regulate food, including the state and local governments responsible for enforcing temperatures at the retail level. Eggs should not be left unrefrigerated at any time.
- Until the egg industry has effective programs in place to control SE, consumers must be warned that they face the risk of illness from eating raw or undercooked eggs. FDA should mandate that the following warning notice be placed on the lids of egg cartons: "Caution: Eggs may contain illness-causing bacteria. Do not eat raw. Cook until yolk is firm." The notice should be designed and positioned to maximize visibility and consumer compliance.

- FDA's Food Code should recommend that restaurants and other establishments not pool unpasteurized eggs unless they are cooked immediately.
- Jurisdiction for food safety scattered among different agencies impairs protection of the public's health, results in duplication of efforts, inhibits needed actions, and wastes government resources. Until food safety functions are consolidated into a single federal food agency, the safety regulation of each food product, such as eggs, should fall under the clearly defined authority of one of the two primary food safety agencies, either FSIS or FDA. Clear jurisdiction is needed to avoid agency competition and miscommunication.
- Congress should significantly increase funding for FDA's food safety functions and should fully fund FSIS's and FDA's efforts to address SE in eggs. President Clinton's recent announcement of additional funding for food safety is an important step in ensuring that these agencies can adequately protect the public health.

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Appendix. Salmonella Enteritidis Increases Throughout the Nation

Isolations from Human Sources Reported to CDC

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

* No data from 1985 is available. This figure is from 1986. Percent difference is between the number of cases reported in 1986 and 1995.

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

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

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



U.S. DEPARTMENT OF AGRICULTURE

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TO: NBC DATELINE

FROM: Isi Siddiqui
Deputy Assistant Secretary for Marketing and Regulatory Programs
United States Department of Agriculture

DATE: April 7, 1998

We recognize the concerns raised by this story and intend to act as quickly as possible to appropriately address these matters. American consumers have the most abundant and safest food supply in the world. To further improve the safety of eggs, USDA and FDA are developing and coordinating a science-based, comprehensive farm-to-table food safety strategy for eggs that will also help to address these concerns. Additionally, we strongly believe that egg producers, handlers, and retailers must take responsibility to ensure the quality and safety of the eggs they sell to their customers.

FSIS

Egg Safety Measures U. S. Department of Agriculture

- Since 1995, the U. S. Department of Agriculture and the Food and Drug Administration have been coordinating a "farm to table" food safety strategy for eggs that is based on science.
- In 1991, Congress amended the Egg Products Inspection Act to require shell eggs packed for consumers to be stored and transported at an ambient air temperature of 45 degrees F.
- As directed by Congress, USDA's Food Safety and Inspection Service plans to soon publish a final rule to mandate ambient temperature requirement during transportation and storage of shell eggs.
- The safety of eggs involves much more than the air temperature, such as the conditions of the eggs themselves and whether the eggs are being cooled at a rate and to a temperature that is adequate to prevent growth of bacteria.
- Since 1995, USDA and FDA have conducted an extensive study to gather data and determine facts about current egg safety programs. The study, which assesses risks to public health from the current programs and data on the egg/egg products industries, is being peer reviewed by experts outside the federal agencies. Peer review is expected to be complete by mid April, and FSIS plans to conclude a revised report by the end of April.
- USDA and FDA expect to soon publish an Advance Notice of Proposed Rulemaking to spell out the framework of the food safety strategy for eggs.
- FDA is preparing a regulatory proposal on a label for the safe handling of eggs similar to the label on raw meat and poultry products required by USDA since 1995 and on the receipt of eggs at retail.
- USDA is preparing to publish a proposed rule later this year to mandate a pathogen prevention and hazard control program for egg products establishments that will be similar to the Hazard Analysis and Critical Control Point system now being implemented in meat and poultry plants.
- The Office of Management and Budget has designated the proposed HACCP rule for egg products establishments economically significant, which means that it requires an extensive economic analysis because of its claimed public health benefits.
- Data compiled by the egg industry about the repacking of eggs after expiration dates become effective could be incorporated into the risk assessment model that FSIS and FDA are using to formulate the food safety strategy for eggs.

Qs&As for Dateline NBC story on eggs
Agricultural Marketing Service
Expected Broadcast: April 7, 1998

Can eggs returned from retail stores be given new expiration and/or Julian dates?

Eggs may be reprocessed, regraded, and repacked into cartons bearing new expiration and/or Julian dates. Only Colorado and Oregon have written legislation against egg repacking.

In plants utilizing the voluntary USDA grading service, eggs identified with an official USDA grademark must be of current production. Current production is defined as shell eggs which have moved through usual marketing channels since they were laid and have not been held in refrigerated storage more than 30 days. Regardless, even if the 30 day period has not elapsed, the reprocessed and regraded eggs are eligible for USDA grade identification only if the eggs still meet the assigned grade.

Why does the federal government allow egg repacking?

USDA does not have authority to restrict egg repacking. The federal Egg Products Inspection Act does not regulate the quality of wholesome eggs.

Are repacked eggs safe to eat?

While egg quality decreases slowly during refrigeration, they remain safe to eat for many weeks unless otherwise contaminated. Therefore, wholesome eggs less than 30 days old may be repacked into new cartons and can be given new expiration dates, except where state egg laws prohibit such a practice.

Is USDA studying the safety of egg repacking?

USDA's Food Safety and Inspection Service and FDA are currently conducting a "farm to table" food safety strategy. Part of the study is to use science to determine if repacked eggs are a food safety issue.

How could USDA get the authority to restrict egg repacking?

The restriction of egg repacking could be done two ways. First, if FDA and USDA decide that repacking eggs is a food safety issue (as described in question above), USDA would seek legislation through Congress to prohibit this practice for all egg producers.

If FDA and FSIS decide that this is not a food safety issue, USDA could propose revising the current quality grading standards. This would be done through a rulemaking process, which does not involve Congress, but seeks comments from all interested parties and issues a proposed rule, and then a final rule. However, it is important to note that only 1/3 of the egg industry currently utilizes USDA's voluntary grading standards, so the restriction, if attached to quality grade standards, would only apply to those companies who utilize the voluntary standards.

What happens when eggs are repacked?

If eggs are packaged into cartons bearing the USDA grademark, the USDA grader will not allow eggs known to be older than 30 days to be repacked. If eggs not older than 30 days are repacked into USDA grademarked cartons, USDA will verify that these eggs meet the same *quality* grade requirements on the day of repacking.

Do any egg laws affect egg repacking?

No. USDA administers two laws affecting shell eggs: the grading program under the Agricultural Marketing Act of 1946; and the Egg Product Inspection Act (EPIA). EPIA does not deal with the repacking issue, as it is concerned primarily with regulating the disposition of restricted shell eggs. This leaves only the USDA grading program and State law to legally limit the repacking of shell eggs.

What action is USDA currently taking against Buckeye Egg Farm?

USDA is now preparing a case for possible legal prosecution against Buckeye Egg Farm in Croton, Ohio. USDA is not able to comment further about any specific details relating to the Buckeye Egg Farm case. USDA can only publicly acknowledge that it is currently reviewing allegations of violations by the Buckeye Egg Farm under the EPIA.

What action has USDA already taken against Buckeye Egg Farm?

Since Oct. 1994, letters of information and warning have been written to Buckeye Egg Farm from USDA. Based on results of destination gradings and the origin inspection results, USDA advised Buckeye Egg Farm that the Secretary of Agriculture was contemplating legal action against them. A case against Buckeye Egg Farm is currently under review.

Has Dateline gathered information from Buckeye Egg Farm?

Dateline NBC did visit Buckeye Egg Farm and interview company president Andy Hansen. They also filmed eggs destined for repacking. AMS and FSIS are not aware of any employees (graders or inspectors) who talked with Dateline NBC on-camera or with hidden cameras.

Who else has given on-camera information to Dateline?

On March 26, Senator Durbin did an interview with Dateline NBC promoting his bill for a single food safety agency. He says USDA and FDA need to act on egg safety.

What laws regulate egg processors and handlers?

EPIA gives the Secretary of Agriculture jurisdiction over egg products processing plants for the mandatory inspection of egg products and over egg handlers engaged in marketing shell eggs. USDA carries out its responsibilities for checking shell egg handlers through its Shell Egg Surveillance (SES) Program.

Does USDA have the authority to issue fines to EPLA violators?

USDA does not have the authority to issue fines against handlers for violating EPLA. Upon conviction, handlers are subject to fines levied by a judge in the U.S. District Court.

What does the SES program regulate?

SES program accomplishes EPLA objectives by recording violations such as: improper labeling of dirty or checked eggs; selling or transporting dirty, checked or leaking eggs that don't meet minimum U.S. Consumer Grade B; and failure to maintain complete records on eggs handled.

Has the SES program been effective?

USDA has seen a 65% decrease in the number of violations reported since the EPLA's inception. In FY74, there were a total of 2,229 violations compared to 782 violations in FY97. USDA is finding fewer violations each year while looking at the same or greater volumes of eggs.

Is shell egg grading mandatory for all egg processors?

AMS administers a voluntary shell egg grading program offered on a fee basis to processing plants that request it and meet equipment, facility, sanitary and processing requirements. Grading is strictly for quality, not food safety.

What does an expiration date on an egg carton mean?

An expiration date on an egg carton has the same meaning as a "pull" or "sell by" date. It is the last date that a store should sell the item as fresh. The expiration date does not relate to egg safety.

Are expiration dates required on all egg cartons?

There is no federal requirement that expiration dates be placed on egg cartons, and they may or may not be required by state regulations or by individual food stores. Most state egg laws are silent on expiration dates, neither requiring them nor placing restrictions on their use.

Are there dating requirements for egg cartons that use the federal grademark?

There are special requirements for dating egg cartons that have the federal grademark on them. The carton must display the date the eggs were packed, using the Julian date (consecutive day of the year), and if the carton carries an expiration date, the expiration date cannot be more than 30 days from the date the eggs were packed. Example: eggs packed on January 1 would have the Julian date 001 and the expiration date EXP JAN 30.

What is a U.S. Consumer Grade AA egg?

Grade AA eggs must have: clean, normal, unbroken shell; clear, firm white; yolk outline slightly defined and practically free from defects; egg content covers a small area; and an air cell of 1/8 inch or less in depth.

What is a U.S. Consumer Grade A egg?

Grade A eggs must have: clean, normal unbroken shell; clear, reasonably firm white; yolk outline fairly well defined and practically free from defects; egg content covers a moderate area; and an air cell of 3/16 inch or less in depth.

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P. 3

What is a U.S. Consumer Grade B egg?

Grade B eggs must have: clean to slightly stained, unbroken, abnormal shell; weak, watery whites with small blood and meat spots present; yolk outline plainly visible, but enlarged or flattened; egg content covers a very wide area; and an air cell of over 3/16 inch in depth.

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USDA, FDA EXPAND EFFORTS TO ENSURE EGG SAFETY

WASHINGTON, May 18, 1998 -- The U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) today announced expanded efforts to ensure the safety of shell eggs. In a notice to be published in the Federal Register on Tuesday, USDA and FDA are asking for public comments on plans to implement a comprehensive, farm-to-table strategy to decrease the food-safety risks associated with shell eggs.

"We are committed to minimizing the public health risks associated with shell eggs," said Dr. Catherine Woteki, USDA's Under Secretary for Food Safety. "Working with FDA, we are looking at every possible step -- from the hen house to the breakfast plate -- as we apply today's best science to this challenge."

Dr. Michael A. Friedman, M.D., FDA Lead Deputy Commissioner, said the agencies' approach on the safety of shell eggs is across-the-board. "Our strategy covers all the links in the chain from production to consumer preparation, including processing, packing, labeling, distribution, and retail and food-service sales," he said. "The measures we are contemplating are important to the public health because eggs contaminated with Salmonella, although only a small fraction of all eggs sold, cause significant numbers of illnesses in U.S. consumers."

The notice asks for comments on such issues as preventing the introduction of Salmonella Enteritidis (SE) in laying chickens and changing egg processing, handling and storage procedures to further enhance egg safety. SE, a pathogen that can cause severe illness in humans, is one of the most commonly reported causes of foodborne illness in the United States.

The notice cites the following actions that are planned or already underway to ensure the safety of shell eggs.

- ▶ A proposal to control the temperature maintained by vehicles transporting shell eggs to market.

-more-

- ▶ A proposal to require labeling on egg cartons providing information to consumers on the proper handling of eggs, and maintenance of cool temperatures at points of retail and food-service sale.
- ▶ Guidance to industry and state and local authorities in FDA's Food Code on safe handling of eggs at retail operations including restaurants, supermarkets and institutions.
- ▶ Guidance to states and industry for implementing egg safety programs on the farm.
- ▶ A formal risk assessment for shell eggs. This report will provide a more definitive understanding of the risks from shell eggs and egg products. It will also help in efforts to evaluate ways in which those risks might be reduced. A draft of the risk assessment was published in September 1997.
- ▶ A nationwide surveillance program for SE to track spread of the infection among layer flocks.
- ▶ Public-private partnerships sponsoring the development of a national food-safety education and training campaign for food-service workers and consumers.
- ▶ Ongoing research about SE.

USDA and FDA share federal regulatory responsibility for egg safety. However, regulation of shell egg safety is primarily the responsibility of FDA.

Public comments on the Advanced Notice of Proposed Rulemaking may be sent to Docket Clerk, Docket No. 96-035A, Room 3806, South Agriculture Building, 1400 Independence Avenue, SW, Washington, D.C. 20250-3700. Comments will be accepted for 90 days after the Federal Register date of publication.

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NOTE: USDA news releases and media advisories are available on the Internet. Access the USDA Home Page on the World Wide Web at <http://www.usda.gov>

Why relabel old eggs?

OUR VIEW Fights over egg, juice labeling reveal how much consumers are at risk.

If the current hot action in the world of food labels has escaped you, perhaps it won't for much longer. Sooner or later — emphasis, one would hope, on the “sooner” — much of the food in your local market or grocery will come equipped with labels that are more accurate and informative. Latest from the front:

► On Friday, the Agriculture Department ruled that federally inspected egg producers no longer may repackage unsold eggs with new expiration dates.

► Then on Monday, the Food and Drug Administration announced a proposal to require a warning label on fruit juice.

► And next Thursday, the comment period on a proposed organic food label closes.

Some of this is easy to grasp. Only about a third of the 35.5 billion eggs sold retail nationwide are inspected by the USDA. It's a voluntary program, but even so the government hardly can condone the practice. Salmonella risks rise with each extra day.

Also a no-brainer: the FDA's proposed juice labels. Only 2% of the packaged juice sold nationwide is not pasteurized. But as many as 48,000 people annually are poisoned by bad juice. In 1996, scores fell ill and an infant died after drinking apple juice contami-

nated with E. coli 0157:H7. The new label, warning of potentially harmful bacteria, may prove a hardship for some small producers. But let's worry about the small consumer first.

The emerging organic food label, designed not as a warning but as a classification, poses a different challenge. A federal standard is plainly required. Currently, 44 states set their own standards. No wonder the organic farming industry wants a single, reliable national label. So should consumers.

Yet the proposed USDA definitions, which have drawn well over 110,000 mostly critical public comments so far, are way too loose. Among the foods that conceivably could qualify as “organic”: irradiated meat from industrial stockyards and bio-engineered produce fertilized with human sewage. Imagine anyone thinking such foods are organic.

The USDA has made no final decisions and is willing to rethink its proposed standards. Rightly so. The appeal of organic foods is not that they are more nutritious but that they connect consumers to a style of farming — eco-sensitive, humane, hands-on — they want to support. A feedlot steer loaded with antibiotics violates the expectation of “organic” as clearly as the egg in a misdated container violates our notion of “fresh.”

Critics say such labeling is more than we need. But although the nation's pantries are farther than ever from the nation's fields, you still are exactly what you eat. You ought to be able to know exactly what that is.

Overlabeling can mislead

OPPOSING VIEW Consumers may overlook important information.

By Frances B. Smith

What's on the label? A lot, if it's on food. Yet government requirements for label information may crowd out critical information and sometimes mislead consumers.

Government today requires food labels to detail ingredients, nutritional data — calories, fat, protein, fiber, vitamins — and serving sizes. Labels may include government-defined terms like “sodium free” or “calorie free.” Warnings are required on certain foods.

Federal organic food labels are next, as the organic industry turns from private to federal standard setting. Under current government proposals, to earn an organic label, food would have to show not only what's in the food but also how it's produced or processed. Can hybrid crops be labeled organic? What about bio-engineered foods? Or foods protected in transit by waxing or fungicides?

Of course, government seeks to minimize criticism of its edicts. A recent proposal to mandate warning labels on fresh juices was very careful to exempt kids' lemonade stands.

The argument for label proliferation is that consumers need more information in our

complex modern age. But how much information? Of what sort? Selected and provided by whom? Labeling used to provide information; now, with government-controlled labels, it seems to be a way of endorsing values, of favoring some popular cause.

And such food labeling excesses can harm consumers. California's Proposition 65, for example, may require prominent warning labels on foods containing even traces of certain chemicals that pose no risk to any human but, indeed, are essential nutrients. Warnings like those may lead consumers to avoid such products and lose vital nutrients.

Information overload is a real problem, causing consumers to miss truly important food safety information. Guidelines on proper food preparation and storage are far more critical than many current and proposed labeling requirements. And food labels alert consumers to other sources of information, like brand names, 800 numbers, product ratings, and private certification (such as “kosher” food).

Growing government mandates may crowd out information that consumers really want — information that helps them enjoy the benefits of safe, nutritious and affordable food.

Frances B. Smith is executive director of Consumer Alert, a non-profit, non-partisan consumer group in Washington, D.C.

Date: 6/25

449, Decline

FAX



Health Division



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Washington, DC 20503

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Fax: 456-7431

From: MATT VAETH

Number of Pages (excluding cover): 23

Subject:

FDA Egg Testimony...

Let me know if you have any comments
Call me at 5-3696.

Thanks - Matt

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Health Division (Front Office)	202/395-4922
Health & Human Services Unit	202/395-4925
Health Programs & Services Branch	202/395-4926
Health Financing Branch	202/395-4930

Fax Numbers:

Health Division (Front Office)	202/395-3910
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Health Division (Room 7002)	202/395-5648



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DATE: 6/25

TO:

Bob P

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395 6/48

Egg testimony

(INCLUDING COVER):

25

REMARKS:

MAH/Richard
deal directly with Roger McClung
(690-7450). He'd like comments by COB
on Monday - 6/28.

Thanks

Bob

FROM:

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United States Senate

COMMITTEE ON
 GOVERNMENTAL AFFAIRS
 WASHINGTON, DC 20510-6000

June 16, 1999

The Honorable Donna E. Shalala
 Secretary of Health and Human Services
 United States Department of Health and Human Services
 200 Independence Avenue, SW
 Room 615F
 Washington, DC 20201

Dear Secretary Shalala:

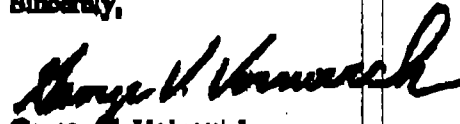
On Thursday, July 1, 1999, the Senate Subcommittee on Oversight of Government Management, Restructuring, and the District of Columbia will hold a hearing on "Egg Safety: Are There Cracks in the Federal Food Safety System?". The purpose of the hearing is to examine the organization and effectiveness of Federal oversight of egg safety. I invite you to testify on GAO's upcoming report on this subject. The hearing is currently scheduled for 10:00 a.m. in room 342 of the Dirksen Senate Office Building.

Committee rules require that 100 copies of your prepared statement be submitted 48 hours in advance of the hearing. Accordingly, I would ask that copies of your written statement be delivered to Julie Vincent, Chief Clerk, in 601 Hart Senate Office Building, no later than 10:00 a.m. on Tuesday, June 29, 1999. In addition, I ask that you submit your statement in text format on a 3.5" disk. While your complete written testimony will be included as part of the hearing record, the Subcommittee requests that all oral testimony be limited to five minutes.

Should you have questions regarding the hearing, please have a member of your staff contact Andrew Richardson, Professional Staff Member, at (202) 224-3682.

I hope your schedule allows you to testify at this hearing, and I look forward to receiving your testimony.

Sincerely,



George J. Voinovich
 Chairman

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

GVV/qiv

DRAFT TESTIMONY OF DR. MORRIS E. POTTER, FOOD AND DRUG
ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES,
BEFORE THE SENATE SUBCOMMITTEE ON OVERSIGHT OF
GOVERNMENT MANAGEMENT, RESTRUCTURING AND THE DISTRICT OF
COLUMBIA, COMMITTEE ON GOVERNMENTAL AFFAIRS,
JULY 1, 1999

I. Introduction

Mr. Chairman, Members of the Committee, I am Morris E. Potter, Director of Food Safety Initiatives, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration (FDA or Agency). I am pleased to be here this morning, to testify generally on FDA's role in the oversight of egg safety and specifically on the General Accounting Office's (GAO) report on the same. As you know, FDA provided comments to GAO on the draft report "U.S. Lacks a Consistent, Farm-to-Table Approach to Egg Safety". The Agency expressed concern that this draft report neglected to reflect or acknowledge that FDA, the Centers for Disease Control and Prevention (CDC), and the U.S. Department of Agriculture (USDA) have been working together for many years on a coordinated approach to understanding and initiating actions to reduce the risk of *Salmonella Enteritidis* (SE) in eggs. An important omission in the report was discussion of Federal research efforts, which have been underway since contamination of eggs with SE was identified as a public health problem. This research has been critical to our better understanding of SE and efforts to develop science-based control schemes from farm to table.

FDA, the Centers for Disease Control and Prevention (CDC), USDA, and the states have a long history of working together to prevent egg-associated illnesses. Nevertheless,

Our goal is best for safety for you
I think we should be more proactive

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much remains to be done to enhance and improve the safety of eggs. While we do not agree with all aspects of the GAO report, you will see by this testimony that FDA concurs with the two recommendations GAO directed to the Agency.

Mr. Chairman, in our testimony we will address the coordination of federal and state agencies with shared food safety responsibilities, and FDA's role in minimizing the SE risk from eggs and egg products. This will include a discussion of how eggs are regulated, SE and egg safety, and the farm-to-table continuum.

In the 1980s SE was identified as a growing public health problem, and was linked to contaminated whole shell eggs in 1986. FDA, CDC, APHIS, and AMS immediately responded by working together and with colleagues in state government, universities, and the egg industry to conduct research on SE and eggs and to put in place mechanisms to share new information on prevention and control as that information developed. Recent nationwide surveillance data show a marked decrease in cases of SE infection, particularly in the Northeast where egg quality assurance program efforts have been the most intense, and active surveillance in FoodNet sites demonstrates a 44% decline in SE infection rates between 1996 and 1998 in those areas of the country. Although we are heartened by this progress, the rate of decline is too slow and the remaining public health burden of egg-associated SE infections requires the Agency to do more to address the problem. FDA and ARS research is continuing to improve the range of prevention and control options available to government and industry.

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Both FDA and FSIS announced initiatives this week that are major steps forward in the egg safety effort. FDA yesterday published a proposed rule that would require refrigeration of shell eggs at retail and labeling to instruct consumers on safe handling of eggs. FSIS also has announced a directive that will implement its refrigeration requirements for storage and transport of eggs.

These new regulatory efforts will ensure that additional preventive controls are in place to enhance the safety of eggs. In addition, FDA and FSIS are committed to developing a comprehensive, science-based farm-to-table SE control strategy that will provide a coordinated blueprint to address remaining egg safety issues. We anticipate completing the strategic planning process by the end of October 1999.

II. Regulation of Eggs

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

USDA has responsibility for implementing the Egg Products Inspection Act (EPIA), which it carries out through programs in the Food Safety and Inspection Service (FSIS)

and the Agriculture Marketing Service (AMS). FSIS has primary responsibility for the inspection of processed egg products to prevent the distribution into commerce of adulterated or misbranded egg products, while AMS conducts a surveillance program to ensure proper disposition of restricted shell eggs. USDA's Animal and Plant Health Inspection Service (APHIS) administers programs for animal health, including an SE control program for flocks that supply hens to laying flocks. FDA has primary responsibility for the production and processing of shell eggs.

In addition, the States play a key role, as they may have their own laws governing eggs, as long as they are consistent with Federal laws. Generally, State laws and regulations focus on how eggs are packed and shipped for sale within their borders, and how eggs are handled by retail stores and food service establishments. FDA and USDA, with help from the States, strive to provide a coherent and comprehensive system to eliminate or reduce the risk of SE contaminated eggs and egg products in each link of the farm-to-table chain.

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

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III. *Salmonella* and Egg Safety

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

a. Salmonellosis

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

The disease salmonellosis is an intestinal infection with *Salmonella*, and is characterized by diarrhea, fever, abdominal cramps, headache, nausea, and vomiting. Symptoms of salmonellosis usually begin within 6 to 72 hours after consuming contaminated food, last for 4 to 7 days, and most healthy people recover without antibiotic treatment. The infection can spread to the bloodstream and other areas of the body, however, leading to severe and fatal illness. Invasive, life-threatening disease is more likely in children, the elderly, and persons with weakened immune systems. In general, the greater the numbers of microorganisms ingested, the greater the likelihood of disease. The likelihood of disease is also affected by the virulence of the microorganism and the susceptibility of the

host, and the infectious dose (i.e., the number of microorganisms required to cause disease) for SE can be very low. About 2 percent of those who recover from salmonellosis may later develop recurring joint pains and arthritis.

b. SE in Eggs

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

c. Epidemiology

Salmonellosis is a notifiable disease, i.e., physicians and medical laboratories are required to report identified infections to the local health departments. These cases are then, in turn, reported to state health departments, which report the annual totals to the Centers for Disease Control and Prevention (CDC). These data are derived from the nationwide, passive reporting system for all serotypes of *Salmonella*. While the numbers of another

common serotype, Typhimurium, have remained relatively stable, SE isolations increased more than 8-fold from 1976 to 1995. Initially, the increases in the United States largely occurred in the Northeast. Later, the increase spread throughout the country. The numbers of SE isolations decreased in 1996 and 1997, especially in the Northeast where control efforts have been the most intense, demonstrating that committed application of good management and strong science during production and concerted efforts to improve egg handling during food preparation and service, especially institutional food service, will bring the numbers down.

The number of *Salmonella* isolates reported to CDC underestimates the true number of infections that occur, however, and this progress should not make us complacent. Most persons infected with *Salmonella* do not seek care, many doctors do not order stool cultures, and some laboratories do not report *Salmonella* isolations to their health department. It has been estimated that only one in 39 *Salmonella* infections are reported to CDC; inasmuch as 7,924 cases of SE were reported to CDC in 1997, approximately 310,000 infections actually occurred.

In addition to the routine passive surveillance for infections with all serotypes of *Salmonella*, CDC also maintains special surveillance of outbreaks of infections with *Salmonella* serotype Enteritidis (SE). In 1985, when this outbreak surveillance began, States reported 26 SE outbreaks (i.e., occurrences of 2 or more cases of a disease related in time and place) to CDC. Nationwide, the numbers of reports peaked in 1990. The numbers of outbreaks increased first in the Northeast in the late 1980s and early 1990s,

but have decreased dramatically in the late 1990s. This progress was partially offset by increasing numbers of outbreaks in the West during the early 1990s. From 1985 through 1998, there have been a total of 794 SE outbreaks reported to CDC that involves 28,644 reported cases of illness, 2839 reported hospitalizations, and 79 reported deaths. Many of these SE outbreaks were attributed to food served in commercial establishments, such as restaurants, hospitals, nursing homes, schools, and prisons, and most (more than 75%) were associated with food that contained undercooked eggs. Although most deaths linked to reported SE-related outbreaks in recent years have occurred among the elderly in hospitals and nursing homes, salmonellosis can be fatal to an otherwise healthy person if a sufficient dose is ingested, and proper treatment is not administered.

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

programs.

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

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

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

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

a. Production

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

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

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

• *Salmonella-free feed.*

Controlling SE during production is crucial in mitigating the risk of SE in eggs, and will be part of our comprehensive strategy. Research in this area is being conducted by both FDA and ARS to uncover all important sources of the SE problem, and to develop ways to maintain SE-free laying hens. Our ability to now move forward on a comprehensive program for improving the safety of eggs is a direct result of the investments in research during the past several years. For example, work done by ARS on transovarian infections of laying hens and factors that influence the frequency of SE contamination of eggs has been important in understanding the transmission of SE and the development of effective quality assurance programs. Progress has been impressive, but there are still scientific data needed to solve this complex food safety problem. Thus, federal agencies continue to aggressively identify, initiate, and support research needed to develop even more effective means for controlling this disease-causing microorganism. Examples of FDA research underway include studying the effects of stress on the immune system of poultry and subsequent infection of shell eggs with SE, which will assess the effects on the immune system of potential factors such as competing organisms, crowding, temperature, air quality, and lighting that affect the risk of SE contamination of shell eggs, and an assessment of the pathogen transmission capacities of various insects found in the production environment.

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As additional data gaps in our understanding of the dynamics of SE during production are filled so we can be certain that our control strategies will be both effective and efficient, we will consider control programs that include HACCP during production. While we are moving controls into place to prevent SE contamination of eggs, we also must react to episodes of contamination and the illness that results from it. In 1995, FDA assumed regulatory responsibility for investigating shell egg outbreaks, tracing back egg-associated SE illnesses to particular producers/flocks, sampling, diverting eggs, and collecting flock data to help track the presence of SE. Prior to 1995, USDA's Animal Plant Health Inspection Service (APHIS) conducted the traceback program.

g. Processing and Packaging:

Processing and packaging are steps in the farm-to-table continuum that involve the washing, grading, and packing of eggs for transport to distributors, retailers, or manufacturers of food products. The principal aspect of SE control during this phase is temperature control to prevent growth of SE already contaminating the internal contents of some of the eggs. The field and laboratory research focus in this area has been on the effects of rapid or delayed cooling, temperature fluctuations, temperatures that will prevent growth of SE, and technologies that achieve the desired time/temperature conditions. The Agencies are aware of ongoing research discussed in the GAO report on methods of rapid cooling. The overall impact on egg safety, costs, and potential problems of the methods being developed in North Carolina and California will be reviewed jointly by USDA and FDA.

h. Transportation

Transportation of shell eggs is the next stage in the farm-to-table continuum.

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

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

FSIS consulted with FDA during development of this final rule. Yesterday, (the President also announced) that FSIS published a Directive to implement this final rule.

c. Retailers:

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

FD-1030 (Rev. 12-1-80) JUN 25 '99 13:30 No. 004 P.17
FDA's Retail Food Code requires in retail and food service establishments:

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

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

FDA also has been working on a proposed rule to address refrigeration and labeling of eggs that is consistent with the requirements of the FSIS rule. The FDA proposed rule, "Food Labeling: Safe Handling Statements: Labeling of Shell Eggs; Shell Eggs: Refrigeration of Shell Eggs Held for Retail Distribution " was placed on public display yesterday, and will be published in the *Federal Register* on June 1, 1999. This proposal directly responds to and corrects problems outlined by GAO. It proposes requirements that all shell eggs be stored and displayed at a temperature of 45 F or less, and would cover shell eggs sold both interstate and intrastate. It also proposes safe handling statements on labels of cartons of shell eggs that have not been treated to destroy *Salmonella*. The statement would read, "Safe Handling

Instructions: Eggs may contain harmful bacteria known to cause serious illness, especially in children, the elderly, and persons with weakened immune systems. For your protection, keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly before eating." FDA is aware that refrigeration and labeling solve only parts of the problem, and the Agency views this regulation as one step in a comprehensive action plan.

d. Consumers:

During final preparation of eggs and egg-containing dishes in our homes, we can protect ourselves by following simple food safety rules, including proper refrigeration and thorough cooking. The primary tool the Agencies have for helping consumers reduce their own risk of foodborne disease is education on safe food handling, and our proposed labeling requirements will be an important adjunct to our other efforts to inform the public. FDA, USDA, and the Environmental Protection Agency are partners with consumer groups and industry in a consumer education campaign begun in 1997 as part of the President's Food Safety Initiative. The Fight BAC! Campaign covers all aspects of food safety, including information that pertains to safe handling of eggs.

The Agencies have coordinated other efforts to enhance egg safety during food preparation. The rulemakings on labeling, discussed above, provide consumers with an immediate reminder of how to safely handle eggs. Both FDA and USDA publish electronically and in print various educational materials to enhance consumer knowledge

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on the safety of eggs and egg products. Additionally, both FDA and FSIS have taken extra measures to reduce the risk to vulnerable populations, such as the immune compromised or elderly. We have provided extra guidance to nursing homes, hospitals, and health care providers regarding the importance of the use of pasteurized eggs for these sensitive populations and on the proper preparation and holding of eggs.

V. Where do we go from here?

Today FDA and USDA are announcing that in 120 days, we will jointly issue our strategic plan that creates a farm-to-table approach of addressing SE and eggs. The ANPR of May 19, 1998 referenced above, was intended to identify farm-to-table actions which will decrease the risks associated with shell eggs. The information from the joint FSIS/FDA 1998 *Salmonella* Enteritidis Risk Assessment, combined with the over 70 comments we received on the joint ANPR, will be used by FDA and USDA to finalize our joint strategic plan for a comprehensive system to assure the safety of eggs and egg products. Strategic planning will be a coordinated interagency effort, and will feature a strong element of public input similar to the process used in our development of good practices guidance for fresh produce.

VI. Conclusion

As you know, managing the risks of SE contamination in eggs in each step of the process from farm to table is a complex and challenging task. Since the time that CDC first identified the growing public health problem of SE infections and their association with eggs, FDA has worked diligently with its federal and state partners, the food industry, and

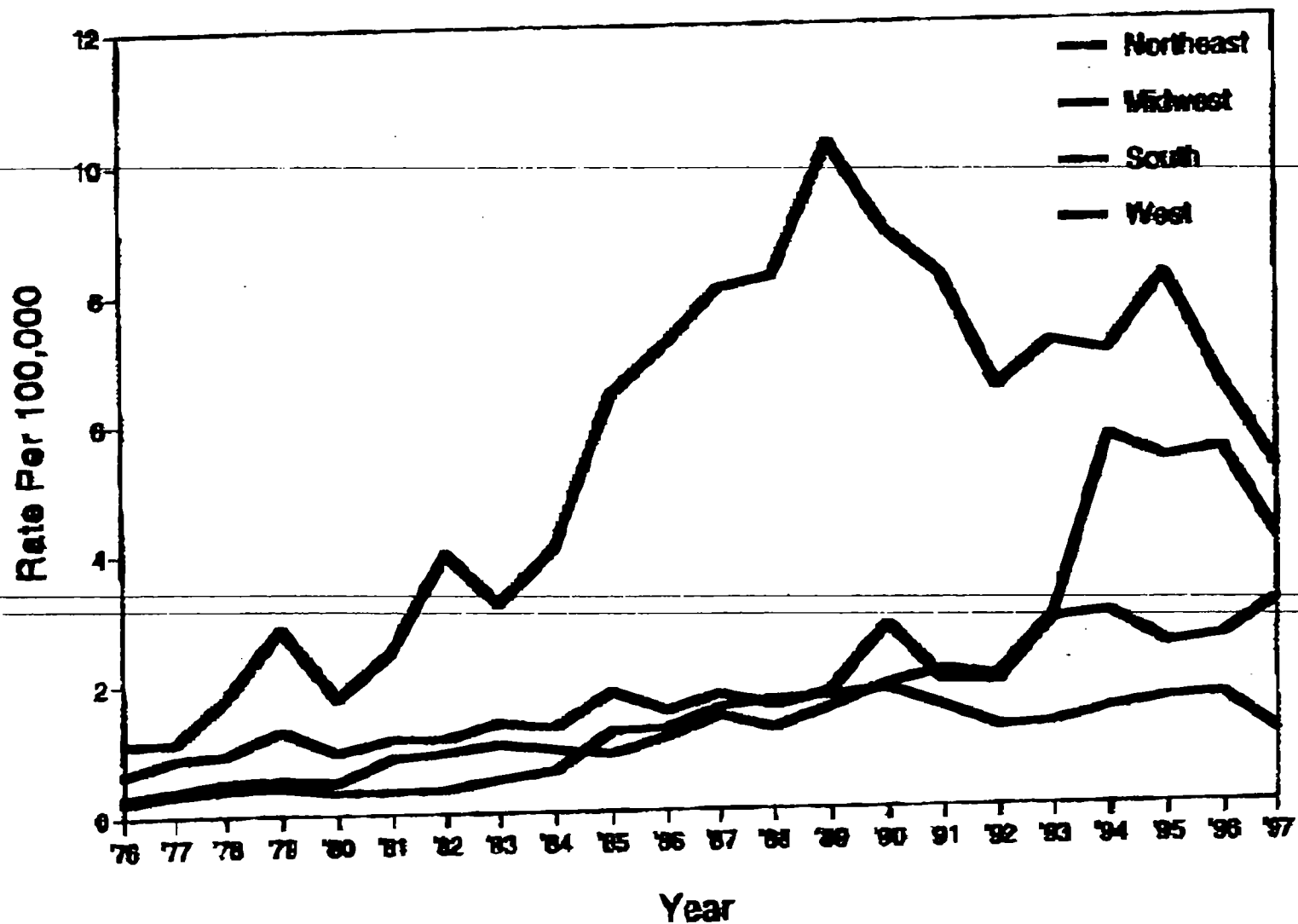
consumers to understand and control SE, and to encourage or require adoption of specific efforts to prevent contamination of eggs and illness among consumers. The decreasing numbers of infections and outbreaks encourages us. We recognize, however, that progress has been too slow and the magnitude of the remaining public health problem is too great. SE and its association with eggs has been hard to understand and has revealed its secrets slowly, and the way toward its control has been less straightforward than we had hoped.

While much has been done to address these challenges, more is needed. We will conceive and construct a disease prevention and control strategy that will pull together all of the separate actions - whether FDA, USDA, or state-based - needed to provide for a more comprehensive, coordinated approach. It is our expectation that the strategic plan we will release by November 1, 1999 will provide that approach.

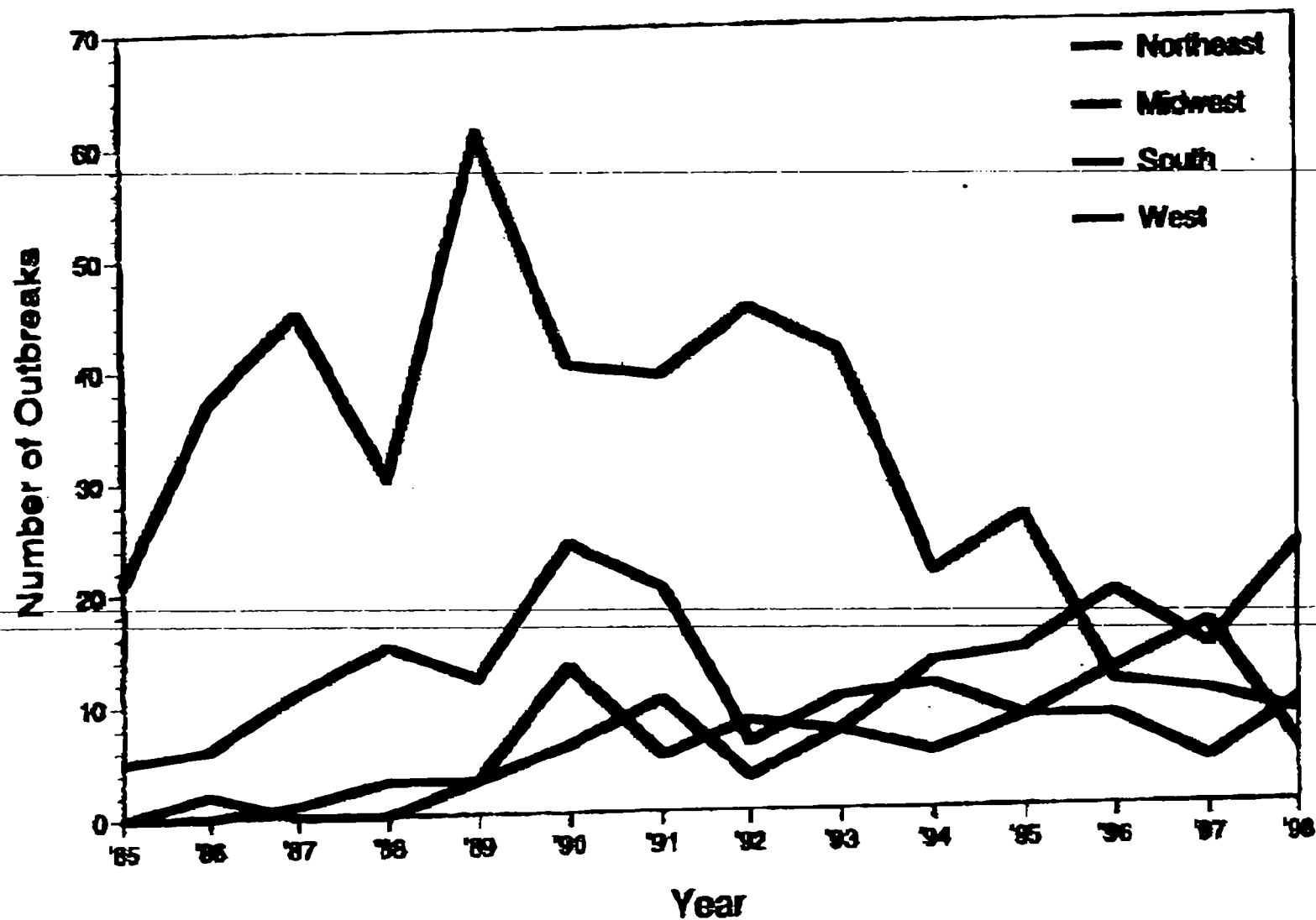
Mr. Chairman, in response to the question posed by the title of this hearing, "Egg Safety: Are There Cracks in the Federal Food Safety System?" we feel that while there clearly are complex lines of jurisdiction over eggs between FDA and USDA, those lines are not "cracks", but seams. We are committed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

I would be happy to answer any questions.

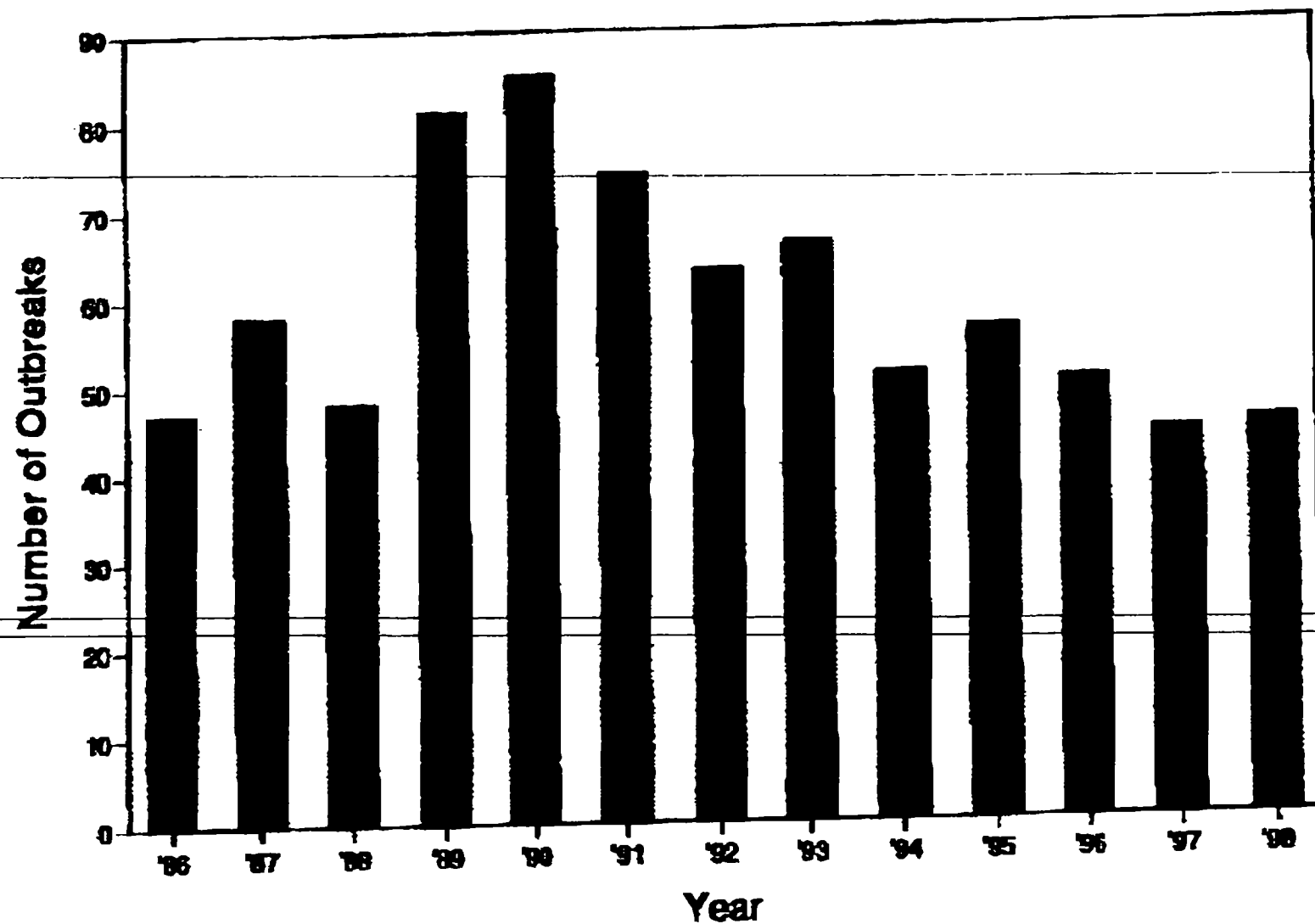
Salmonella Enteritidis Isolation Rates by Region, 1976-1997



Salmonella Enteritidis Outbreaks by Region, U.S. 1985-98

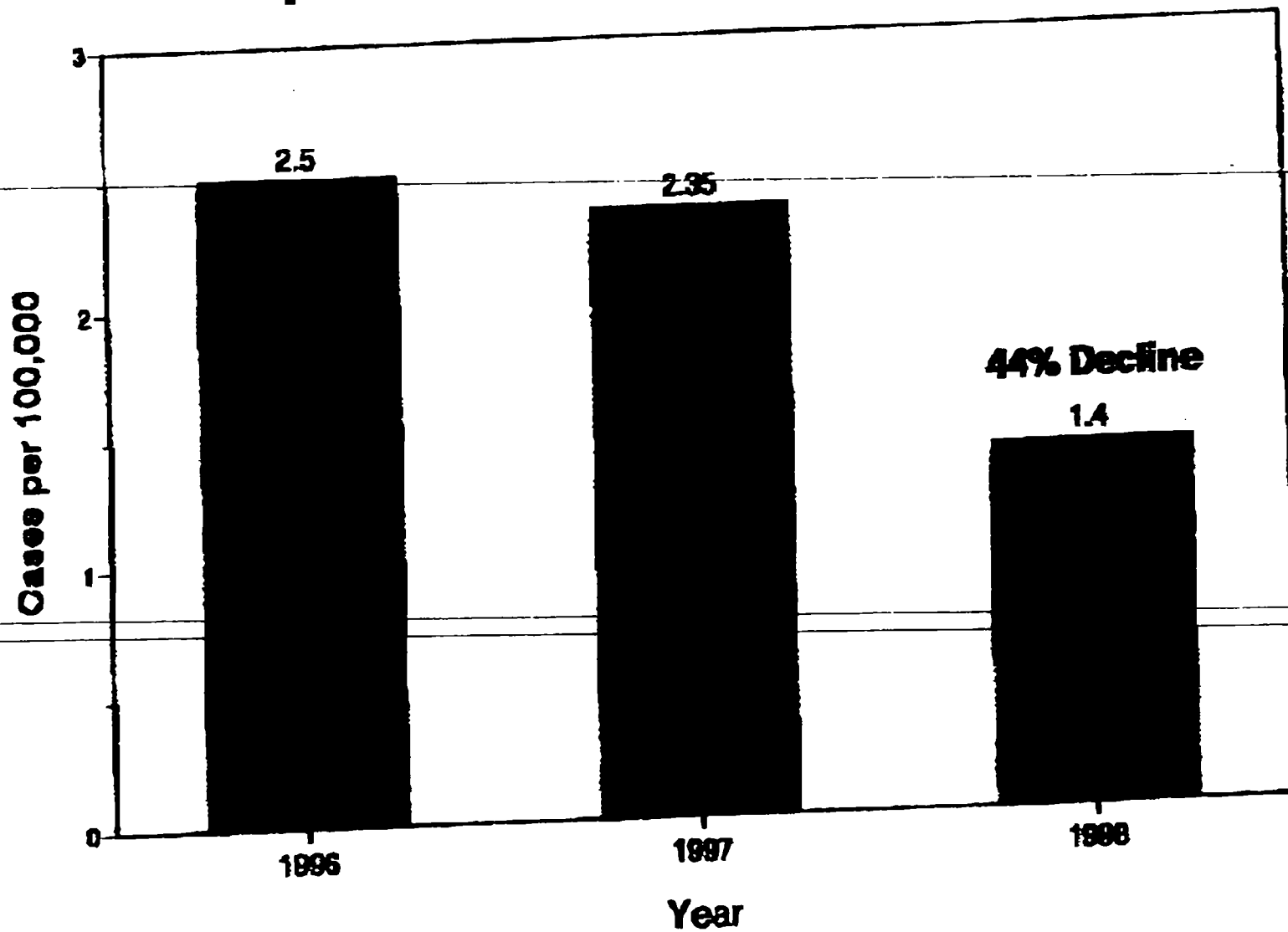


Reported Outbreaks of *Salmonella Enteritidis* Infections in the United States, 1985-98



CDC SE Outbreak Surveillance, N=794

FoodNet Salmonella Enteritidis Cases per 100,000 Population, 1996*-98



*Only data from original 1996 outbreak cases included.

06/24/98 10:35 AM 10.004 P.24

Total Pages: 12

LRM ID: MLG170

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

Monday, June 28, 1999

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

FROM: *John D. Burnim*
John D. Burnim (for) Assistant Director for Legislative Reference

OMB CONTACT: Michael L. Goad
E-Mail: Michael_L_Goad@omb.eop.gov
PHONE: (202)395-3857 FAX: (202)395-5691

SUBJECT: AGRICULTURE Oversight Testimony on USDA/Food Safety Inspection Service's Egg Products Inspection Program

DEADLINE: 2:00 PM, Tuesday, June 29, 1999

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

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**LRM ID: MLG170 SUBJECT: AGRICULTURE Oversight Testimony on USDA/Food Safety
Inspection Service's Egg Products Inspection Program**

**RESPONSE TO
LEGISLATIVE REFERRAL
MEMORANDUM**

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet. If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.

You may also respond by:

(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or

(2) sending us a memo or letter

Please include the LRM number shown above, and the subject shown below.

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 Office of Management and Budget
 Branch-Wide Line (to reach legislative assistant): 395-6194**

**FROM: _____ (Date)
 _____ (Name)
 _____ (Agency)
 _____ (Telephone)**

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other: _____

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

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

July 1, 1999

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

Let me begin by emphasizing USDA's commitment to improving the safety of the foods it regulates—meat, poultry, and egg products. Over the past several years, USDA has implemented a strategy for change that emphasizes the need to prevent food safety problems before they happen and the need to address food safety hazards all along the farm-to-table chain. This strategy also emphasizes the responsibility of industry to produce safe food and the responsibility of government to establish and monitor science-based food safety standards and to ensure that they are met.

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

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

We have not won the war against foodborne illness by any means, and eggs still remain a major source of SE. But the steps we have taken are making a difference, and we at USDA are committed to further progress in reducing the incidence of foodborne illness attributable to meat, poultry, and egg products.

USDA Reorganization Act of 1994

FSIS has a long history of inspecting meat and poultry products, but the Agency's involvement in egg products inspection is relatively new. The USDA Reorganization Act

of 1994 set the stage for FSIS involvement in egg products inspection by transferring this responsibility from AMS to FSIS.

Under the Egg Products Inspection Act (EPIA), FSIS is responsible for

✓ continuous Federal inspection in plants processing liquid, frozen, and dried egg products.

~~FSIS IS ALSO RESPONSIBLE FOR THE LABELING +~~

^ The regulations governing the inspection of eggs and egg products specify minimum

~~TRANSPORTATION OF SHELL EGGS.~~

requirements for plant facilities, equipment, sanitation, processing procedures, and the

testing of pasteurized products for *Salmonella*. The regulations also require continuous

inspection of the packaging and labeling of egg products. During fiscal year 1998, 102

FSIS inspectors monitored operations at 73 egg products plants around the country. FSIS

also had cooperative agreements with six States to provide inspection of egg products.

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

The current statutory framework for egg safety established by Congress has been described as “fragmented,” and I am not here today to counter that description. But I do want to make the point that USDA activities regarding shell eggs and egg products go beyond FSIS, and any effort to adjust the current statutory framework for egg safety should consider the broad range of activities carried out by USDA agencies.

For example, the AMS administers a voluntary grading program, supported by user fees, as a service to shell egg processing plants. On April 27, 1998, AMS announced a prohibition on the repackaging of eggs packed under its voluntary grading program, and public rulemaking to permanently prohibit this practice is in the final stages of clearance.

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

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

voluntary program, NPIP participation is necessary for those producers that ship interstate or internationally. In addition, APHIS -- in conjunction with FSIS -- monitors the importation of shell eggs from countries under disease restrictions to ensure that exotic Newcastle disease and *Salmonella enteritidis* phage type 4 are not present.

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

USDA also carries out food safety research through ARS and through the National Research Initiative Competitive Grants Program administered by USDA's Cooperative State Research, Education & Extension Service (CSREES). For example, Washington University in St. Louis, Missouri has received a three-year grant to study how *Salmonella* adheres to chicken cells, and Indiana's Purdue University is in the midst of a project to develop an oral vaccine against SE.

Through ARS research, we have gained important knowledge, such as the fact that hens infected with SE can produce eggs that are contaminated internally, and that feed withdrawal may increase the transmission of SE infections in flocks. We have new

methods for detecting strains of SE that are epidemiologically important, and we have helped to develop new products that competitively exclude *Salmonella* from chickens.

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

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

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

FSIS/FDA Cooperation

Of course, FSIS shares statutory authority for egg safety with the Food and Drug Administration (FDA). Despite the challenges posed by this statutory framework, FSIS and FDA have worked closely together to develop a coordinated approach to the problem of SE in eggs and egg products. This type of challenge is not new to the two agencies. Over the past several years, we have worked together on a number of food safety issues

that involve both agencies. For example, FSIS and FDA have worked closely on HACCP implementation for various foods. We have worked closely together on foodborne disease surveillance and outbreak response. And we both are working to strengthen the *Food Code* and to encourage its adoption by States and local jurisdictions.

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

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

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

On August 27, 1998, FSIS published a final rule to implement the requirements for the refrigeration and labeling of shell eggs that were mandated by the 1991 amendments to the EPIA. The rule requires that shell eggs packed for consumers be

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

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

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

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

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

Upcoming Initiatives

The risk assessment will enable us to better evaluate interventions in terms of public health impact as we further develop our food safety strategy for shell eggs and processed eggs.

For example, the risk assessment is being used to develop a proposed rule that is similar in many ways to the Pathogen Reduction and HACCP rule for meat and poultry products published in 1996. The rule would mandate HACCP for egg products and set science-based performance standards for pasteurization. It also would mandate Sanitation Standard Operating Procedures and remove the prior approval requirements for equipment and blueprints. We hope to publish the rule by Spring 2000.

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

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

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Stephane Williams
224-5441
Archie Lindberg

Imports

Hubbard

Sunny

g/a

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Eric

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Tim Calum

(unrecorded) 301-827-3370

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Karen Anderson
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Food is listed - Wholesale, not retail value

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Shirley MacMurray

violate the rules and work to subvert the system. We must give the agencies responsible for food safety the tools necessary to deal with the importers who try to break the rules. While the Food and Drug Administration (FDA) inspects domestic facilities, it has, in conjunction with the United States Customs Service (Customs), relied primarily on border inspection to ensure the safety of imported foods.

I recognize there are limitations on our resources and statutory authority to take measures to protect consumers against unsafe imported foods. Indeed, there are currently bills before Congress that would grant explicit authority to improve the safety of imported foods. I applaud these legislative efforts and will continue to work with Congress to improve our authority and resources.

Nevertheless, consistent with our international obligations, we must take whatever steps we can to protect the public health in this area and provide the necessary tools to ensure the safety of imported food. Consequently, I direct the Secretaries of HHS and Treasury, in consultation with other relevant federal agencies, most particularly the Department of Agriculture, to report back to me, through my Food Safety Council, within 90 days on administrative actions available to FDA and Customs working together or separately to protect consumers from unsafe imported foods. Specifically, I direct you to take all actions available to:

- (1) Prevent distribution of imported unsafe food by means such as requiring food to be held until reviewed by FDA; *before storage - take it out of the importer control*
- (2) Destroy imported food that poses a serious public health threat; *— right now up to importer*
- (3) Prohibit "port shopping" -- *FDA will promote to work* preventing imported food that had been previously refused admission from being reimported without being brought into compliance with United States laws and regulations; *— not illegal now / letting go*
- (4) Require the marking of shipping containers and/or papers of imported food that is refused admission for safety reasons;
- (5) Require prenotification to Customs and FDA of information about imported food prior to its arrival at the border in order to allow the agencies to target their resources as necessary to better prevent the importation of food that poses risks to health; *chronic violations*
- (6) Set standards for private laboratories for the collection and analysis of samples of imported food for the purpose of gaining entry into the United States;
- (7) Increase the amount of the bond posted for imported foods when necessary to deter premature and illegal entry into the United States; and *3 times as the standard amount*
- (8) Impose civil monetary penalties for violations of United States laws related to the importation of foods.

Customs has penalties - force them to comply to Customs - get force

FOCUS-Democrats launch new attempt for food safety bill

By Julie Vorman

116

WASHINGTON, June 24 (Reuters) - Two dozen House and Senate Democrats introduced a bill on Thursday to create a single food safety agency, saying the recent food scares in Europe showed it was vital for the U.S. government to "speak with one voice" on all food safety issues.

The legislation, which would combine food inspectors and regulators from a dozen existing federal agencies, has been introduced three previous times in Congress without success.

This time, a lone Republican -- Rep. Tom Latham of Iowa -- also joined 25 Democrats in sponsoring the bill.

"The political momentum for this is growing," said Sen. Dick Durbin, an Illinois Democrat who has repeatedly pressed for a single food safety agency.

"Unless we speak with one voice about food safety, we will lose credibility with consumers," he added, referring to an EU food crisis over Belgian meat, milk and eggs suspected of contamination with cancer-causing dioxin.

Two U.S. agencies -- the Food and Drug Administration and the U.S. Agriculture Department -- have each announced a ban on imports of foods linked to the dioxin contamination. The USDA regulates meat and poultry while the FDA has responsibility for most other foods. Both share jurisdiction over eggs.

As many as 80 million Americans annually fall ill with diarrhea and other symptoms ranging from E. coli in fresh fruits to deadly listeria in hot dogs, according to the government's best estimates. About 9,000 die.

The U.S. food industry has fiercely opposed all efforts to combine regulatory divisions into a single food agency. It contends that better cooperation is needed among existing regulators, not a new bureaucracy.

Durbin said he expected a cabinet member, whom he did not identify, to soon endorse the bill.

But the Clinton Administration is not convinced that a single food safety agency would offer consumers better protection, Agriculture Secretary Dan Glickman said.

The administration prefers to step up coordination of the food safety activities, research and budgets that already exist within a dozen federal agencies, he said in an interview following a speech to a school nutrition meeting.

"These issues of reorganizing the boxes of government sometimes get in the way of what makes a real difference," Glickman said. "The jury is still out" on whether a single food safety agency would do a better job, he added.

Under current federal law, the USDA must inspect meat and poultry plants daily while the FDA typically inspects other food plants once every five to ten years.

A study by the National Academy of Sciences last year recommended that a single powerful government official be appointed to oversee all food safety issues from farm to table. The group's report said that a cabinet-rank food safety agency was one of several possible ways to achieve the goal of a unified federal policy.

The General Accounting Office, the investigative arm of Congress, has repeatedly endorsed a single food safety agency in reports during the past decade.

The U.S. government spends more than \$1 billion annually on a variety of food safety programs, the bulk of which goes to the USDA for meat and poultry inspections.

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Top News**Gov't. Egg-Safety Efforts Hampered**Sports

By JENNIFER LOVEN Associated Press Writer

Lotteries

WASHINGTON (AP) -- Too many federal agencies are doing too little, too slowly to protect Americans from being sickened by salmonella-contaminated eggs, a new report concludes.

major

International

don't get it

NationalWashington

Raw or undercooked eggs -- found in thick-cut French toast, Caesar salad, homemade ice cream, unbaked cookie dough and other American favorites -- are among the most common sources of salmonella.

NBC-

Business

NOT

Wall Street

The General Accounting Office report, obtained Tuesday by The Associated Press, concludes that more consistent oversight is needed to bring eggs safely from the chicken to the table.

EntertainmentHealth/ScienceRegional

Among the problems found by Congress' investigative arm were that:

--Despite support from large egg producers, state agencies and others, the federal government has yet to fully develop a food-safety inspection system for egg farms and processing plants that is based on scientific testing rather than visual inspections.

41/43

--A new federal egg refrigeration requirement, to take effect in August -- eight years after it was mandated by Congress -- sets a temperature that may not be cool enough to be as effective as possible. Also, the rules only cover the eggs from packing until they reach retail locations, but not what happens on store shelves or in restaurants.

USDA
FDA

--The Food and Drug Administration and the Food Safety and Inspection Service have not agreed on a comprehensive approach to egg safety, although a 1992 GAO report said a plan was needed.

--With responsibilities distributed among four federal agencies, the nation's egg safety efforts lack an organizational focus and contain gaps, inconsistencies and inefficiencies," the researchers wrote. --Progress on

developing a comprehensive egg safety strategy has been slow."

The report plays neatly into the hands of Sen. Dick Durbin, D-Ill., who requested the study. Durbin, consumer groups and others on Capitol Hill have been pushing to consolidate the federal government's fragmented food-safety system. Food inspection and safety enforcement currently is divided mainly among the Agriculture Department, Commerce Department, FDA and Environmental Protection Agency.

"They have done very little to meet their statutory responsibility with respect to egg safety," Durbin said. "It is impossible to explain or defend."

Durbin plans to present the GAO report at a Senate Government Affairs subcommittee Thursday. He later intends to introduce legislation to consolidate all egg safety responsibility within USDA, require expiration dates and warning labels on eggs, prohibit the repackaging of old eggs and require a science-based inspection system.

Responding to the report, USDA and FDA said the positive things they have done, which have resulted in declining incidences of salmonella from eggs, were ignored by the GAO. But both agencies generally agreed with the GAO's recommendations.

"The USDA and FDA have been working together for many years on a coordinated approach to the problem of salmonella enteritidis in eggs," they said in separate letters.

Recently released data from the Centers for Disease Control and Prevention in Atlanta found a 44 percent decline in the number of salmonella cases from contaminated eggs in selected cities and states between 1996 and 1998.

Dr. David Swerdlow, a CDC epidemiologist, attributed the progress to better controls at the farm and during transport, as well as to increased public awareness. But he said it is still an important public health concern.

From the mid-1980s to the mid-1990s, egg-linked salmonella went from making up 6 percent of all salmonella cases to 23 percent, he said. In 1997, salmonella enteritidis appeared to have sickened 300,000 and caused at least 115 deaths.

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06/30

DRAFT

Stephane

445

Food Safety:

Nation Lacks a Consistent, Farm-to-Table Approach
to Egg Safety

DRAFT

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DRAFT

Dear Senator Durbin:

Eggs contaminated by the *Salmonella enteritidis* bacteria have been recognized as a public health problem since 1988. Each year, about 320,000 illnesses and between 115 and 230 deaths occur as a result of these contaminated eggs, according to the Centers for Disease Control and Prevention. These illnesses and deaths cost the nation between \$220 million to \$3 billion, according to the U.S. Department of Agriculture (USDA). The health risks associated with eating contaminated eggs is greater in older eggs that have not been properly refrigerated.

No single federal agency has overall responsibility for the policies and activities needed to ensure the safety and quality of eggs and egg products. Rather, these responsibilities are distributed among the Animal and Plant Health Inspection Service, the Agricultural Marketing Service, and the Food Safety and Inspection Service (FSIS) in USDA and the Food and Drug Administration (FDA) in the Department of Health and Human Services. Responsibilities for ensuring egg safety and quality shift among these agencies as eggs make their way from the farm to the table. In particular, FDA has primary responsibility for the safe production and processing of whole eggs and FSIS is responsible at processing plants where eggs are broken to create egg products. In addition, two agencies in each state generally share egg safety responsibilities.

Concerned about the risks associated with eating eggs contaminated with *Salmonella enteritidis* you asked us to review the adequacy of the nation's system for ensuring the safety of eggs. Specifically, we examined whether (1) a risk-based approach to food safety has been applied to egg production and processing, (2) a new federal policy on egg refrigeration will effectively reduce the risks associated with contaminated eggs, (3) federal and state policies on serving eggs to vulnerable populations and dating of egg cartons are consistent, and (4) federal egg safety resources are used efficiently and policies are coordinated effectively. As part of our review, we surveyed state officials responsible for egg regulation in the 50 states.

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Background

Among the many strains of salmonella, only *Salmonella enteritidis* (S.e.) is commonly found in eggs. *Salmonella enteritidis* was first found inside clean, intact shell eggs in 1988. Since that time, shell eggs have been identified as the leading source of S.e. infection, among cases where the source could be identified. From 1987 to 1997, reports of S.e. infections increased, as did the proportion of cases involving S.e., among the various strains of salmonella. Although not necessarily indicative of a national trend, recent Centers for Disease Control and Prevention data from selected counties and states has shown a decrease in S.e. cases for 1996 through 1998. *Salmonella enteritidis*, as well as other strains of salmonella, typically causes such symptoms as abdominal pain, fever, headache, and vomiting, but it can also lead to chronic conditions, such as arthritis, meningitis, and pneumonia. And it sometimes kills, particularly when victims are elderly. S.e. in shell eggs is believed to originate with the infection of the laying hen. Proper refrigeration can retard the growth of salmonella, and pasteurization or thorough cooking can kill it. (See app. I. for additional information on the prevalence, causes and illnesses related to S.e. contamination in eggs.)

The marked growth in bacterial foodborne illnesses, including salmonella, has led to changes in the federal food safety system. One notable change has been the introduction over the past few years of Hazard Analysis and Critical Control Point (HACCP) systems in meat, poultry, and seafood processing. In addition, in April 1998 FDA issued a proposed regulation requiring HACCP plans for all fruit and vegetable juice processors. HACCP is designed to actively monitor and control contamination throughout the food production process by identifying places where the greatest food safety risks exist, implementing methods to control the risks at those points, and then monitoring the efficacy of the controls.

The egg industry in the United States produced about 67 billion eggs in 1998. About 70 percent of these eggs are sold whole and are known in the industry as shell eggs. The production and distribution of shell eggs from the farm to the table is a multi-step process that involves (1) breeding of laying hens, (2) egg production on farms, (3) cleaning and packing of eggs at processing plants, (4) transportation of eggs from processing facilities to wholesalers and retailers, and (5) handling and preparation of eggs in restaurants, institutions and homes. The remaining 30 percent of the eggs produced are broken, pasteurized, and processed into liquid,

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frozen, or dried egg products. These egg products are incorporated in such foods as commercial baked goods and ice cream. (For more information on egg production and processing, see app. II.)

Egg regulatory laws have traditionally assigned responsibilities to federal agencies based on whether the concern is egg safety or quality and whether the egg is in the shell or is broken to create an egg product. Under this fragmented regulatory structure, responsibility for egg safety shifts back and forth among several federal agencies, and often two agencies in each state, throughout the farm to table continuum. (See fig. 1.) First, the Animal and Plant Health Inspection Service manages a program that establishes breeding practices to assure that laying hens are born free from S.e. At the next stage, farms where eggs are laid, the Food and Drug Administration has authority for egg safety. Once the eggs arrive at processing plants where they are either packed as whole shell eggs or broken for egg products, the authority is split between two agencies – FDA for whole shell eggs and the Food Safety and Inspection Service for egg products. While shell eggs are being processed, they may also be inspected by the Agricultural Marketing Service under a voluntary program to assure shell egg quality. Once transported to the retail level, both shell eggs and egg products are under FDA authority, but the millions of restaurants, institutions and other retail food operations throughout the United States are generally inspected by either a state agriculture or health department under state laws. FDA encourages uniformity among state laws by publishing and encouraging states to adopt the provisions of FDA's Food Code which recommends model practices for ensuring safer food. (See app. III. for additional information on federal and state agency egg safety and quality responsibilities.)

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

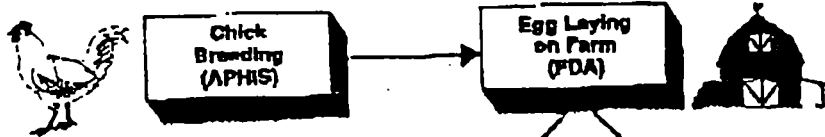
The Federal Government and the States Have Not Instituted a Consistent Risk-Based Approach to Egg Safety

Outbreaks of food borne illness are regularly traced back to egg production farms that have become contaminated with *Salmonella enteritidis*. Although risk reduction programs such as HACCP are generally recognized as the most effective method for identifying and reducing

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Production



Processing



Transportation



Storage



Preparation and Consumption



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bacterial contamination, no federal program exists to reduce or eliminate this contamination during egg production and processing.

In our 1992 report¹ on S.e. in eggs, we recommended that the Secretary of Agriculture and the Commissioner of FDA work together to develop a comprehensive program to control S.e. throughout the egg production, distribution, and consumption process. Six years later, in May 1998, USDA and FDA published an advance notice of proposed rule making in the Federal Register requesting comments by August 1998 on various proposals for improving farm-to-table egg safety, one of which related to HACCP on egg farms. The agencies received comments from state government agencies, egg industry associations, egg productions farms, public interest groups and individual citizens. Our analysis of the comments found strong support for a uniform, voluntary, national HACCP-based program to control SE during egg production. The state governments that commented were the most supportive of the idea. The idea was also supported by the largest egg industry trade association, the United Egg Producers, whose membership represents the owners of approximately 80 percent of all egg-laying hens in the country. As of April 1999, FDA, which has regulatory authority over shell egg production, had not taken any actions based on the comments received.

Some states, in cooperation with the egg industry, have established voluntary state-wide HACCP-based programs to control or eliminate S.e. during egg production. These programs are generally known as quality assurance programs even though their objective is to improve egg safety. In our survey of state egg regulatory officials, 13 states², which account for about 38 percent of the nation's egg production, reported that they have a voluntary quality assurance program. About half of these quality assurance programs began recently as 7 of the 13 states reported starting their programs in 1997 or 1998. In addition, producers may participate in other quality assurance programs such as the one designed by the United Egg Producers or establish a HACCP program on their own. FDA has entered into partnership agreements to provide guidance and technical support to some of the states that have adopted quality assurance plans.

¹ Food Safety and Quality: Salmonella Control Efforts Show Need for More Coordination (GAO/RCED-92-69, Apr. 21, 1992)

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

Seven elements are commonly found in state quality assurance plans: (1) purchasing chicks from National Poultry Improvement Plan approved breeders, (2) rodent and pest control, (3) bio-security procedures³, (4) cleaning and disinfecting hen houses, (5) environmental testing for S.e., (6) refrigeration of eggs, and (7) record keeping. The existing state egg quality assurance programs share many common elements, although some significant variations exist. While 11 of the plans require program participants to use rodent control and bio-security measures, 2 of the plans do not. All 13 of the plans require testing the egg laying environment for the presence of *Salmonella enteritidis*. In some states, if S.e. is found in the environment, the eggs are immediately diverted to breaking facilities where they will be pasteurized to kill the bacteria. In the other states, after environmental contamination is detected the eggs are checked. If S.e. is found in any eggs, all the eggs will be diverted to breaking facilities. In about half of the plans environmental testing is only done 8 weeks before the end of the flock's production cycle.⁴ However, 2 states have more extensive testing regimens that start before the chicken begins to produce eggs and continues periodically throughout the 2 year egg production cycle. This testing schedule allows problems to be identified before the chickens begin to produce contaminated eggs whereas the testing done in the other states, which comes near the end of the egg production cycle, provides less risk reduction.

The reliability and validity of a quality assurance program can be assessed through third party oversight. This oversight is generally performed by a government entity or other organization independent of the egg industry and provides assurances to the public that elements in the quality assurance programs are being faithfully performed. Most of the plans we reviewed, 9 of 13, contained provisions for oversight. In several of these plans the oversight was performed in part by industry associated groups, not by an independent third party. In addition the frequency and procedures used to conduct the oversight varied among the plans.

After eggs are produced on farms they go to a facility where they are cleaned, processed and packed. Egg packers and processors are not required to establish HACCP programs to prevent microbial contamination in the plants where shell egg are processed and packed for consumers.

³Bio-security procedures are designed to prevent S.e. from being carried into poultry houses from outside sources.

⁴ Hens in commercial egg laying operations produce eggs for about 2 years after which the birds are generally destroyed and a new flock begins production.

FDA has regulatory authority over shell egg processing plants and has not proposed HACCP requirements in this area. However, the Agricultural Marketing Service, which is primarily responsible for quality grading of eggs, has recently developed a fee-for-service plant sanitation program for its grading customers that includes some HACCP-like elements. (See app. III.)

At egg products plants eggs are washed, broken, separated, and pasteurized using automated processes. The Food Safety Inspection Service, which has regulatory authority over egg products, does not require HACCP in these plants. Under the Egg Products Inspection Act an FSIS inspector is required to be present at each egg products plant every day it is in operation.⁵ There are currently similar inspection requirements under federal law for meat and poultry processing plants. However, FSIS has recently issued regulations requiring the implementation of HACCP programs in meat and poultry plants. Implementation of this requirement has begun and preliminary results indicate a reduction in the presence of harmful pathogens on animal carcasses. In public statements, FSIS officials have indicated that implementation of HACCP at egg products plants is appropriate. However, to date the agency has not developed a plan nor taken any actions to accomplish this end. Despite the absence of a federal requirement some egg products plants have implemented HACCP plans on their own.

New Federal Refrigeration Requirements May Not Be As Effective As Possible

A soon-to-be implemented federal egg refrigeration requirement may not be as effective as possible in reducing the risks from Salmonella enteritidis contamination. In the multistep process used to bring eggs to consumers, egg safety can be jeopardized at many points because of lack of adequate refrigeration. Beginning in August 1999, FSIS will require that eggs be refrigerated at an air temperature of 45 degrees from the time they are packed until they reach the consumer. This requirement—initially mandated in the 1991 amendments to the Egg Products Inspection Act—was put into place only after the Congress threatened in 1998 to withhold \$5 million of FSIS' annual appropriation if the agency did not issue implementing regulations. In 1996, FSIS had informed the Congress that the agency had delayed in implementing the 1991 amendments because a regulation establishing an air temperature at

⁵ There are some minor exceptions to the continuous inspection requirement. For example, on weekends plants are permitted to operate without an inspector present.

which eggs must be held and transported would not address many of the underlying food safety problems posed by eggs.

Under the 1991 amendments, USDA is authorized to inspect shell egg processors and packers, including transport vehicles, to ensure that shell eggs are being held at no more than 45 degrees and cartons are properly labeled to indicate that they require refrigeration. USDA is required to conduct these inspections on a quarterly basis. FDA is authorized to ensure compliance with the same requirements at all other locations, such as food manufacturing establishments, health care facilities, and restaurants, as often as FDA determines inspections are appropriate.

USDA has not yet established how it will implement the refrigeration requirements. For example, USDA has not determined which agency—FSIS or the Agricultural Marketing Service—will be responsible for enforcing the new regulations. In addition, none of the procedures for implementing the temperature requirement have been established. For example, a key implementation question is how temperature will be measured: whether it should be a single measurement or an average over some time period and what part of the storage area or vehicle will be measured? In commenting on the final rule, the United Egg Producers said it was concerned “that the proposed regulation offers little more detail than is required in the 1991 law.” Furthermore, problems in resolving implementation questions have delayed the enforcement of California’s egg temperature law.

FDA officials do not believe that they need to develop implementing regulations for the new refrigeration requirement because they had authority under the Egg Products Inspection Act to conduct retail inspections. However, given the large number of food manufacturing establishments, restaurants, and institutions in the United States, and FDA’s limited inspection resources, it is not clear how FDA will enforce the new requirement. Although FDA has a retail food program that addresses food safety issues, including eggs, states or local jurisdictions have traditionally conducted the primary regulatory activity at the retail level, and FDA has supported state activities through training, technical assistance, and issuing guidance such as the Food Code.

While implementing the 1991 amendments is an important first step, FSIS and other egg experts have raised concerns about the effectiveness of an air temperature requirement in improving egg safety. According to FSIS, an internal temperature requirement would be more effective in controlling the growth of S.e. in contaminated eggs and therefore result in greater improvement in egg safety.

Salmonella enteritidis growth is severely limited at temperatures under 45 degrees. However, when eggs are processed and packed, according to UDSA, they are often in the 70 to 80 degree temperature range. Because of the way eggs are packed, even if they are immediately put into a cooler, research has shown it may take from 3 to 6 days before the egg's internal temperature is reduced to the air temperature. During this time any S.e. bacteria present can replicate and the more bacteria the egg contains the more dangerous it will be if eaten raw or undercooked. In a risk assessment study performed by FSIS, the agency found an 8 percent reduction in human illness when eggs are maintained at an air temperature of 45 degrees. In contrast, the study found a 12 percent reduction in illness, a 50 percent improvement, if eggs are immediately cooled after lay to an internal temperature of 45 degrees.

New technologies show promise in achieving more rapid cooling at a relatively low cost. Researchers at North Carolina State University have experimented with cryogenic gas to rapidly cool eggs. Their research found that during commercial processing eggs could be cooled to 46 degrees within 9 minutes using cryogenic gases and that this approach would reduce the likelihood of Salmonella enteritidis growth in or on eggs. One company has developed a prototype cooling method using cryogenic gases, which will soon be tested in production. According to the company, this process will add about 3 cents or less to the cost of a dozen eggs. In addition, other research is being conducted on the use of forced cold air to reduce egg cooling time, and a process of in-shell pasteurization that has recently begun commercial application also includes rapid cooling of the eggs after pasteurization.

In the absence of federal refrigeration requirements, all but two states had adopted their own, but these requirements varied. Most significantly, 19 states do not require refrigeration from the time eggs are packed until they reach the consumer. For example, 15 states do not require eggs to be refrigerated during transportation, although refrigeration is generally required once they

reach their destination. Our survey found strong support for the establishment of uniform, national temperature requirements. Forty-three states said uniform national temperature requirements for egg storage and transportation should be a high priority for federal government action.

Inconsistent Policies and Practices Hamper Egg Safety Efforts

Once eggs reach consumers, federal and state efforts to ensure egg safety have weaknesses in two areas: (1) inconsistent protection of populations known to be particularly vulnerable to S.e. infections, such as the elderly in nursing homes; and (2) inconsistent rules for repackaging and using expiration dates that are misleading and could pose a food safety risk.

Vulnerable Populations Are Not Consistently Protected

Certain populations—such as the elderly in nursing homes—are more likely to experience severe health problems from eating S.e.-contaminated eggs than the general population. For example, the Centers for Disease Control and Prevention reported that 54 of the 79 deaths associated with outbreaks of S.e. between 1985 and 1998 were of individuals in nursing homes. In addition, the agency found that the likelihood of dying from a foodborne illness contracted in a nursing home was 13 times higher than from outbreaks in other settings. Shell eggs were implicated as the responsible food in 82 percent of the outbreaks analyzed where a cause was identified.

Because of the problems associated with S.e.-contaminated eggs, FDA's 1997 Food Code recommended that food service operators serving highly susceptible populations⁶ should substitute pasteurized shell eggs or egg products for raw shell eggs (1) in foods such as Caesar salad, mayonnaise, ice-cream and others that typically use raw or undercooked eggs and (2) when eggs are broken and combined in a container before cooking or are held for service after cooking. In the 1999 version of the Food Code, FDA modified its provisions on highly susceptible populations to include an exemption to the requirement to substitute pasteurized eggs when eggs are broken and combined if the food is prepared under a HACCP plan that ensures S.e. growth is controlled before and after cooking and is destroyed during cooking.

⁶ Highly susceptible populations include (1) the immune compromised, (2) the elderly in nursing homes or hospitals, and (3) pre-school age children in facilities such as day care centers.

According to our survey of state egg regulatory officials, many states have not fully adopted the 1997 Food Code recommendations regarding serving eggs to highly susceptible populations. Twenty-four of the 50 states told us that they did not require food service operators that serve highly susceptible populations to use pasteurized eggs for any food item that usually contains raw eggs, such as Caesar salad dressing. Furthermore, in 26 states, food service operators are not required to use pasteurized eggs when they crack, combine, and hold a number of eggs prior to cooking or after cooking and prior to service, such as scrambled eggs on a buffet table. In addition, according to a 1998 Dietary Managers Association⁷ survey of 136 private nursing homes, hospitals, and other care facilities and 29 Air Force hospitals across the nation, 38 percent of these institutions use unpasteurized shell eggs in the preparation of batters for foods that may not be fully cooked, such as French toast.

Inconsistent Rules on Repackaging and Dating Egg Cartons

Two key risk factors can affect the ability of S.e. to grow in eggs—age and temperature. Experts agree that an egg's natural defenses to S.e. can break down as an egg ages or an egg is exposed to high or fluctuating temperatures. Therefore, ensuring that eggs are fresh and maintained under a consistent, appropriate temperature from packing to the table are critical S.e. reduction measures.

Because of these risk factors, concerns have surfaced about the practice of repackaging and redating shell eggs that are about to reach their expiration date. In April 1998, a national news organization reported that eggs are sometimes removed from grocery stores a few days before their expiration or sell-by dates and returned to an egg processing plant, where they are rewashed, repackaged, placed in cartons with fresh eggs, and given a new expiration date. While FDA, USDA, state agriculture and industry officials told us that they do not believe this practice is widespread, some officials contend that it may present a food safety hazard. Eggs that are repackaged must be transported to the processing plant and therefore may be subject to temperature fluctuations as well as additional heating during rewashing.

⁷ The Association represents approximately 15,000 dietary managers and food protection professionals nationwide.

USDA and FDA have reacted differently to these concerns. USDA's Agricultural Marketing Service announced that, as of April 27, 1998, the practice of repackaging and redating eggs would be temporarily prohibited for the one-third of the nation's eggs graded and packed under its voluntary grading program because the practice can mislead consumers about the eggs' freshness. The Service is currently developing regulations to make this prohibition permanent. FDA, which has regulatory authority over all shell eggs, announced in May 1998 that it was considering appropriate measures to address repackaging but, as of April 1999, had not taken any action to prohibit the practice. The differences in these two practices may be misleading to consumers because USDA-graded and non-USDA-graded eggs are colocated in grocery store coolers. The United Egg Producers have stated that a federal prohibition on repackaging eggs should be consistently applied to all eggs, whether they are packed in cartons bearing the USDA grade shield or not. Our survey of state egg regulatory officials found that only 10 of the 50 states have laws prohibiting repackaging.

With respect to expiration dates, neither the Agricultural Marketing Service nor FDA require them on egg cartons. However, according to agency officials, almost all producers in its voluntary grading program take this optional step. If they do, the Service requires that the expiration date can be no more than 30 days from the date the eggs were packed. Egg processors that do not participate in the agency's grading program typically include expiration dates of either 30 or 45 days although some do not provide any expiration date. Because some eggs are packed under the agency's voluntary grading program and others are not, expiration dating practices are not consistent.

While the difference in safety between an egg that is 30 days versus 45 days may be negligible, according to some experts, inconsistent expiration dating practices can mislead consumers. For example, both USDA-graded and non-USDA graded egg cartons sit side-by-side in the retail cooler. When comparing carton dates, a consumer may be more likely to select the eggs not graded by USDA because the later date on the carton seems to imply that those eggs will be fresher for a longer period of time. FDA recognizes that this inconsistency may be misleading to consumers and in a May 1998 notice in the Federal Register sought comments on whether this practice violates the Federal Food Drug and Cosmetic Act provisions on misbranding. As of April 1999, FDA has not issued any rules on expiration dating.

Our survey of state egg regulatory officials found that only 17 of the 50 states require either an expiration or a sell-by date on egg cartons sold in their state. A National Egg Regulatory Officials' committee⁶ plans to work towards developing guidelines for its members for uniform labeling of egg cartons because many eggs are transported interstate. These officials believe that such uniformity would help assure the safety and quality of the product.

Fragmented Structure Makes Effective Resource Allocation and Policy Coordination Difficult

The fragmented regulatory structure for eggs has hampered the federal government's ability to act efficiently and effectively to improve egg safety. Since different agencies are assigned different responsibilities for egg safety, the government does not have an effective mechanism for assessing overall risk and assigning resources accordingly. Furthermore, although FSIS and FDA are trying to work around this fragmentation, they have been unable to achieve improvements on egg carton labeling or a comprehensive egg safety approach in a timely fashion.

Egg Safety Inspection Resources Not Allocated Based on Risk

Under the current regulatory and organizational framework, there is no overall federal policy focus for ensuring egg safety resources are used in the most efficient manner. As discussed earlier, responsibility for ensuring the safety of shell eggs and egg products is split between FDA in the Department of Health and Human Services and FSIS in the Department of Agriculture. In approaching its egg safety responsibilities, each agency independently assigns resources for egg inspections based upon its own regulatory approach, priorities and available funding for food safety activities.

FDA generally follows a regulatory approach that allows foods to enter the market without preapproval and, therefore, does not inspect foods on a regular schedule. As a result of this approach, and due to limited resources, FDA almost never inspects shell egg production and processing operations. USDA, on the other hand, follows a regulatory approach that generally

⁶The National Egg Regulatory Officials is an organization with members from 35 state departments of agriculture involved in shell egg and egg products regulations and programs.

requires inspections before a product reaches the market. For example, FSIS is required by law to conduct daily continuous inspections of all egg products plants in the U.S..

Under the current regulatory system, egg safety inspection resources are not directed to the areas of highest risk. Most federal egg safety inspection resources are currently directed toward egg products even though during processing the eggs are pasteurized to kill harmful bacteria such as salmonella enteritidis. In fiscal year 1998 FSIS had 102 full-time inspectors dedicated to daily, continuous inspection at all egg products plants in the country. In contrast, even though shell eggs generally are not pasteurized, given FDA's limited inspection resources the agency almost never inspects egg farms and inspects plants where shell eggs are processed and packed only about once every 10 years. The focus of FDA inspections in these plants is sanitation practices and does not routinely include testing for S.e..

As we previously reported,⁹ this diverse regulatory approach results in inconsistent oversight and a system that does not base inspection frequency on food safety risk. If HACCP systems are implemented in all egg products plants it may be possible to reduce or eliminate the current practice of continuous inspection which could allow inspection resources to be redirected to areas of higher risk. As we have reported in regards to continuous inspections of meat and poultry plants, this type of inspection will be unnecessary to protect food safety after the introduction of HACCP systems.¹⁰

Actions on Egg Carton Labeling and Comprehensive Egg Safety Strategy Have Been Slow

Although FDA and FSIS have announced their intention to work together on egg safety activities, progress has been slow. In our 1992 report¹¹, we found that USDA's and FDA's efforts to control illness from S.e. contaminated eggs was stymied by questions about jurisdiction, among other things. Because FSIS and FDA have jurisdiction over different aspects of egg safety, the agencies are each currently developing different egg carton labeling requirements.

⁹ Food Safety and Quality: Uniform, Risk-based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992)

¹⁰ Food Safety: Risk-Based Inspection and Microbial Monitoring Needed for Meat and Poultry (GAO/RCED-94-110, May 19, 1994)

¹¹ Food Safety and Quality: Salmonella Control Efforts Show Need for More Coordination (GAO/RCED 92-69, April 1992)

The 1991 amendments to the Egg Products Inspection Act included a requirement that egg cartons be labeled "keep refrigerated" or words of similar meaning. However, FSIS did not write regulations implementing the 1991 amendments until August 27, 1998 which become effective a year later. In commenting on the proposed regulations some respondents recommended additional food safety labeling requirements. In response FSIS said that "with regard to the recommendations for additional labeling requirements, the statute does not specify any additional labeling provisions, and the Agency is not including additional labeling requirements in these regulations." FDA, however, has begun developing a proposal for an egg safety label that would go beyond the keep refrigerated requirement soon to be implemented by FSIS. FDA has not yet made public the language it will propose although other groups have suggested, for example, advising that eggs should not be eaten raw and should be cooked until firm. Consumers have already waited 8 years for FSIS to implement the Congressionally mandated refrigeration label for eggs. Now there will be further delay as another federal agency develops additional egg safety labeling requirements.

Our survey of the states found that while 23 states at a minimum require egg containers to be labeled "keep refrigerated", 27 other states have no such requirements. In the absence of federal or state requirements some egg producers may voluntarily label egg cartons to show that refrigeration is required. We asked state regulatory officials whether their state requires egg cartons to contain words that tell the consumer not to eat eggs raw and to cook the eggs thoroughly. Only one state told us that they require either of these consumer warnings.

In our 1992 report on S.e. control efforts, we reported that coordination difficulties resulted from the split regulatory structure and consequently the federal government had not agreed on a unified approach to addressing the problem of S.e. in eggs. Now 11 years after the problem of S.e. in eggs was first identified the federal government still has not agreed on a unified approach to address the problem. In May 1998, FDA and FSIS issued a joint advance notice of proposed rulemaking seeking to identify farm-to-table actions that would decrease the food safety risks associated with eggs. The notice recognized that eggs contaminated with S.e. continue to be a public health concern and sought comments by August 1998 on a wide range of actions that could be taken by the two agencies to improve farm-to-table egg safety.

Little progress has been made by FSIS and FDA in developing a unified farm-to-table egg safety approach. Although FSIS received about 70 comments from state regulatory agencies, industry associations and other interested parties, no official FDA/USDA group has been formed to review these comments or to establish a unified regulatory strategy. According to FSIS officials, there is no established time table for completing the strategy and as of April 1999 they had not formed an FDA/FSIS team to work on the issues.

Scope and Methodology

To conduct this review we spoke with, and obtained studies, data and other information on egg safety from FDA, the Centers for Disease Control and Prevention, the Animal and Plant Health Inspection Service, the Agricultural Marketing Service, and FSIS. We also conducted a telephone survey of all 50 states in January and February 1999 and visited egg regulatory agencies in four states –California, Georgia, Illinois, and Pennsylvania. To obtain answers to all of the survey questions we frequently spoke to several egg regulatory officials from different agencies in each state. We completed interviews with all 50 states for a response rate of 100 percent.

To determine whether the risk-based approach to food safety, known as HACCP, has been applied to egg production and processing, we (1) conducted interviews with USDA , FDA and state officials, (2) analyzed the HACCP-based safety plans being implemented in 13 states, and (3) reviewed HACCP regulations for meat, poultry and seafood. To determine whether federal policies on egg refrigeration are effective, we discussed with USDA, FDA and state officials the reasons for their egg refrigeration requirements and reviewed the scientific literature on the effect of temperature on the growth of salmonella.

To determine if federal and state policies on serving eggs to vulnerable populations and dating of egg cartons are consistent, we reviewed FDA's Food Code and federal and state egg safety laws and regulations and discussed current policies and practices with federal and state officials. To determine whether federal egg safety resources are used efficiently and policies are coordinated effectively, we interviewed USDA and FDA officials regarding the scope and frequency of egg safety inspections for shell egg and egg products plants. We also discussed their efforts to

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coordinate implementation of egg carton labeling requirements and to develop a farm-to-table egg safety strategy.

We conducted our work from August 1998 through April 1999 in accordance with generally accepted government auditing standards.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time we will send copies to the congressional committees with jurisdiction over food safety issues; Dan Glickman, the Secretary of Agriculture; Donna E. Shalala, the Secretary of Health and Human Services; and other interested parties. We will also make copies available to others on request.

If you have any questions about this report please contact me at (202) 512-5138. Major contributors to this report are listed in appendix ??.

Sincerely yours,

Lawrence J. Dyckman

Director, Food and Agriculture Issues

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Appendix I

Salmonella Enteritidis Contamination in Eggs

Over the last decade, shell eggs contaminated with *Salmonella enteritidis* bacteria have increasingly been implicated as the cause of foodborne illness in the United States. According to the best available data from the Centers for Disease Control and Prevention, *Salmonella enteritidis* may have caused up to 320,000 illnesses in 1997, resulting in 115 to 230 deaths. Significant economic costs result from S.e. illnesses and deaths, with estimates ranging from approximately \$225 million to \$3 billion in 1996. Although not all S.e. infections are linked to eggs, between 1985 and 1998, 81.7 percent of S.e. outbreaks¹² with an identified cause were associated with eggs.¹³

Increasing *Salmonella Enteritidis* Infections

Officials at the Centers for Disease Control and Prevention first cast doubt on the internal safety of shell eggs in a 1988 study of S.e.-related foodborne illness outbreaks that occurred in 1986 and 1987. The research in several northeastern states found that 77 percent of illnesses with an identified cause were associated with undercooked, clean, grade A shell eggs. Since this initial connection, illnesses related to S.e. in eggs have been a growing problem through the mid-1990s. S.e. progressed from an infrequent cause of human illness to one of the most common strains, or serotypes, of *Salmonella*, growing from 15.6 percent of total *Salmonella* cases in 1987 to 22.9 percent in 1997. Recently released data from the Centers for Disease Control and Prevention for 1996 through 1998 indicate a possible change in trends, as S.e. infections decreased by 44 percent in selected counties and states. S.e. also fell from the most common strain of *Salmonella* from 1993 to 1996 to the second most common strain in 1997. According to agency officials, while these data are encouraging, they are not conclusive evidence of a nationwide reduction in S.e.

¹² An "outbreak" is defined as two or more people having a similar illness which can be traced to eating a common food. In contrast, sporadic cases involve individuals who report foodborne illnesses outside a recognized outbreak.

¹³ In only 44 percent of cases could a responsible food be identified.

Factors Contributing to Salmonella Enteritidis in Eggs

Though no single explanation exists for salmonella's virulence and rapid rate of growth in the United States, several contributing factors have been identified, including changes in methods of animal food production and slaughter, changes in cooking practices, increasing centralization of food production, and larger scale distribution. For example, the increased amount of food produced and consumed outside the home may create an opportunity for incorrect preparation or cross-contamination, which can cause disease.

The transmission of S.e. from the farm environment, to egg-laying flocks, to eggs is still not fully understood. However, research at Pennsylvania egg producers during the early 1990s identified several factors that may increase bacterial levels and chicken contamination. These factors included heavy rodent population, older flocks, and forced molting.¹⁴ Once infected, chickens can pass the pathogen directly from their ovaries to the contents of eggs they lay. Some freshly produced eggs are thus contaminated before the shell forms around their contents. The exact scope and frequency of this problem are not known, but USDA estimates that about 2.3 million of the approximately 47 billion shell eggs consumed annually are infected with S.e.

Salmonella enteritidis infection in an egg does not always result in illness, though, since proper refrigeration will inhibit bacterial growth and cooking can ultimately kill it. Microbiological studies have found that Salmonella will grow at temperatures between 46 and 113 degrees and, therefore, refrigerating eggs at temperatures of 45 degrees and below will greatly inhibit the bacteria's replication. Moreover, cooking food at 160 degrees will instantly kill S.e. bacteria. For example, homemade ice cream and eggnog can be made safely only if the egg mixture is cooked to 160 degrees. Similarly, a hard cooked egg should be safe to eat; however, soft-cooked eggs may not be safe if they are not cooked long enough. For disease to occur, then, eggs usually must be contaminated at the farm or during processing and then improperly handled, inadequately refrigerated, or undercooked or consumed raw.

¹⁴ Forced molting is done to improve egg production. During a forced molt, chickens are deprived of feed for a week, which causes them to lose their feathers. After food is returned the birds will produce more eggs for a longer period of time than they would have without molting.

Salmonella Enteritidis Outbreaks and Illnesses

Over the years, outbreaks of S.e. have continued to be associated with a wide variety of egg-related foods, such as Caesar salad dressing, Hollandaise sauce and bread pudding. In many cases, these dishes contained either raw or undercooked eggs. (See table I.1.)

Table I.1: Examples of Salmonella Enteritidis Outbreaks and Egg-associated Foods, 1990-95

Year	Food associated with Salmonella enteritidis outbreaks
1990	Undercooked eggs in bread pudding
1991	Undercooked bread stuffing containing pooled raw eggs
1992	Cross contamination of cooked foods from uncooked, pooled eggs
	Banana pudding containing undercooked eggs
	Egg sandwiches
1993	Omelet, egg salad, scrambled eggs
	Hollandaise & Béarnaise sauce containing pooled raw eggs
	Sandwiches containing contaminated mayonnaise
1994	Hollandaise sauce containing raw eggs
1995	Baked eggs
	Caesar salad dressing containing raw eggs
	"Jamaican Malt Beverage" (a homemade drink of beer, raw eggs, milk, oatmeal and ice)

Source: Centers for Disease Control and Prevention

Human illnesses resulting from S.e. bacteria can cause a variety of serious health problems. Short-term salmonella problems, usually beginning 12 to 72 hours following contamination, include abdominal pain, bloody stools, diarrhea, fever, headache, and vomiting. More chronic diseases associated with Salmonella range from pneumonia to arthritis and meningitis. Patients' symptoms and the severity of their sickness can vary according to their personal characteristics and extent of exposure. Immune-compromised individuals, young children, and elderly patients in nursing homes are more susceptible to S.e. infections and have more severe symptoms and greater incidence of hospitalization and death. In S.e. outbreaks between 1985 and 1998, for example, approximately 68 percent of S.e.-related deaths occurred among nursing home residents. Moreover, the death rate for S.e. outbreaks in nursing homes was approximately 13

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times greater than the rate for all outbreaks. The higher death rates among the elderly have been attributed to many causes, including pre-existing illnesses and reduced immunity.

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Appendix II

Egg Production, Processing and Distribution From Farm to Table

Eggs are a significant agricultural commodity and an important part of most Americans' diets. Americans consume about 245 eggs per capita annually, fueling a domestic egg industry that produced 67 billion eggs for human consumption in 1998. These eggs had a retail value of \$3.65 billion.

Though eggs are sold and processed in almost every state, over 60 percent of egg production remains concentrated in the top 10 producing states. (See table II.1.) Geographically, these states vary widely, from California in the West; to Iowa, Indiana, Minnesota, and Ohio in the Midwest; to Pennsylvania and Georgia in the East. From 1985 to 1996, the number of commercial egg farms declined from approximately 3,000 to 900, and today the majority of egg production is concentrated on a relatively small number of large farms. About 340 egg producers have flocks of over 75,000 chickens, which together represent 97 percent of all domestic egg-laying hens.

Table II.1: Top 10 Egg-Producing States in 1998

States	Total number of eggs (millions)	Percentage of total egg production	Value of production (Millions of dollars)
1. Ohio	7,395	9.3	351
2. California	6,608	8.3	309
3. Pennsylvania	5,983	7.5	304
4. Iowa	5,969	7.5	225
5. Indiana	5,831	7.3	286
6. Georgia	5,126	6.4	376
7. Texas	4,257	5.3	254
8. Arkansas	3,233	4.1	263
9. Minnesota	3,152	4.0	126
10. Nebraska	2,706	3.4	97
Totals:	50,260	63.1	2,591

Source: National Agricultural Statistics Service

Note: Total egg production includes both eggs for consumption and for breeding purposes. Although exact data are not available, in 1998 about 84 percent of total eggs produced were eggs for consumption.

Egg production, processing, and distribution is a multi-step process. For eggs that are sold whole, known as shell eggs, this process involves five major steps: (1) chick breeding, (2) egg production on farms, (3) washing and candling, (4) weighing, sorting and packing, and (5) transportation and sale. Typically, commercial firms breed chicks for egg laying and sell them to egg farmers or independent pullet growers. The chicks then grow for 20 weeks before they mature and begin to lay eggs. After laying, eggs are processed in either in-line or off-line operations. At in-line facilities, eggs are transported by conveyor belts from the laying house directly to an adjacent processing plant. In some cases, in-line facilities may also process eggs that have been gathered and transported from an outside location. At off-line facilities, eggs are gathered by hand and stored on the farm before being transported to a processing facility at another location.

Upon arrival for processing, eggs are washed and sanitized to remove dirt, feces, and bacteria collected in the laying house. Following washing and sanitizing, they are dried to remove remaining moisture and oiled to seal pores in the shell. Processing plant employees use a candling machine, which shines light through the egg shell, to ensure the quality and wholesomeness of the contents by identifying and removing any eggs that are dirty, cracked, leaking, or rotten, as well as those that contain blood spots. The eggs are then sorted, weighed, and packed in cartons labeled with their appropriate grade and size. Eggs are graded for quality as AA, A, or B based on interior and exterior factors including the shell, air cell, yolk and white. Size grades include jumbo, extra large, large, medium, small, or peewee. The packaged eggs are then consolidated into boxes and flats and stored in coolers until they are transported to retail stores and institutions.

While shell eggs are sold whole to consumers, some eggs are broken to create egg products. These products are sold dried, frozen, or maintained in liquid form for individual or commercial use. The ability of egg products to be used separately or combined with other ingredients gives them many uses. These uses range from frozen egg patties for fast food restaurants to liquid

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eggs, yolks, or whites used for cooking. In addition, egg yolks with sugar added can be used in the commercial production of ice cream, while egg yolks with salt can be used in producing mayonnaise.

The processing of egg products shares many similarities with the multi-step approach that defines shell egg processing. Upon arrival at an egg breaking plant, eggs are washed and candled and dirty, cracked or other problem eggs are removed. The eggs are then separated into yolks and whites by an automated breaking machine. Liquid eggs are pasteurized to kill any bacteria that may be present. Following pasteurization, the eggs are chilled or frozen. At the completion of the process, egg products are packed into containers or loaded directly as a chilled liquid in tankers.

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Appendix III

Federal and State Egg Safety and Quality Responsibilities

From the farm to the table, responsibility for egg safety and quality is distributed among four federal agencies in two departments—in the Department of Agriculture, the Animal and Plant Health Inspection Service (APHIS), the Food Safety and Inspection Service (FSIS), and the Agricultural Marketing Service (AMS) and, in the Department of Health and Human Services, the Food and Drug Administration (FDA). These agencies have responsibilities for egg safety and quality under five different laws and as a result use different regulatory approaches in addressing these issues.

APHIS Manages a Program to Produce Disease Free Chicks

Producing eggs and bringing them from the farm to the table is a multi-step process. At the first step in this process, prior to egg production on farms, USDA offers a program that attempts to ensure chicks that will become egg laying hens are born free of diseases, including Salmonella enteritidis (S.e.). In 1935, USDA implemented the National Poultry Improvement Plan for the improvement of poultry, poultry products, and hatcheries throughout the country. APHIS currently operates this program under the Department of Agriculture Organic Act of 1944, as amended (7U.S.C. 429).

The National Poultry Improvement Plan is a program that certifies that poultry breeding stock and hatcheries are free from egg-transmitted and hatchery-disseminated diseases. Program participation is available to producers or sellers of poultry and poultry products who demonstrate that their facilities, personnel, and practices adequately carry out the Plan's provisions. The states can also implement regulations that further define these provisions, or establish higher standards compatible with the Plan. The program is mandatory for those producers who ship interstate or internationally and voluntary for those who ship intrastate. However, although it is voluntary, farms often cannot sell their birds without the Plan's certification. According to APHIS officials, during 1998, 320 hatcheries in 36 states participated in the program.

APHIS changes the Plan's provisions from time to time as new information about poultry diseases becomes available from industry. For example, in July 1989 APHIS added a Plan component designed to reduce the incidence of Salmonella enteritis organisms in chicks that will grow up to produce eggs for human consumption, through an effective and practical sanitation program at the breeder farm and in the hatchery. APHIS operates the program through memorandums of understanding with state agencies. Either an APHIS inspector or an authorized state inspector assures that the Plan's standards are implemented, by inspecting the farm environment, collecting samples, and conducting blood tests of participating breeding flocks. Inspectors test breeder farms and hen houses every month for diseases throughout the life of the flock. If initial environmental test samples of the farm show the presence of bacteria, the birds are tested. To do this, the inspector draws blood samples for official tests conducted by authorized laboratories. If the birds test positive, the entire breeding flock is destroyed.

Egg Safety Responsibilities Are Divided Between FDA and FSIS

Federal authority to regulate the safety of eggs and egg products at egg farms and egg processing plants is shared by the Food and Drug Administration and USDA's Food Safety and Inspection Service. FDA has traditionally been responsible for shell eggs¹⁶ and FSIS for egg products. Soon to be implemented changes to the Egg Products Inspection Act will give USDA increased enforcement authority over shell eggs while they are being stored at processing plants and transported. FDA and USDA have different regulatory approaches. FDA generally follows a regulatory approach of allowing foods to enter the market without inspection, while USDA generally inspects products before they reach the market.

Food and Drug Administration Responsibilities

FDA has regulatory authority for shell eggs at three points in the farm-to-table process: (1) at egg farms, (2) at egg processing plants where eggs are washed and packed, and (3) at the retail level where eggs reach the consumer. The agency has sole federal authority for regulating food safety on egg farms under its authority to prevent the spread of communicable diseases, granted by the Public Health Service Act, and the adulteration provisions of the Federal Food Drug and

¹⁶ Shell eggs include whole shell eggs packed in cartons for individual consumers or packed in bulk for institutional use, as well as cooked shell eggs, such as hard boiled eggs, which may be sliced or chopped for use at the retail level.

Cosmetic Act. FDA currently conducts two main activities at egg farms. First, it conducts egg farm inspections, known as traceback investigations, only when a foodborne illness outbreak has been identified. Once the source of an outbreak is determined, FDA requires that eggs from S.e.-positive flocks are diverted from sale to the public and destroyed or sent to egg breaking plants for pasteurization. Second, to help prevent the introduction of S.e. into the farm environment, FDA has entered into partnership agreements to provide guidance and technical assistance to some of the states that have taken the initiative to adopt HACCP-like egg safety programs for farms, known as quality assurance programs.

Once eggs move from the egg farm to processing plants, FDA also has regulatory authority, which is derived from the Federal Food, Drug and Cosmetic Act, as amended. Under this act, FDA generally follows a regulatory approach of allowing foods to enter the market without preapproval. Food firms are generally not required to register, nor is FDA required to inspect foods or food firms on a given schedule. According to FDA officials, the agency almost never conducts inspections at the approximate 700 shell egg processing plants that wash, grade, and pack shell eggs in the U.S.. When these inspections are done, they are focused on sanitary practices and do not routinely include testing to identify S.e.. Under this act, FDA also has the authority to enforce provisions prohibiting false or misleading labeling of foods, including labels used on egg cartons.

At the retail level, FDA has the authority to set standards for eggs and egg products under two different laws. The Public Health Service Act states that FDA will assist states in the prevention of and suppression of communicable disease. State laws and regulations generally establish food safety requirements for the millions of restaurants, institutions, and other retail food operations throughout the United States, and state and local health departments inspect these establishments to ensure compliance. FDA works with state and local governments and encourages uniformity among state laws through its model Food Code. The Food Code is not federal regulation and only has the force of law when adopted by a state or local government entity. These jurisdictions may adopt the entire code or selected provisions. As of March 2, 1999, 15 states and 5 local jurisdictions reported to FDA that they had adopted some or all of the provisions of the code, and 23 states reported that they are in the process of doing so. The Code classifies raw shell eggs as a "potentially hazardous food" and sets requirements for egg handling and preparation, such as proper cooking temperatures. The Code also places restrictions on

preparing and serving shell eggs to highly susceptible populations such as infants, the elderly, and individuals with compromised immune systems.

The Egg Products Inspection Act, passed in 1970, is the second law giving FDA authority over egg safety at the retail level. Although this act previously covered only egg product safety, the 1991 amendments to the Act included requirements for shell eggs safety. The amendments, which become effective August 27, 1999, give FDA the responsibility for ensuring that eggs are stored at an air temperature of 45 degrees and appropriately labeled to show they require refrigeration at all locations except those that process and pack eggs. This is a departure from FDA's traditional role at the retail level under the Public Health Service Act, where the agency promotes egg safety by encouraging states to adopt the Food Code. In addition, although FDA previously had sole authority over shell eggs, the 1991 amendments split enforcement authority for the temperature and labeling requirements between FDA and USDA.

Food Safety and Inspection Service Responsibilities

Food Safety and Inspection Service responsibility for eggs begins when shell eggs are sent to a plant where they are broken to make egg products. When Congress passed the Egg Products Inspection Act in 1970, it provided for the mandatory and continuous inspection of liquid, frozen, and dried egg products of all U.S. egg products plants.¹⁶ For the next 25 years, the Poultry Division of USDA's Agricultural Marketing Service inspected egg products to ensure that they were wholesome, unadulterated, and properly labeled and packaged. However, in May 1995, when food safety responsibilities were reorganized within USDA, the Food Safety and Inspection Service assumed responsibility for inspecting egg products. FSIS now inspects all egg products during production, with the exception of those products that the act exempts, such as egg substitutes and imitation eggs. However, once egg products leave the plant and enter commerce, they become FDA's regulatory responsibility.

To ensure food safety, FSIS follows a regulatory approach of inspecting products before they reach the market. The Egg Products Inspection Act requires that USDA provide continuous

¹⁶ Egg products are eggs removed from their shells for processing. Examples of egg products include whole eggs, whites, yolks and various blends with or without non-egg ingredients that are processed, pasteurized, and available in liquid, frozen, and dried forms.

supervision while egg processors are operating, to ensure that eggs are properly pasteurized, and that pasteurized products test negative for salmonella. In fiscal year 1998, FSIS had 102 full-time inspectors monitoring operations at the 73 egg products plants in the country. In addition, in that same year the agency had cooperative agreements with six states—Arkansas, Georgia, New Jersey, New York, South Carolina, and Utah—to provide inspections of egg products. Under these agreements, state inspectors may conduct inspections for FSIS and are reimbursed for their services.

FSIS' inspectors (1) check the eggs' quality and condition as they enter the plant, (2) inspect the plant equipment, flooring, processing, and storage areas to ensure overall sanitation and cleanliness, (3) observe operations as the eggs are washed, sorted, broken, pasteurized, and cooled for storage, and (4) monitor the staff's personal hygiene practices. As a part of the inspection program, all plants must maintain a Salmonella enteritis testing program. Under this program, an FSIS inspector or a plant official takes samples from product lots and sends them out for laboratory analysis to identify the presence of S.e. If testing shows the presence of salmonella, the product is re-pasteurized, destroyed, or diverted to pet food or other products not for human consumption. FSIS also maintains a salmonella monitoring program to check on the testing programs at egg processors. Under this monitoring program, FSIS takes about 3,000 samples a year from the full range of egg products being produced in the 76 plants.

USDA's regulations specify the temperatures required for the storage of egg products at the plant, which depend upon the type of product—liquid, frozen, or dried. However, once the egg products leave the plant, temperature requirements for transportation and for storage of these products, as well as inspections to ensure compliance of those requirements, are the responsibility of FDA.

In the 1991 amendments to the Egg Products Inspection Act, Congress expanded USDA's authority to include enforcing shell egg refrigeration and labeling safety requirements at processing plants and during transportation. Previously, USDA had authority only for the safety of egg products. Regulations implementing the amendments become effective on August 27, 1999. As of April 1999, USDA had not determined whether FSIS or AMS will enforce these regulations.

AMS Offers Programs for Egg Quality and Safety

AMS' traditional role is to assist in the marketing of eggs by assuring they meet USDA quality standards, but the agency has recently offered two programs that also address egg safety. AMS' two longstanding programs are its voluntary grading program provided as a service to shell egg processing plants and supported by user fees and its Shell Egg Surveillance program, which provides for periodic monitoring to assure that eggs are being packed to meet AMS requirements. In addition, AMS began offering a voluntary HACCP-based sanitation program in August 1998 and third-party monitoring services for participants in the United Egg Producer's 5-Star egg safety program in February 1999.

The shell egg grading program assists egg producers in providing quality eggs to consumers. The Agricultural Marketing Act of 1946 authorizes USDA to conduct a voluntary grading program for various commodities. Under this authority, AMS currently grades about one-third of the nation's eggs as either AA, A, or B based on internal and external quality factors. For example, the highest quality eggs, Grade AA, must have a clean and unbroken shell, an air cell inside the egg of 1/8th inch or less in depth, a clear and firm white, and a slightly defined yolk. Shell egg packers who pay for the grading service can label eggs packed in cartons for retail sale or in bulk for restaurants and institutions with the official USDA grade shield. USDA graders are present while eggs are processed and identified with the official grade shield, to confirm that all program requirements are met. USDA staff grade eggs in some plants, while state employees, working under cooperative agreements between AMS and their state, grade eggs in others.

AMS also conducts a Shell Egg Surveillance Program, under authority of the Egg Products Inspection Act, to ensure that eggs are wholesome, unadulterated, and properly labeled. Under this regulatory program, shell eggs sold to consumers can contain no more restricted eggs than permitted in U.S. Consumer Grade B and restricted eggs must be disposed of properly.¹⁷ To verify that shell eggs packed for consumer use meet program requirements, a federal or state shell egg inspector visits each registered egg packing plant, at least four times a year. This

¹⁷ Restricted eggs are defined as eggs with cracks or checks in the shell, as well as dirty, inedible, and leaking eggs among others. Cracked and dirty eggs may be shipped to an official egg products plant for processing pasteurization--otherwise, restricted eggs must be either destroyed or diverted for use other than human consumption.

inspection includes observation of plant conditions, product sampling, and a review of records, among other things.

AMS developed its Plant Sanitation and Good Manufacturing Practices Program as a comprehensive voluntary sanitation service for egg processors that participate in the shell egg grading program. This fee-for-service program complements the official quality grade certification by allowing participating processors to place a USDA shield on egg cartons verifying that the plant has complied with USDA's sanitation and good manufacturing practices. Participants are required to develop and implement a "quality manual" of standard operating procedures that addresses how the plant monitors generally recognized control points in egg processing and handling. Program requirements include elements that are quality focused, as well as elements that are HACCP-like and focus on control points, such as suppressing rodents and pests and checking wash water and cooling room temperatures, among other things. As an additional step to promote egg safety, participants can request the optional service of environmental sampling of flocks, equipment, or premises to identify the presence of Salmonella enteritidis. AMS has only recently developed the plant sanitation program, and so far, very few producers are using it.

AMS has recently developed another program that assists industry in its efforts to ensure egg safety. Based on a request from the United Egg Producers, an industry group, AMS is offering a voluntary fee-for-service program to conduct third-party monitoring for the producer's 5-Star program. The United Egg Producer's program is a voluntary HACCP-like program that includes continuous monitoring of critical control points at egg farms and in egg processing plants. The AMS third-party monitoring program is offered to all egg farms and processing plants that participate in the 5-Star program, including those that do not participate in AMS' voluntary grading service. The monitoring program includes quarterly audits to determine a producer or packer's compliance with the 5-Star program and identify specific areas for improvement. The audits include verification of each of the program's 5-Star points, including: (1) cleaning and disinfecting, (2) rodent and pest elimination, (3) egg washing, (4) bio-security, and (5) refrigeration. In addition, auditors review the producer's or packer's environmental sampling program which is used to validate the effectiveness of the program.

States Share Responsibilities for Egg Safety and Quality

As eggs move from farm to table, the states share safety and quality inspection responsibilities with the federal government. State inspectors working under agreements with USDA share responsibility for (1) inspecting the breeding farm environment and testing breeding flocks under APHIS' National Poultry Improvement Plan, (2) conducting mandatory inspections at egg products plants for FSIS, and (3) conducting egg quality inspections for AMS under its voluntary grading and mandatory shell egg surveillance programs.

Besides sharing these egg safety and quality responsibilities with USDA, some states have their own programs for ensuring shell egg quality and safety. Thirteen states told us they are addressing safety concerns on egg farms using voluntary HACCP-based programs, known as quality assurance programs. These programs generally include measurable control points to prevent the introduction of S.e. into egg laying flocks. For instance, the Pennsylvania Department of Agriculture partnered with the state's egg industry to develop the Pennsylvania Egg Quality Assurance Program to provide reasonable assurance to consumers that the state's eggs are a minimal risk of causing foodborne disease from *Salmonella enteritidis*. In addition, some states conduct their own inspections of shell egg processing plants. About half of the states told us they conduct inspections of processing plant sanitation but only one tests for the presence of S.e.. Also, the states are primarily responsible for conducting food safety inspections at retail locations, including restaurants, grocery stores, hospitals, and other institutions. Finally, one of the states we visited, Pennsylvania, had developed its own egg quality certification program.

States generally model their programs after the federal model of shared authority by dividing egg quality and safety responsibilities among the responsible state departments, for example, agriculture and health. Our state survey found that in 43 of the 50 states responsibility for regulating egg quality and safety is shared by two or more agencies. For example, in California the State Department of Agriculture is responsible for periodically spot-checking egg processing plants to assure they are packing eggs that meet state quality standards. On the other hand, California's Department of Health Services is primarily responsible for food safety inspections at the retail level, as well as working as a partner on quality assurance programs and conducting traceback investigations of foodborne illnesses.

Food Safety

~~Eggs~~

Eggs

	Request	Passback	01 Appeal	Estimated annual costs
FDA				
FSI	60.06	15	+45	
Eggs	0		15	about 30
USDA				
FSI	27	26	none?	
Eggs	9	0?	4.5	about 6

Recommendation:

FY01

If FDA gets full FSI (like USDA) they can fund the eggs implementation from those funds (this is what they proposed originally). Alternatively give them \$10 million for eggs and don't bump the FSI up as much.

USDA should get an additional \$3-4 million for eggs.

Outyears

FDA told me they could do the job for \$20 million/year

USDA's request of \$6 million/year seems reasonable.

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FDA

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PRESIDENT'S COUNCIL ON FOOD SAFETY



December 10, 1999

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The Honorable William J. Clinton
President
The White House
Washington, DC 20500

Dear Mr. President:

We are transmitting by this letter "Egg Safety From Production to Consumption: An Action Plan to Eliminate *Salmonella* Enteritidis Illnesses Due to Eggs," which was developed by your Council on Food Safety. The action plan is an important part of your Administration's initiative to improve the safety of the nation's food supply, a high priority for American consumers. While the Council is continuing its work on developing a comprehensive food safety strategic plan by July 2000 as well as a coordinated federal food safety budget for FY 02, it recognizes that egg safety is a food safety issue that warrants immediate federal agency attention. Americans consume an average of 234 eggs per person per year. An estimated one in 20,000 eggs in the nation's food supply will contain the *Salmonella* Enteritidis (SE) bacteria and can cause illness if eaten raw in foods or not thoroughly cooked before consumption. From 1985 to 1998, there were 28,644 illnesses and 79 deaths associated with 794 SE outbreaks reported to the Centers for Disease Control and Prevention (CDC).

The Egg Safety Action Plan being transmitted to you today identifies the systems and practices that must be implemented to reduce and ultimately eliminate eggs as a source of human SE illnesses. While the plan's overarching goal is eventual total elimination, its interim goal is an ambitious, but achievable, 50 percent reduction in egg-associated SE illnesses by 2005.

The Council identified 1998 baseline values on numbers of SE cases, isolates, and outbreaks against which the plan's progress can be measured.

Sincerely,

Dan Glickman
Secretary of Agriculture

Donna E. Shalala
Secretary of Health
and Human Services

Neal Lane
Assistant to the President



**PRESIDENT'S COUNCIL
ON FOOD SAFETY**



EGG SAFETY

FROM PRODUCTION TO CONSUMPTION:

AN ACTION PLAN

TO ELIMINATE SALMONELLA ENTERITIDIS ILLNESSES

DUE TO EGGS

December 10, 1999

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**EGG SAFETY FROM PRODUCTION TO CONSUMPTION:
AN ACTION PLAN TO ELIMINATE SALMONELLA ENTERITIDIS ILLNESSES DUE TO EGGS**

EXECUTIVE SUMMARY

PURPOSE. The President's Council on Food Safety has identified egg safety as one component of the public health issue of food safety that warrants immediate federal, interagency action. The Egg Safety Action Plan presented in this report identifies the systems and practices that must be implemented to reduce and, ultimately, eliminate eggs as a source of human *Salmonella* Enteritidis (SE) illnesses. The overarching public health goal of the Council is to eliminate SE illnesses associated with the consumption of eggs by 2010. The interim goal of the Egg Safety Action Plan is a 50 percent reduction in egg-associated SE illnesses by 2005.

BACKGROUND. Americans consume an average of 234 eggs per person per year. While eggs are an important source of protein in the diet, an estimated 1 in 20,000 eggs in the U.S. supply will contain the SE bacteria and can cause illness if eaten raw in foods or not thoroughly cooked before consumption. Because eggs can become contaminated internally from the hen, common egg-handling practices are now considered to be unsafe. These practices include temperature abuse (i.e. holding eggs and egg-containing foods at room temperature instead of under refrigeration), inadequate cooking, and pooling eggs to prepare a large volume of an egg-containing food that is subsequently temperature abused or inadequately cooked.

The SE risk assessment model for shell eggs and egg products, developed jointly by the Food Safety and Inspection Service (FSIS) and Food and Drug Administration (FDA) in 1998, predicted that using multiple interventions could achieve a more substantial reduction in SE illnesses than using any one intervention alone. This finding suggests that a broadly based policy is likely to be more effective in eliminating egg-associated SE illnesses than a policy directed solely at one stage of the egg production to consumption continuum.

On August 26, 1999, the President's Council held a public meeting to obtain input during the development of the action plan to address egg safety. A single theme resounded from representatives of the consumer groups and the egg industry: The federal government needs a set of mandatory national standards. These standards should: (1) provide consumers an assurance that all eggs are subject to the same safety standards across the U.S. and (2) provide egg producers and processors a "level playing field" industry-wide.

RECOMMENDATIONS. The President's Council on Food Safety concluded that the development and implementation of the Action Plan outlined in this report is an effective way to prevent human SE infections due to the consumption of SE-contaminated eggs. The Action Plan reflects our current understanding of the steps needed to reduce egg-associated SE illness. As we move forward with the Plan and develop the proposals, we will assess the impact of the individual action items, consult with stakeholders, and refine the Plan to reflect the best information available to achieve our public health goal.

At each stage of the egg production-to-consumption continuum, the Plan identifies the systems and activities necessary to achieve our food safety public health goals. The Plan offers industry the flexibility to choose from two equivalent SE reduction strategies, each delivering eggs into distribution and to the consumer at an equivalent level of safety. The strategy selection by egg producers and packer/processors determines the point at which the pathogen reduction steps are taken:

- Strategy I: SE testing-egg diversion system on farm
- Strategy II: Lethal treatment, or "kill step" at packer/processor

For the distribution and retail stages, the Plan specifies the safe handling practices necessary to ensure consumers receive a safe food product. Furthermore, the Plan clearly describes the surveillance, research, and education activities that must also be conducted to achieve the elimination of egg-associated SE illnesses. The relative difference in emphasis between the two strategies is highlighted in Figure 1 on page 6.

A comparative summary of the activities in Strategy I and Strategy II is provided in Table 1 on page 7.

To consolidate egg safety oversight responsibilities and provide clarity, the President's Council on Food Safety identified one responsible agency for each stage of the farm-to-table continuum, based on the strengths of each agency, as follows:

- FDA develops standards for the producer and the States provide inspection and enforcement on the farm.
- FSIS develops standards for both shell egg packers and egg products processors and provides inspection and enforcement for both.
- FDA and CDC conduct surveillance and monitoring activities. CDC focuses on human health and FDA on the food supply.

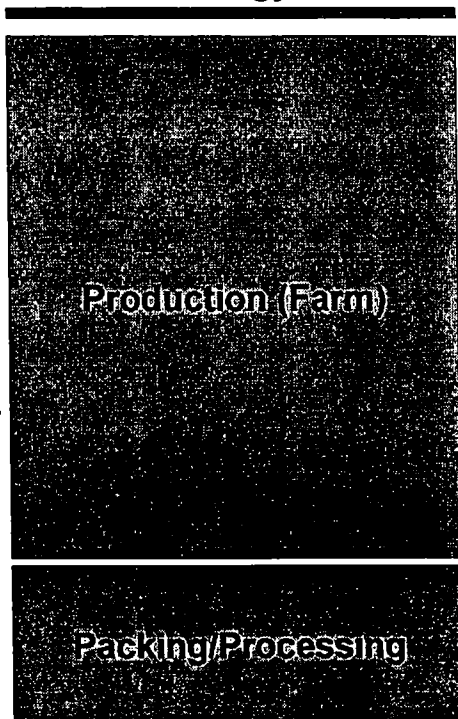
The performance measures that will be used to assess the progress of the Plan toward its goal are the numbers of SE cases, isolates, and outbreaks annually. The data will be collected using the following existing systems: (1) Foodborne Diseases Active Surveillance Network (FoodNet), (2) National Salmonella Surveillance System (via PHLIS), and (3) National SE Outbreak Surveillance System and Foodborne Diseases Outbreak Surveillance System. The new data will be compared to the 1998 baseline values of: (1) 1.9 cases per 100,000 persons; (2) 5,900 SE isolates; and (3) 45 SE outbreaks, respectively.

Figure 1. DEPICTION OF PROGRAM STRATEGIES FOR ACTION PLAN

Eggs: From Farm to Table

Problem: *Salmonella* Enteritidis in Eggs
Goal: Eliminate It as a Source of Human Illness

Strategy I



Strategy II

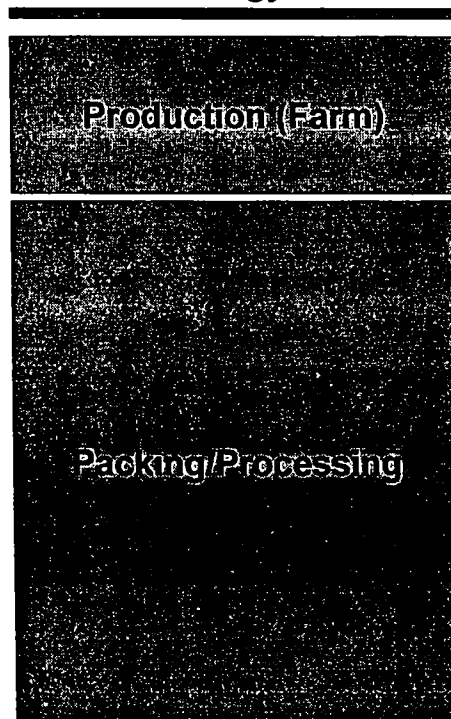


Table 1. COMPARISON OF PROGRAM STRATEGIES FOR ACTION PLAN

<i>Activity</i>	Strategy I	Strategy II
PRODUCTION (On-Farm): Objective 1.1		
Chicks from SE-free breeder flocks	√	√
SE Environmental Testing (chicks, pullets, layers)	√	
SE Environmental Testing (at depopulation)	√	√
SE Egg Testing (w/positive environmental results)	√	
Diversion of shell eggs to pasteurization	√	
Biosecurity	√	√
Rodent/Pest control	√	√
Decontamination (Cleaning & Disinfection)	√	√
PACKING: Objective 1.2		
Prerequisite programs	√	√
HACCP system with a "kill" step		√
PROCESSING: Objective 1.3		
Prerequisite programs	√	√
HACCP system with a "kill" step	√	√
DISTRIBUTION: Objective 1.4		
Refrigeration during transport and storage	√	√
RETAIL: Objective 2		
Food Code (egg-relevant provisions)	√	√
SURVEILLANCE: Objectives 3-6		
Monitoring human and poultry SE infections	√	√
RESEARCH: Objective 7		
	√	√
EDUCATION: Objective 8		
	√	√

¹ Prerequisite programs must address: basic sanitation of facilities and premises; rodent and pest control; employee hygiene and health; safety of water and food packing materials; and washing, sanitizing, and packaging.

² FSIS Final rule; FDA Proposed Rule

EGG SAFETY FROM PRODUCTION TO CONSUMPTION: AN ACTION PLAN TO ELIMINATE SE ILLNESSES DUE TO EGGS

INTRODUCTION

Americans consume an average of 234 eggs per person per year. While eggs are an important source of protein in the diet, an estimated 1 in 20,000 eggs in the U.S. supply will contain the *Salmonella* Enteritidis (SE) bacteria and can cause illness if not thoroughly cooked before consumption. The federal agencies responsible for ensuring the safety of eggs, under the auspices of the President's Council on Food Safety, have jointly developed an Action Plan to eliminate SE illnesses due to the consumption of contaminated eggs.

The Action Plan presented in this report is an aggressive, comprehensive approach to address egg safety that will reduce the number of SE illnesses attributed to eggs in the United States by 50 percent by the year 2005. The Plan identifies systems that must be designed and implemented and activities that must be conducted at each stage of the farm-to-table continuum to reach the overarching goal of eliminating egg-associated SE illnesses. The Plan also recognizes and encompasses federal, state, and local systems already in place and industry activities already occurring. The Action Plan reflects our current understanding of the steps needed to reduce egg-associated SE illness. As we move forward with the Plan and develop the proposals, we will assess the impact of the individual action items, consult with stakeholders, and refine the Plan to reflect the best information available to achieve our public health goal.

SCOPE

This comprehensive, science-based plan contains elements identified by the National Academy of Sciences' Committee to Ensure Safe Food from Production to Consumption as necessary components of an effective food safety system.³

³ Institute of Medicine/National Research Council, NAS. *Ensuring Safe Food: From Production to Consumption*. National Academy Press, Washington, DC, 1998.

- To promote consistency, the Plan calls for a consistent, nationwide program that addresses each stage of the farm-to-table continuum, including on the farm, at the packer or processor, during distribution, as well as for proper handling and preparation practices at retail. The Plan also highlights the proposed and final rules requiring refrigeration at retail and during distribution, respectively, as well as a proposed rule that would require a safe handling statement on the package.
- To provide a science-based foundation, the development of the Plan began with a review of the comprehensive, quantitative risk assessment of SE for shell eggs and egg products. The findings and research needs identified in the risk assessment report were incorporated into the Plan.
- The Plan identifies promising developments in science and technology, such as SE vaccines and in-shell pasteurization, for further research including field and pilot studies.
- The Plan recognizes the need for adequate surveillance, including active surveillance of SE illnesses in regions of the country where the most contaminated eggs are produced and consumed, and calls for expansion of FoodNet activities.
- The Plan identifies gaps in the scientific understanding of the SE bacterium and its route of on-farm transmission to SE-free chicks. The Plan also highlights the federal government's current education efforts focused on the use of safe egg handling practices by food preparers at retail and at home.
- In development of the Plan, the personnel and funds necessary to implement and maintain the specific systems and activities listed, through FY2005, were considered. Therefore, the Plan highlights existing partnerships and encourages the formation of new ones.
- The Plan clearly identifies the agencies responsible for the development and implementation of the new egg safety activities proposed.

The Egg Safety Action Plan presented in this report clearly and concisely describes a way to reduce the number of SE-contaminated eggs in the marketplace and to eliminate SE illnesses caused by consumption of eggs. By combining new and existing systems and activities targeted at both eggs and illnesses, the plan presents a comprehensive, integrated nationwide approach to address an important food safety and public health concern so that Americans can continue to enjoy one of the safest food supplies in the world.

BACKGROUND

President's Food Safety Initiative. On January 25, 1997, the President directed the Secretaries of Agriculture and Health and Human Services and the Administrator of the Environmental Protection Agency to identify specific steps to further improve the safety of the food supply and to further reduce the incidence of foodborne illness to the greatest extent feasible.⁴ In May 1997, they presented the President with a report entitled, "Food Safety from Farm to Table: A National Food Safety Initiative." Under this initiative, the federal government, in concert with state and local governments, industry and academia, are conducting research, risk assessments, and cost-benefit analyses to determine how foodborne illnesses occur and can be prevented or controlled in the most efficient and cost-effective manner. The federal government is also improving surveillance and investigative efforts to locate and monitor illnesses caused by food, updating its approach to inspections of food processors to monitor the safety of the food supply, and reinvigorating education of food preparers focusing on the use of safe practices.⁵

President's Council on Food Safety and Its Strategic Plan. In August 1998, the President established a Council on Food Safety under Executive Order No. 13100 to protect the health of the American people by preventing foodborne illness using science-based regulation and well-coordinated surveillance and investigation,

⁴ EPA/HHS/USDA. *Food Safety From Farm To Table: A National Food-Safety Initiative.* A Report to the President. May 1997.

⁵ Ibid.

inspection, enforcement, research, and educational programs.⁶ In the Order, the President directed the Council to "develop a comprehensive strategic food safety plan for Federal food safety activities" and "advise Federal agencies in setting priority areas for investment in food safety."⁷ He also ordered the Council to make recommendations to him on how to implement a comprehensive science-based strategy to improve the safety of the food supply and enhance coordination among Federal agencies, State, local, and tribal governments, and the private sector. The Council's Food Safety Strategic Plan will focus on "core food safety activities" including activities intended to enhance the safety of the nation's food supply and to protect public health by reducing the annual incidence of acute and chronic foodborne illness. The strategic plan will include Federal programs for research, monitoring, surveillance, regulation, prevention, voluntary and mandatory certification and inspection, enforcement, labeling, and education.⁸ The plan will be used to set priorities, improve coordination and efficiency, identify and close gaps in the current food safety system, enhance and strengthen prevention and intervention strategies, and develop performance measures to monitor progress.⁹

Council's Egg Safety Action Plan. The President's Council on Food Safety has identified egg safety as one component of the overall public health issue of food safety that warrants immediate federal, interagency action. Under the auspices of the President's Council, the Strategic Planning Task Force commissioned an Egg Safety Task Force composed of designees of the federal food safety agencies responsible for egg safety to develop an action plan to eliminate egg-associated SE illnesses. Those agencies are DHHS' Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) and USDA's Food Safety and Inspection Service (FSIS), Animal and Plant Health Inspection Service (APHIS), Agriculture Marketing Service (AMS), and Agriculture Research Service (ARS). The Egg Safety Action Plan

⁶ President's Council on Food Safety. *Charter*. Dec. 16, 1998.

⁷ President Clinton. *Executive Order 13100: President's Council of Food Safety*. Aug. 25, 1998.

⁸ President's Council on Food Safety. *Scope of the Council's Comprehensive Strategic Food Safety Plan*. Dec. 16, 1998.

⁹ President's Council on Food Safety. *Discussion Paper: Process for developing a Food Safety Strategic Plan for all Federal food safety agencies*. Dec. 16, 1998.

developed by the Task Force and presented in this report identifies the systems and practices that must be implemented to reduce and, ultimately, eliminate eggs as a source of SE illnesses.

Salmonella Enteritidis Contamination of Eggs. *Salmonella* of various serotypes are commonly found in the digestive tracts of animals and frequently contaminate our environment. Originally, *Salmonella* contamination of shell eggs was believed to occur primarily when organisms present on the egg passed through the shell into the egg's contents. However, more recently transovarian SE contamination of egg contents has been determined to occur from SE-infected laying hens. The rate of transovarian egg contamination has been estimated at about 1 SE-positive egg in every 20,000 eggs produced in the U.S.¹⁰

Human SE illnesses. From 1985 to 1998, there have been a total of 794 SE outbreaks reported to CDC involving 28,644 illnesses, 2,839 hospitalizations, and 79 deaths.¹¹ In 1997 alone, an estimated 300,000 infections may have occurred.¹² A typical case of salmonellosis is characterized by diarrhea, abdominal cramps, nausea, vomiting, fever, and headache. Symptoms usually begin within 6 to 72 hours after consuming food, last 4 to 7 days, and resolve without antibiotic treatment for most people who do not have underlying health problems. However, the infection can enter the bloodstream leading to severe and fatal illness. The invasive, life-threatening form of the disease is more likely in highly susceptible populations, including children, the elderly, and persons with weakened immune systems. CDC reported that 54 of the 79 deaths associated with outbreaks of SE between 1985 and 1998 were of individuals in

¹⁰ Food Safety and Inspection Service, USDA. *Salmonella Enteritidis Risk Assessment for Shell Eggs and Egg Products*. Final Report. June 12, 1998.

¹¹ Potter, M.E. Testimony before the Subcommittee on Oversight of Government Management, Restructuring, and the District of Columbia, Committee on Governmental Affairs, United States Senate. July 1, 1999.

¹² Ibid. Based on 7,924 cases, reported to CDC, multiplied by a factor of 38. The estimated degree of underreporting of nontyphoidal *Salmonella* is 38-fold. Ref: Mead, P.S. et al, 1999. *Food-related Illness and Death in the United States*. Emerging Infectious Diseases 5(5): 619.

nursing homes.¹³ In addition, about 2 percent of those who recover from salmonellosis may later develop recurring joint pains and arthritis.

CDC surveillance data show that the rate of isolation of SE from infected humans increased throughout the U.S. during 1976-1994 from 0.5 to 3.9 per 100,000 population. Evaluation of regional trends for the years 1990-1994 actually indicates a decrease in the SE isolation rate from 8.9 to 7.0 per 100,000 population in the Northeast, where egg quality assurance efforts had been the most intensive. In contrast, the rate increased approximately threefold in the Pacific region, with California reporting an increase in SE isolates from 11% in 1990 to 38% in 1994.¹⁴

The benefits associated with preventing human salmonellosis are: (1) the economic benefits of reducing loss of productivity associated with human illness, (2) reduced pain and suffering, and (3) reduced expenditures on medical treatment. The costs associated with human salmonellosis due to SE are estimated to range from \$150 million to \$870 million annually.¹⁵

Egg-Handling Practices. Traditionally, practices such as the use of raw eggs in foods and the undercooking and non-refrigeration of eggs were not considered unsafe. More recently, however, the potential for internal SE contamination of eggs has been established and egg-handling practices have been reevaluated. Common egg-handling practices now considered to be unsafe include: temperature abuse (i.e. holding eggs and egg-containing foods at room temperature instead of under refrigeration); inadequate cooking; and pooling eggs to prepare a large volume of an egg-containing food that is subsequently temperature abused or inadequately cooked. The presence of SE bacteria in a raw egg, alone, does not guarantee illness upon consumption. However, the likelihood of developing an SE infection increases when the egg is not handled safely by permitting the bacteria to multiply and a greater number of bacteria to

¹³ U.S. General Accounting Office. *Food Safety: U.S. Lacks a Consistent Farm-to-Table Approach to Egg Safety*. GAO/RCED-99-184. July 1999.

¹⁴ Centers for Disease Control and Prevention. *Outbreaks of Salmonella Serotype Enteritidis Infection Associated with Consumption of Raw Shell Eggs—United States, 1994-1995*. Morbidity and Mortality Weekly Report 45(34). Aug. 30, 1996.

¹⁵ Food Safety and Inspection Service, USDA. *Salmonella Enteritidis Risk Assessment: Shell Eggs and Egg Products*. Final Report. June 12, 1998.

be ingested with the food. Investigations of SE outbreaks show that the consumption of foods prepared with SE-contaminated eggs that are not cooked or are undercooked or that are held at room temperature is a common scenario. In fact, many of the SE outbreaks that occurred between 1985 and 1998 were attributed to commercial establishments, such as restaurants, hospitals, nursing homes, schools, and prisons, and greater than 75 percent of those SE outbreaks with an identified source were associated with foods containing undercooked eggs. In addition, the 1996-97 Food Consumption and Preparation Diary Survey showed that 27 percent of all egg dishes consumed were undercooked, described as being runny or having a runny yolk or runny white.¹⁶ On average, each person in the survey consumed undercooked eggs 20 times a year. Within those subgroups at risk, women over 65 and children under 6 consumed undercooked eggs 21 times a year and 8 times a year, respectively.

U.S. Egg Industry. On a per capita basis, Americans consume about 234 eggs per year. In 1998, the U.S. table egg industry produced 67.3 billion eggs, up 3 percent from 1997.¹⁷ U.S production is relatively stable and has increased only slightly from about 60 billion eggs in 1984. The total value of the table eggs (eggs produced for human consumption, not hatching) produced in the U.S. in 1995 was estimated at \$3.96 billion.¹⁸ Generally, about 70 percent of the table eggs produced are sold as shell eggs while the remainder are processed into liquid, frozen or dried pasteurized egg products. The majority of egg products are destined for institutional use or further processing into foods such as cake mixes, pasta, ice cream, mayonnaise, and bakery goods.

Flocks associated with egg production fall into three categories: breeders (grandparents), multipliers (parents), and laying flocks (including both immature hens, or pullets, and laying hens, or layers). There were roughly 300,000 breeding hens, 3 million multipliers, and 300 million layers. The value of laying flocks alone is estimated

¹⁶ Lin, C-T., R.A. Morales, and K. Ralston. *Raw and Undercooked Eggs: A Danger of Salmonellosis.* Food Review 20:27-32, 1997.

¹⁷ National Agricultural Statistics Service, USDA. *Layers and Egg Production 1998 Summary.* January 1999.

¹⁸ Food Safety and Inspection Service, USDA and Food and Drug Administration, HHS. *Salmonella Enteritidis in Eggs.* Federal Register, Vol. 63, No. 96. Proposed Rules. May 19, 1998.

to be nearly \$1 billion.¹⁹ Geographically, commercial egg production in the western U.S. is concentrated in California and in the eastern U.S. is centered in Ohio, Indiana, and Pennsylvania. Other states in which major producers are located include Iowa, Texas, Minnesota, and Georgia. About 5,000 producers have 3,000 or more layers, representing 99 percent of all domestic egg-laying hens and accounting for 99 percent of total egg production.²⁰ An additional 65,000 farms have less than 3,000 egg-laying hens accounting for the balance of eggs produced.²¹

Current Regulation of Shell Eggs. Federal authority to regulate egg safety is shared by the Department of Health and Human Services' (HHS') Food and Drug Administration (FDA) and the United States Department of Agriculture's (USDA's) Food Safety Inspection Service (FSIS). In addition, USDA's Animal and Plant Health Inspection Service (APHIS) conducts a control program that certifies poultry breeding stock and hatcheries as SE-free and USDA's Agricultural Marketing Service (AMS) conducts a surveillance program to ensure proper disposition of restricted shell eggs. (See Figure 2, page 16; see glossary.)

FDA has jurisdiction over the safety of foods generally, including shell eggs, under the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. 301 *et seq.*). Under the Public Health Service Act (PHSA; 42 U.S.C. 201 *et seq.*), FDA also has the authority to prevent the spread of communicable diseases, including the authority to regulate foods when the foods may act as a vector of disease, as in the case of SE in eggs. FDA is responsible for: (1) investigating SE outbreaks, reported by CDC and State/local health departments, due to foods in interstate commerce, (2) performing trace backs to identify the source of the implicated eggs, (3) testing flocks, (4) diverting eggs from SE-positive flocks, (5) collecting flock data to help track the spread of SE among layer flocks, and (6) promoting better quality control.

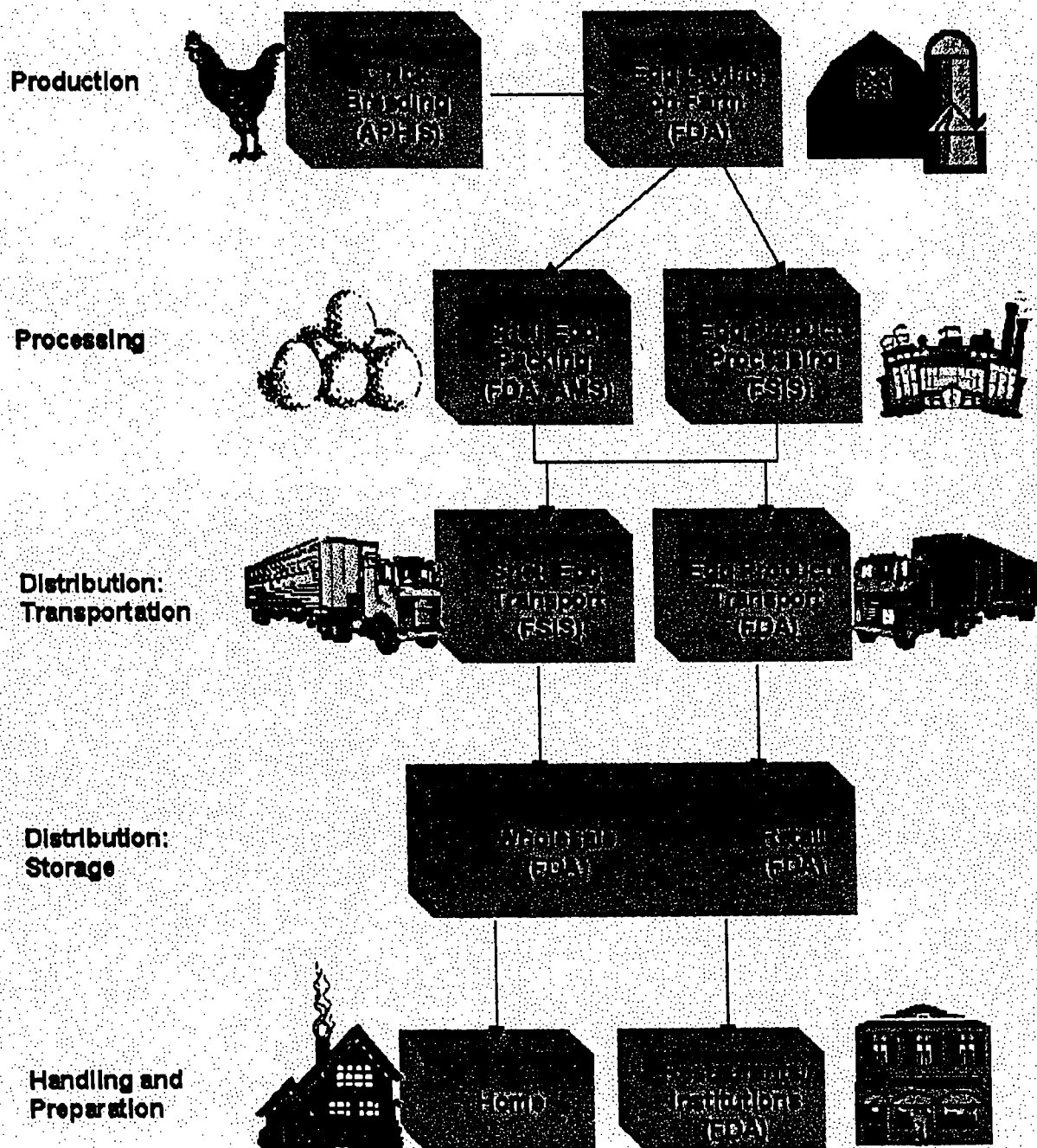
USDA has primary responsibility for implementing the Egg Products Inspection Act (EPIA; 21 U.S.C. 1031 *et seq.*). Under EPIA, FSIS has primary responsibility for the

¹⁹ Ibid.

²⁰ AMS correspondence with FDA. 10/1/99.

²¹ National Agricultural Statistics Service, USDA. 1997 *Census of Agriculture*. Poultry Inventory and Sales.

Figure 2. Egg Safety from Production to Consumption



inspection of processed egg products to prevent the distribution of adulterated or misbranded egg products. Also under EPIA, AMS conducts a surveillance program to ensure proper disposition of restricted shell eggs and visits producer/packers periodically to ensure: (1) that eggs packed for commercial sale contain no more restricted eggs than permitted for US Consumer Grade B, (2) that restricted and inedible product is properly labeled, and (3) that restricted and inedible eggs are denatured and properly disposed of. Under current federal regulations, all major commercial egg producers are required to register with AMS and are subject to periodic onsite inspections by AMS. In FY1998, 698 producer/packers were registered with AMS, with a balance of about 4,300 producers that do not process (pack).²²

Quantitative Risk Assessment of SE in Eggs. In December 1996, FSIS and FDA jointly began a comprehensive risk assessment in response to an increasing number of human illnesses associated with the consumption of eggs.²³ A team of scientists developed a quantitative model to characterize the risks associated with the consumption of eggs contaminated internally with SE, using information obtained from academic, government, and industry sources and scientific literature. The risk assessment model consists of discrete modules that may be used independently to evaluate the effect of variable changes during a particular stage of the farm-to-table continuum. However, the overall model encompasses the entire continuum, from the chicken through egg production, to egg consumption and human illness. The model continues to serve as a quantitative tool for FSIS and FDA decision-makers to use in the design of a comprehensive, integrated risk reduction strategy.

The risk assessment of SE in eggs: (1) established the unmitigated risk of foodborne illness from SE; (2) evaluated potential risk reduction strategies; and (3) identified knowledge gaps where future research is needed. First, the model predicted the risk of a hen laying an SE-contaminated egg to be 1 in 20,000. Second, two interventions showed great promise in reducing the number of SE illnesses associated with contaminated egg consumption: (1) lowering the temperature at which shell eggs

²² AMS correspondence with FDA. 9/20/99.

are maintained and (2) diverting eggs produced by SE-positive flocks from the shell egg market to the pasteurized, egg products market. In addition, the model predicts that the probability of any cases of SE illness resulting from the consumption of pasteurized egg products is low. However, the risk of illness may be further reduced by basing the egg product pasteurization time-temperature standards on: (1) the amount of bacteria in the raw product, (2) the specific process used to treat the raw product, and (3) the intended use of the finished egg product. Third, several research needs were identified and have been incorporated into the research objective of this Action Plan. Overall, the model predicted that while using any one intervention could achieve a modest reduction in human SE illnesses, using multiple interventions could achieve a more substantial reduction for those interventions tested. This finding suggests that a broadly based policy is likely to be more effective in eliminating egg-associated SE illnesses than a policy directed solely at one stage of the egg production to consumption continuum.

FDA and FSIS Egg Safety Regulations. As a result of the risk assessment findings, FDA has proposed a rule to require: (1) safe handling statements on labels of shell eggs that have not been treated to destroy *Salmonella* bacteria and (2) that shell eggs be stored and displayed under refrigeration at a temperature of 7.2°C (45°F) or less when held at retail establishments.²⁴ These proposed actions complement FSIS' final rule that requires: (1) shell eggs be stored and transported at an ambient air temperature of 7.2°C (45°F) or less and (2) consumer containers of shell eggs be labeled to indicate that refrigeration is required.²⁵ The label statements are intended to ensure that consumers have the information necessary to protect themselves from eggs contaminated with SE. The refrigeration requirements are intended to ensure that eggs be held at temperatures that restrict pathogen growth. Careful coordination of these efforts in the overall strategy presented in the SE Action Plan will amplify their individual

²³ Food Safety and Inspection Service, USDA. *Salmonella Enteritidis Risk Assessment for Shell Eggs and Egg Products*. Final Report. June 12, 1998.

²⁴ Food and Drug Administration, HHS. *Safe Handling Label Statement and Refrigeration at Retail Requirements for Shell Eggs*. Federal Register, Vol. 64, No. 128. Proposed Rules. July 6, 1999.

²⁵ Food Safety and Inspection Service, USDA. *Refrigeration and Labeling Requirements for Shell Eggs*. Federal Register, Vol. 63, No. 166. Final Rule. Aug. 27, 1998.

impact and will provide early progress toward meeting the public health goals of the Action Plan.

AN ACTION PLAN FOR EGG SAFETY

On August 26, 1999, the President's Council held a public meeting to obtain input during the development of the action plan to address egg safety. A single theme resounded from representatives of the consumer groups and the egg industry. The federal government needs a set of national, mandatory standards. These standards should: (1) provide consumers an assurance that all eggs are subject to the same safety standards across the U.S. and (2) provide egg producers and processors a "level playing field" industry-wide.

With this in mind, the Council concluded that the further development and implementation of the Action Plan presented in this section of the report is the most effective way to achieve its public health goals. This comprehensive Action Plan identifies the sum of activities necessary to reach the overarching goal of the elimination of SE illnesses associated with the consumption of eggs. While the Plan focuses on SE and eggs, major components of the Plan offer food safety benefits well beyond the specific goal of eliminating egg-associated human SE illnesses. For example, upgrading the information systems at public health departments will contribute to reductions in all foodborne illnesses.

The Action Plan consists of 8 objectives, each with at least one performance measure, covering all stages of the farm-to-table continuum as well as support functions. The farm-to-table continuum encompasses: egg production, shell egg processing (or packing), egg products processing, egg distribution, and egg handling and preparation. The support functions are surveillance of human and poultry SE infections (including outbreak and traceback investigations) and eggs, research, and education.

Regulatory approach. The Action Plan presented in this report clearly lays out the components for an effective program to prevent human SE infections resulting from consumption of contaminated eggs. At each stage of the egg production-to-consumption continuum, the Plan identifies the systems and activities necessary to achieve our food safety public health goals. The Plan offers industry the flexibility to choose from two equivalent SE reduction strategies, each delivering eggs into distribution at an equivalent level of safety. The strategy selection by egg producers and packer/processors determines the point at which the pathogen reduction steps are taken:

- Strategy I: SE testing-egg diversion on farm
- Strategy II: Lethal treatment, or "kill step" at packer/processor

For the distribution and retail stages, the Plan specifies the safe handling practices necessary to ensure consumers receive a safe food product. Furthermore, the Plan clearly describes the surveillance, research, and education activities that must also be conducted to achieve the elimination of egg-associated SE illnesses.

Both Strategies I and II require an on-farm regulatory presence and a packer/processor regulatory presence; therefore, an industry shift over time from one strategy to the other should not change the overall human resource needs. Because reaching our public health goals requires that each stage of the farm-to-table continuum achieve its objectives, oversight and enforcement at every stage will be key to the Plan's success.

As the federal agencies develop consistent nationwide standards through the public process, they encourage States and the egg industry to adopt, in the interim, measures such as the Pennsylvania Quality Assurance program (PEQAP), United States Animal Health Association (USAHA) SE Reduction Program or equivalent.

Organizational structure. To consolidate egg safety oversight responsibilities and provide clarity, the Council identified one responsible agency for each stage of the farm-to-table continuum, based on the strengths of each agency, as follows:

- FDA develops standards for the producer and the States provide oversight and enforcement on the farm.
- FSIS develops standards for both shell egg packers and egg products processors and provides inspection and enforcement for both.
- FDA and CDC conduct surveillance and monitoring activities. CDC focuses on human health and FDA on the food supply.

Therefore, the plan can be implemented quickly without legislation.

The performance measures that will be used to assess the progress of the Plan toward its goal are the numbers of SE cases, isolates, and outbreaks annually. The data will be collected using the following existing systems: (1) Foodborne Diseases Active Surveillance Network (FoodNet), (2) National Salmonella Surveillance System (via PHLIS), and (3) National SE Outbreak Surveillance System and Foodborne Diseases Outbreak Surveillance System. The new data will be compared to the 1998 baseline values of: (1) 1.9 cases per 100,000 persons; (2) 5,900 SE isolates; and (3) 45 SE outbreaks, respectively.

EGG SAFETY ACTION PLAN

OVERARCHING GOAL:

To eliminate SE illnesses associated with the consumption of eggs by 2010. The Egg Safety Action Plan has set an interim goal of a 50% reduction in egg-associated SE illnesses by 2005.

Performance measures: Numbers of SE cases and outbreaks decrease annually. Data from: (1) Foodborne Diseases Active Surveillance Network (FoodNet), (2) National Salmonella Surveillance System (via PHLIS), and (3) National SE Outbreak Surveillance System and Foodborne Diseases Outbreak Surveillance System.

1998 Baseline data: (1) 1.9 cases per 100,000 persons; (2) 5,900 SE isolates; and (3) 45 SE outbreaks, respectively.²⁶

Objective 1:

Reduce the number of SE-containing eggs marketed to the consumer.

Performance measure: Number of production sites testing positive for SE reduces annually, according to agency and producer data. (Proxy measure for eggs marketed baseline to be determined.).

- 1.1 Establish a consistent, nationwide SE reduction program for egg production that includes components such as:
 - 1.1.1 SE environmental testing
(For example, chick papers; pullets at 12-14 weeks and layers at 25-30 weeks of age; post-molt, if molted; 2-4 weeks prior to de-population.)
 - 1.1.2 Restricting access and movement of personnel and equipment
 - 1.1.3 Using SE-negative feed
 - 1.1.4 Using chicks from SE-negative breeders
 - 1.1.5 Cleaning and disinfection of poultry houses and equipment
 - 1.1.6 Improving rodent and pest control in houses
 - 1.1.7 Diverting of eggs to pasteurization if SE testing yields a positive.
(With option to test eggs and sell SE-negative eggs as shell eggs.)
 - 1.1.8 Training agency inspection force

²⁶ CDC correspondence with FDA. 10/27/99.

Timeline: Proposed rule - FY2000; final rule - FY2001; implementation following.

- 1.2 Establish a HACCP-based system for shell egg processing and prerequisite programs that includes components such as:

- 1.2.1 Basic sanitation of premises and facilities
- 1.2.2 Rodent and pest control
- 1.2.3 Employee hygiene and health
- 1.2.4 Safety of water and food packing materials
- 1.2.5 Washing, sanitizing, grading, packaging, cooling, and repackaging

Timeline: Proposed rule - FY2002; final rule - FY2003; implementation following.

- 1.3 Establish a HACCP-based system for egg products processing and prerequisite programs that includes components such as:

- 1.3.1 Basic sanitation of premises and facilities
- 1.3.2 Rodent and pest control
- 1.3.3 Employee hygiene and health
- 1.3.4 Safety of water and food packing materials
- 1.3.5 Washing, sanitizing, packaging

Timeline: Proposed rule - FY2000; final rule - FY2001; implementation following.

- 1.4 Finalize and implement refrigeration and labeling regulations for eggs from processor to consumer.

Timeline: Final rule - FY2000; implementation following.

Objective 2:

Reduce exposure of consumers to SE-containing foods.

Performance measure: Number of egg-associated SE illnesses due to unsafe handling practices at the retail stage decreases annually.

- 2.1 Establish safe egg handling and preparation practices using egg-relevant sections of FDA's 1999 Food Code, specifically practices such as:

- 2.1.1 Acquisition

- 2.1.2 Storage
- 2.1.3 Preparation
- 2.1.4 Service

Timeline: Proposed rule - FY2000; final rule - FY2001; implementation following.

- 2.2 Identify and address barriers to implementing Food Code provisions in facilities serving high-risk populations, through the collaborative efforts of interagency Federal Food Safety Coalition. These facilities include:

- 2.2.1 Child and adult day care centers
- 2.2.2 Senior centers and home-delivered meals
- 2.2.3 Preschools and elementary schools
- 2.2.4 Nursing homes
- 2.2.5 Hospitals
- 2.2.6 Detention and penal facilities

Timeline: Ongoing

Objective 3:

Expand and upgrade surveillance systems for human SE infection

Performance measures: Number of public health laboratories that rapidly report SE isolates and SE outbreak surveillance data electronically increases; number of SE isolates phage-typed increases

- 3.1 Conduct active surveillance in a location where SE is prevalent. (Requires an additional FoodNet site.)

Timeline: By FY2005

- 3.2 Upgrade information systems, at State and local public health departments, for electronic reporting of laboratory-confirmed SE isolations (via Public Health Laboratory Information System) and SE outbreak surveillance data.

Timeline: By FY2005

- 3.3 Maintain CDC's role as the national SE phage typing reference and support center for human isolates. Continue phage-typing SE isolates submitted through

the National Antimicrobial Resistance Monitoring system-Enteric Bacteria (NARMS-EB).

Timeline: Ongoing

- 3.4 Begin phage typing human SE isolates from FoodNet sites.

Timeline: By 2001

- 3.5 Conduct SE case-control studies at FoodNet sites to monitor changes in risk factors for human SE infection and association with egg consumption.

Timeline: By FY2005

Objective 4:

Expand surveillance and upgrade surveillance systems for poultry SE infection

Performance measures: Availability of data on prevalence of SE infections in poultry increases; number of SE-isolates phage-typed increases.

- 4.1 Monitor SE prevalence in layer breeding flocks.

Timeline: Ongoing

- 4.2 Complete USDA NAHMS Layers '99 Study.

Timeline: By FY2000. (Repeat survey in FY2005.)

- 4.3 Phage-type SE isolates submitted through Layers '99 Study.

Timeline: By 2001

- 4.4 Define, assess and enhance surveillance capacities and data at industry and animal health agencies.

Timeline: By 2005

- 4.5 Maintain USDA's National Veterinary Services Laboratories (NVSL) role as the national SE phage typing reference and support center for feed and animal isolates.

Timeline: Ongoing

Objective 5:

Accelerate SE outbreak detection and initiation of outbreak investigations and improve completeness of outbreak investigations.

Performance measures: Number of SE outbreaks investigated completely increases; number of egg-associated outbreaks in which source of eggs is identified increases.

- 5.1 Develop and implement new outbreak detection algorithms. Use Salmonella Outbreak Detection Algorithm (SODA) to analyze SE surveillance data.

Timeline: Ongoing

- 5.2 Identify and address reasons for delayed investigation and reporting of SE outbreaks from state agencies.

Timeline: By FY2005

- 5.3 Assess practices and environmental circumstances during outbreak investigations to identify common contributing factors.

Timeline: By FY2005

- 5.4 Establish product identification and tracking system requirements to facilitate identification of egg sources during outbreaks.
(Note: May require new statutory authority to access product records.)

Timeline: By FY2005

- 5.5 Establish national egg traceback procedures.

Timeline: By FY2005

Objective 6:

Improve communication among Federal, State, and local agencies involved in SE outbreak and traceback investigations and by agencies with industry and the public about outbreaks.

Performance measure: Number of days to notify other relevant government agencies of outbreaks decreases.

- 6.1 Establish a listserve to communicate SE outbreak information among public health authorities and other partners.

Timeline: By FY2001

- 6.2 Conduct an SE outbreak information needs assessment with industry and the public.

Timeline: By FY2001

- 6.3 Develop and maintain an internet site for posting SE surveillance and outbreak data for industry and public access.

Timeline: By FY2001

Objective 7:

Ensure adequate, current information is available to make decisions about SE preventive controls, surveillance, and education based on sound science.

Performance measure: Number of research questions answered increases.

- 7.1 Conduct research to develop and evaluate on-farm intervention strategies or technologies including:

- 7.1.1 Forced molting and other stress factors
- 7.1.2 Vaccines and immunomodulators
- 7.1.3 Competitive exclusion
- 7.1.4 Ion air scrubbers in hatcheries

Timeline: By FY2005

- 7.2 Conduct research to provide additional information about commercial processing technologies and practices including:

- 7.2.1 In-shell pasteurization of eggs
- 7.2.2 Rapid cooling before and after processing
- 7.2.3 Continuous rewashing
- 7.2.4 Repackaging
- 7.2.5 Pasteurization of egg products with additives

Timeline: By FY2003

- 7.3 Conduct research to improve testing methodologies for SE on the farm and in eggs, including the identification of virulence factors and development of rapid tests, screening tests, sampling protocols, and molecular methods for subtyping SE isolates.

Timeline: By FY2005

- 7.4 Conduct research to understand the ecology and epidemiology of SE in the hen and farm environment, including:

- 7.4.1 Sources of SE in the environment
- 7.4.2 Mechanism of colonizing the layer house
- 7.4.3 Factors affecting infection of the hen and contamination of the egg
- 7.4.4 Characteristics of SE that promote infection in hens and humans
- 7.4.5 Biochemical characteristics of SE strains causing variations in virulence
- 7.4.6 Immunological and other factors in humans that affect infectivity
- 7.4.7 Risk factors associated with the on-farm presence of SE isolates.

Timeline: By FY 2008

Objective 8:

Educate individuals throughout the production to consumption continuum using science-based materials.

Performance measures: Number of partnerships increases; number of education materials available increases; percentage of consumers using unsafe egg-handling practices decreases.

8.1 Develop and distribute materials for the egg, retail, and foodservice industries, using partnerships:

- 8.1.1 For egg producers and processors/packers about their role in egg safety, using egg industry organizations.
- 8.1.2 For retailers and food service workers about regulations and adoption of the Food Code, using retail and institutional organizations.
- 8.1.3 For food packages including safe food handling tips, using food industry representatives.

Timeline: FY 2000-2005

8.2 Develop and distribute materials for target audiences of:

- 8.2.1 Healthcare practitioners, including physicians, about diagnosing and treating foodborne illness, through professional organizations, such as the AMA.
- 8.2.2 Patients and at-risk populations, about safe handling and preparations of foods, including eggs, through professional organizations, such as the AMA.
- 8.2.3 Food preparers at facilities serving highly susceptible populations, including nursing homes, daycare centers, and hospitals, about proper egg handling and preparation practices.
- 8.2.4 Under-served populations, including Hispanics and African-Americans, about proper egg handling and preparation practices, through magazines and newspapers.
- 8.2.5 Senior citizens, about proper egg handling and preparation practices, using the Food Safety Information for Seniors, the Senior food safety website, the Senior food safety video, and the Senior food safety publication.
- 8.2.6 Women and men, about proper egg handling and preparation practices, through women's, men's, and health magazines.
- 8.2.7 Students and parents, advice on not eating foods containing uncooked eggs, such as homemade raw cookie dough.

Timeline: FY 1999-2000

8.3 Conduct a nationwide telephone survey to assess consumer knowledge about and proper practices of egg handling and consumption, including:

- 8.3.1 Consume raw or undercooked (runny) eggs, by age group
- 8.3.2 View eggs as a high-risk food
- 8.3.3 Awareness of safe handling and warning label statements

8.3.4 Cooking time-temperatures

8.3.5 Pooling

Timeline: FY 1999-2000

- 8.4 Conduct a survey at retail establishments (e.g. restaurants, institutions) to assess food preparer knowledge and proper practices of egg handling, as in 8.3.

Timeline: FY 2001-2002

[End of Action Plan]

Appendix 1. Action Plan Timeline

Task Name	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
1.1 Establish a consistent, nationwide SE reduction program for egg production.											
1.2 Establish a HACCP-based system for shell egg processing and prerequisite programs.											
1.3 Establish a HACCP-based system for egg products processing and prerequisite programs.											
1.4 Finalize and implement refrigeration and labeling regulations for eggs from processor to consumer.											
2.1 Establish safe egg handling and preparation practices using egg relevant sections of FDA's 1999 Food Code.											
2.2 Identify and address barriers to implementing Food Code provisions in facilities serving high-risk populations through the collaborative efforts of the interagency Federal Food Safety Coalition.											
3.1 Conduct active surveillance in a location where SE is prevalent.											
3.2 Upgrade information systems, at State and local public health departments, for electronic reporting of laboratory-confirmed SE isolations and SE outbreak surveillance data.											
3.3 Continue phage-typing SE isolates submitted through National Antimicrobial Resistance Monitoring system-Enteric Bacteria (NARMS-EB) and isolates from SE outbreaks.											
3.4 Begin phage typing human SE isolates from Food Net sites.											
3.5 Conduct SE case-control studies to monitor changes in risk factors for human SE infection and association with egg consumption.											
4.1 Monitor SE prevalence in layer breeding flocks.											
4.2 Complete USDA NAHMS Layers '98 Study.											
Repeat USDA NAHMS Layers '98 Study.											
4.3 Phage-type SE isolates submitted through Layers '98 Study											
4.4 Define, assess and enhance surveillance capacities and data at industry and animal health agencies.											
4.5 Maintain USDA's National Veterinary Services Laboratories (NVSL) role as the national SE phage typing reference and support center for feed and animal isolates.											
5.1 Develop and implement new outbreak detection algorithm. Use SODA to analyze SE surveillance data.											
5.2 Identify and address reasons for delayed investigation and reporting of SE outbreaks from state agencies.											
5.3 Assess practices and environment circumstances during outbreak investigations to identify common contributing factors.											
5.4 Establish product identification and tracking system requirements to facilitate identification of egg sources during outbreaks.											
5.5 Establish national egg traceback procedures.											
6.1 Establish a listserv to communicate SE outbreaks among public health authorities and other partners.											
6.2 Conduct an SE outbreak information needs assessment with industry and the public.											
6.3 Develop and maintain an internet site for posting SE surveillance and outbreak data for public access.											
7.1 Conduct research to develop on-farm intervention strategies or technologies.											
7.2 Conduct research to provide additional information about commercial processing technologies and practices.											
7.3 Conduct research to improve testing methodologies for detection of SE on the farm and in eggs.											
7.4 Conduct research to understand the ecology and epidemiology of SE in the hen and in the farm environment.											
8.1 Develop and distribute materials for the eggs, retail, and foodservice industries, using partnerships.											
8.2 Develop and distribute materials for target audiences.											
8.3 Conduct a nationwide telephone survey to assess consumer knowledge about and proper practices of egg handling and consumption.											
8.4 Conduct a survey at retail establishments (e.g. restaurants, institutions) to assess food preparer knowledge and proper practices of egg handling.											

APPENDIX 2. GLOSSARY

Biosecurity. The term refers to procedures designed to prevent SE from being carried into poultry houses from outside sources and may include all or some of the following: use of chicks from SE-negative breeder flocks, use of SE-negative feed ingredients; proper use of medications and pesticides; and restricted access and movement of personnel and equipment in/out of hen houses.

Eggs. The term is used in this document to include both shell eggs and egg products.

Egg products processing. The processing of shell eggs into egg products involving breaking, filtering, mixing, stabilizing, blending, pasteurizing, cooling, freezing or drying, and packaging.

Egg production. The on-farm activities of egg-laying and collection.

Egg products. The term refers to eggs that have been removed from their shells and processed. The term applies to whole eggs, whites, yolks, and various blends with or without non-egg ingredients, regulated by FSIS. The term does not apply to freeze-dried products, imitation egg products, and egg substitutes which are the responsibility of FDA.

Federal Food Safety Coalition. The interagency working group consists of members from: Department of Veterans Affairs, Veterans Health Administration; USDA, Food and Nutrition Service's School Lunch Program, WIC Program, and Infant Formula Program; Department of Justice, Bureau of Prisons; HHS, Head Start Program, Administration on Aging, Indian Health Service, Health Care Financing Administration, and CFSAN.

Food Code. A reference document for regulatory agencies responsible for overseeing food safety in retail outlets, such as restaurants, grocery stores, and institutions (including nursing homes and daycare centers), consisting of recommendations for adoption by local, state, and federal governmental jurisdictions, offered by FDA.

FoodNet (Foodborne Diseases Active Surveillance Network). A network consisting of 8 sites that conduct active surveillance, investigations, and epidemiologic studies. The information is used to: (1) determine the frequency and severity of foodborne diseases; (2) determine the proportion of common foodborne diseases that result from eating specific foods; (3) describe the epidemiology of new and emerging foodborne pathogens; and (4) assess the effectiveness of new food safety control measures. It is a collaborative project among CDC, the 8 sites, FSIS and FDA.

HACCP (Hazard Analysis-Critical Control Points). The process of identifying the hazards (hazard analysis) present in a process and determining critical points

throughout the process (critical control points) at which loss of control would result in the presence of a hazard posing a serious risk to human health.

Layers. Hens (including those being molted) or pullets producing table or commercial type shell eggs, usually at least 20 weeks of age.

“Layers 99” NAHMS Survey. A study to: (1) describe baseline health and management practices used by the U.S. layer industry; (2) estimate the national prevalence of SE in layer flocks by testing the environment and at layer operations; (3) identify potential risk factors associated with the presence of SE; and (4) describe biosecurity practices.

Molt. A process during which hens stop laying and shed their feathers, occurring naturally every 12 months. May be artificially induced by withholding feed or water for a period of time. Forced molting is done to improve egg production.

National Animal Health Monitoring System (NAHMS). An animal health monitoring system, established by APHIS in 1990, (1) to help government officials and industry organizations define public risks and identify research needs and (2) to identify opportunities for producers and veterinarians to improve management and product quality.

National Antibiotic Resistance Monitoring System (NARMS). A system for monitoring emerging resistance to antibiotics in foodborne pathogens, established in 1996 as an interagency cooperative activity.

National Poultry Improvement Plan (NPIP). A program that certifies that poultry breeding stock and hatcheries are free from egg-transmitted and hatchery-disseminated diseases, including SE.

National Veterinary Services Laboratories (NVSL). A national laboratory providing veterinary diagnostic, laboratory support, and reference services related to domestic and foreign livestock and poultry diseases for programs, including NAHMS and NPIP, and administered by APHIS.

Outbreak. Two or more people having a similar illness that has been traced to eating a common food.

Public Health Laboratory Information System (PHLIS). An electronic reporting system used by State public health laboratories to report isolates of *Salmonella* from human sources to CDC's National Salmonella Surveillance System.

Pullet. A female chicken that has not yet started to lay eggs.

Restricted eggs. Eggs with cracks or checks in the shell, dirty eggs, incubator rejects, and inedible, leaker, or loss eggs.

Salmonella Enteritidis (SE). A bacterium of the genus *Salmonella*, species *enterica*, and serotype Enteritidis.

SE Isolation Rate. The rate of isolation of *Salmonella* Enteritidis from infected humans.

“Sell by” period. The time within which retailers must sell shell eggs.

Shell eggs. The term refers to eggs still in their shells.

Shell egg handlers. Firms that grade and pack shell eggs for commercial distribution (packing plants) and hatcheries.

Shell egg processing. The phase of processing involving the washing, segregation and packaging of shell eggs for distribution to retail, institutional, and other commercial users.

Shell Egg Surveillance program. A quarterly inspection program, mandatory for shell egg handlers, to verify that: (1) restricted eggs are properly disposed of and (2) no more restricted shell eggs than permitted in U.S. Consumer Grade B are sold to the consumer

Salmonella Outbreak Detection Algorithm (SODA). A statistical algorithm designed to detect unusual clusters of isolates of *Salmonella* infection and to compare current *Salmonella* isolates reported through PHLIS by serotype to an historical baseline for that serotype, implemented in 1996.

Spent Hen. A breeder or commercial type egg hen that no longer performs at desired production levels.

Undergrade. Any edible shell eggs that does not meet the requirements (standards) for the indicated grade, Grade AA, Grade A, or Grade B.

Whole Eggs. Consist of yolk (yellow portion) and albumen (white or clear portion). For the various types of egg products - liquid, frozen, and dried - the yolks and albumen are separated during the breaking. Customers may request whole eggs (entire contents of egg) or a combination of yolks and albumen to produce egg product for specific uses.

#

1ST STORY of Level 1 printed in FULL format.

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December 10, 1999; Friday 02:04 Eastern Time

SECTION: Washington - general news

LENGTH: 403 words

HEADLINE: USDA: Food Safety Program at Risk

BYLINE: PHILIP BRASHER

DATELINE: WASHINGTON

BODY:

The government says its new food-safety program is at risk unless a judge allows the shutdown of a Texas meatpacking plant that failed a series of salmonella tests.

The Agriculture Department withdrew its inspectors from the Supreme Beef Processors Inc. plant in Dallas Nov. 30, effectively closing the facility, but was forced to send them back later in the day when U.S. District Judge A. Joe Fish granted a temporary restraining order. A hearing on the dispute was scheduled today.

The new safety program requires companies to implement controls to prevent foodborne pathogens in excess of government standards. Previously, companies relied on USDA inspectors to poke and sniff for problems.

'Supreme Beef's products are continuing to receive USDA's seal of approval, notwithstanding USDA's belief that they should not be entering commerce at all,' the Justice Department said in a court filing Thursday.

'This is an untenable position for USDA, and the longer it continues the more it will undermine the integrity of, and public confidence in, the government's meat inspection program,' the filing said.

Officials said the plant supplies about 15 percent of the ground beef the department buys annually for school lunch programs. USDA suspended purchases from the facility Nov. 30.

The company challenged the testing program's fairness, calling the standards 'arbitrary and capricious,' and disputed the department's sampling results. The company also says that salmonella isn't a public health issue because the pathogen is destroyed during cooking.

Although the pathogen is destroyed by cooking, consumers who handle meat contaminated with salmonella risk spreading the pathogen to other food, health expert say. Salmonella kills an estimated 550 people and causes 1.4 million illnesses a year, according to the Centers for Disease Control and Prevention.

AP Online December 10, 1999; Friday

Separately Thursday, USDA released a letter disputing Mexico's Nov. 24 ban on imports of meat and chicken from 17 other American plants. In some cases, the countries differ about safety standards. In others, USDA officials dispute the findings of Mexican inspectors.

'The two governments have been talking almost every day. There has been a lot of energy put into trying to resolve this,' said Karen Sutck, an official with the department's Food Safety and Inspection Service. All 17 plants are safe, she said.

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Subject: Radio Address on Food Safety

	ACTION	FYI		ACTION	FYI
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PODESTA	☒	☐	MARSHALL	☐	☐
ECHAVESTE	☒	☐	MOORE	☐	☐
RICCHETTI	☒	☐	NASH	☐	☐
LEW	☐	☐	NOLAN	☐	☐
BAILY	☐	☐	REED	☒	☐
BERGER	☐	☐	SOSNIK	☒	☐
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JOHNSON, J.	☒	☐	<u>Mary Smith</u> → ☒		☐
LANE	☐	☐	<u>Clifford Gabriel</u> → ☒		☐
LEWIS	☒	☐		☐	☐

REMARKS:

Comments to Jeff Shesol 62796

RESPONSE:

Draft 12/09/99 7:45pm
Jeff Shesol

**PRESIDENT WILLIAM J. CLINTON
RADIO ADDRESS ON FOOD SAFETY
LITTLE ROCK, ARKANSAS
December 11, 1999**

Good morning. The holidays are upon us; and across our nation families and friends are gathering to celebrate the season. Today, I want to talk about the steps we must take to make sure the food we serve at these festivities – indeed, the food we serve every day – is the safest in the world.

For seven years now, our administration has worked hard to update our food-safety standards for the 21st Century. We have made significant strides by using the newest research and best technology available. We are using new, science-based standards for meat, poultry, and seafood; and have updated our standards for fruit and vegetable juices. We also established a nationwide early-warning system for foodborne illness – to catch problems sooner and prevent them from happening in the first place.

But the holiday season is only our latest reminder: when it comes to what we feed our families, we can always work harder, and make our food even safer. We know that certain foods carry a special risk for children, the elderly, and those with weakened immune systems. My Council on Food Safety has identified eggs as one of those foods. One egg in every 20,000 may be infected with salmonella bacteria. That's 2.3 million eggs every year, resulting in about 300,000 cases of illness. Now, the number of cases has been on the decline; but when infected eggs still make it from farm to table, we know we have more work to do.

That is why, today, I am taking executive action on egg safety – to cut in half, over the next five years, the number of salmonella cases attributed to eggs; and to eliminate these cases altogether by 2010. This aggressive action plan permits egg producers and processors to choose between two strategies of safety. The first happens at the farm, where extensive tests and rigorous practices will help prevent infected eggs from ever reaching your local grocery. The second happens at the packaging plant, where new technologies – like “in-shell pasteurization” – will help keep eggs safe and free of bacteria.

I am also announcing new steps to keep unsafe food imports outside our borders and out of our marketplace. Americans are eating more imported food than ever – more than double the amount we consumed just seven years ago. It used to be that only a dozen fruits and vegetables were available year-round. Now it's not uncommon to find as many as 400 varieties, whether in the heat of summer or the chill of winter.

We have no reason to believe imported food is any less safe than the food we grow at home. But after several outbreaks of illness were traced to imported foods, I directed the Department of Treasury and the Department of Health and Human Services to take action against unsafe imported food, and to better protect the American consumer. Today, they are responding

with a comprehensive plan. It sets forth steps to prevent “port shopping” – so unsafe food stopped at one port can’t find another way in. Customs and the FDA will also stamp rejected food with a clear label – “Refused U.S.” – and step up our policy of destroying imported food that poses a serious health threat to our people.

Food safety is part of our people’s basic contract with their government. Any food that fails to meet clear and strict standards for safety should not make it to the marketplace. It’s that simple. But every parent, too, has a responsibility – to be mindful of the way their food is handled and served. In these ways, all our families can have the peace of mind they deserve – this, and every, holiday season. Thank you for listening.



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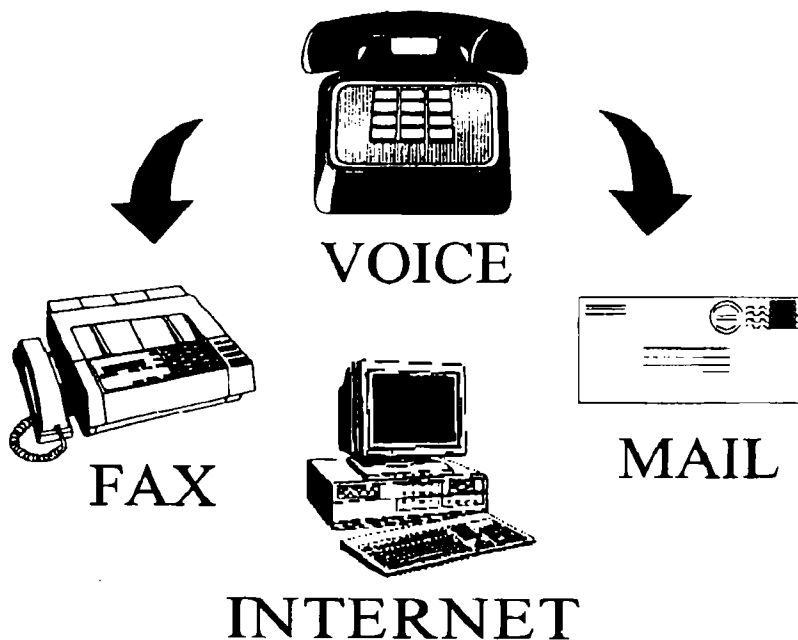
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DEC 16 1999

Food and Drug Administration
Washington DC 20204

Dear Colleague, FDA Foods Community:

This past Saturday, President Clinton's weekly radio address was devoted to food safety. The President announced both our Egg Safety Action Plan and our Imported Foods Action Plan. The plans are summarized in the attached materials. A copy of the December 11 address, as well as copies of both Action Plans can be found on our web page at www.cfsan.fda.gov.

The Egg Safety Action Plan, which was developed under the auspices of the President's Council on Food Safety, identifies the systems and practices that must be implemented to reduce and ultimately eliminate eggs as a source of human *Salmonella* Enteritidis (SE) illnesses. The goal of the plan is to eliminate SE illness associated with the consumption of eggs by 2010. The interim goal is a 50 percent reduction in egg-associated SE illnesses by 2005. By combining new and existing systems and activities across the entire farm-to-table continuum, the plan presents a comprehensive nationwide strategy to address an important food safety and public health concern. The plan will be implemented by the FDA, the U.S. Department of Agriculture and the Centers for Disease Control and Prevention, in conjunction with state authorities from across the country.

The Import Plan was issued in response to the President's July 3, 1999 radio address. In that address, the President directed FDA and the U.S. Customs Service to initiate actions to further protect consumers from unsafe imported food. Accordingly, the Import Plan includes actions that FDA and Customs will take to: (1) prevent the distribution of imported unsafe food by means such as requiring food to be held until reviewed by FDA; (2) destroy imported food that poses a serious public health threat; (3) prohibit the re-importation of food that has been previously refused admission; and (4) require the marking of shipping containers of imported food that is refused admission for safety reasons.

We will continue to engage and consult with our many stakeholders as we work through the implementation phase of these plans. Close interaction between government, consumers, and industry is critical if we are going to achieve these important goals.

In closing, I would like to quote from President Clinton's December 11 radio address: "Food safety is part of our citizens' basic contract with the government. Any food that fails to meet clear and strict standards for safety should not make it to the marketplace; it's just that simple." Within that spirit, I look forward to working with you as we continue to enhance the safety of America's food supply.

Sincerely,

Joseph A. Levitt
Director

Center for Food Safety and Applied Nutrition

Attachments

President's Council on Food Safety



U.S. Department
of Agriculture



Department of Health
and Human Services



Environmental
Protection Agency



Department
of Commerce

EGG SAFETY

From Production to Consumption:

AN ACTION PLAN to Eliminate Salmonella Enteritidis Illnesses Due to Eggs

December 10, 1999

Executive Summary

Purpose. The President's Council on Food Safety has identified egg safety as one component of the public health issue of food safety that warrants immediate federal, interagency action. The Egg Safety Action Plan presented in this report identifies the systems and practices that must be implemented to reduce and, ultimately, eliminate eggs as a source of human *Salmonella* Enteritidis (SE) illnesses. The overarching public health goal of the Council is to eliminate SE illnesses associated with the consumption of eggs by 2010. The interim goal of the Egg Safety Action Plan is a 50 percent reduction in egg-associated SE illnesses by 2005.

Background. Americans consume an average of 234 eggs per person per year. While eggs are an important source of protein in the diet, an estimated 1 in 20,000 eggs in the U.S. supply will contain the SE bacteria and can cause illness if eaten raw in foods or not thoroughly cooked before consumption. Because eggs can become contaminated internally from the hen, common egg-handling practices are now considered to be unsafe. These practices include temperature abuse (i.e. holding eggs and egg-containing foods at room temperature instead of under refrigeration), inadequate cooking, and pooling eggs to prepare a large volume of an egg-containing food that is subsequently temperature abused or inadequately cooked.

The SE risk assessment model for shell eggs and egg products, developed jointly by the Food Safety and Inspection Service (FSIS) and Food and Drug Administration (FDA) in 1998, predicted that using multiple interventions could achieve a more substantial reduction in SE illnesses than using any one intervention alone. This finding suggests that a broadly based policy is likely to be more effective in eliminating egg-associated SE illnesses than a policy directed solely at one stage of the egg production to consumption continuum.

On August 26, 1999, the President's Council held a public meeting to obtain input during the development of the action plan to address egg safety. A single theme resounded from representatives of the consumer groups and the egg industry: The federal government needs a set of mandatory national standards. These standards should: (1) provide consumers an assurance that all eggs are subject to the same safety standards across the U.S. and (2) provide egg producers and processors a "level playing field" industry-wide.

Recommendations. The President's Council on Food Safety concluded that the development and implementation of the Action Plan outlined in this report is an effective way to prevent human SE infections due to the consumption of SE-contaminated eggs. The Action Plan reflects our current understanding of the steps needed to reduce egg-associated SE illness. As we move forward with the Plan and develop the proposals, we will assess the impact of the individual action items, consult with stakeholders, and refine the Plan to reflect the best information available to achieve our public health goal.

At each stage of the egg production-to-consumption continuum, the Plan identifies the systems and activities necessary to achieve our food safety public health goals. The Plan offers industry the flexibility to choose from two equivalent SE reduction strategies, each delivering eggs into distribution and to the consumer at an equivalent level of safety. The strategy selection by egg producers and packer/processors determines the point at which the pathogen reduction steps are taken:

- Strategy I: SE testing-egg diversion system on farm
- Strategy II: Lethal treatment, or "kill step" at packer/processor

For the distribution and retail stages, the Plan specifies the safe handling practices necessary to ensure consumers receive a safe food product. Furthermore, the Plan clearly describes the surveillance, research, and education activities that must also be conducted to achieve the elimination of egg-associated SE illnesses. The relative difference in emphasis between the two strategies is highlighted in Figure 1. A comparative summary of the activities in Strategy I and Strategy II is provided in Table 1.

To consolidate egg safety oversight responsibilities and provide clarity, the President's Council on Food Safety identified one responsible agency for each stage of the farm-to-table continuum, based on the strengths of each agency, as follows:

- FDA develops standards for the producer and the States provide inspection and enforcement on the farm.
- FSIS develops standards for both shell egg packers and egg products processors and provides inspection and enforcement for both.
- FDA and CDC conduct surveillance and monitoring activities. CDC focuses on human health and FDA on the food supply.

The performance measures that will be used to assess the progress of the Plan toward its goal are the numbers of SE cases, isolates, and outbreaks annually. The data will be collected using the following existing systems: (1) Foodborne Diseases Active Surveillance Network (FoodNet), (2) National Salmonella Surveillance System (via PHLIS), and (3) National SE Outbreak Surveillance System and Foodborne Diseases Outbreak Surveillance System. The new data will be compared to the 1998 baseline values of: (1) 1.9 cases per 100,000 persons; (2) 5,900 SE isolates; and (3) 45 SE outbreaks, respectively.

Figure 1. Depiction of Program Strategies for Action Plan

Eggs: From Farm to Table

Problem: *Salmonella* Enteritidis in Eggs
Goal: Eliminate It as a Source of Human Illness

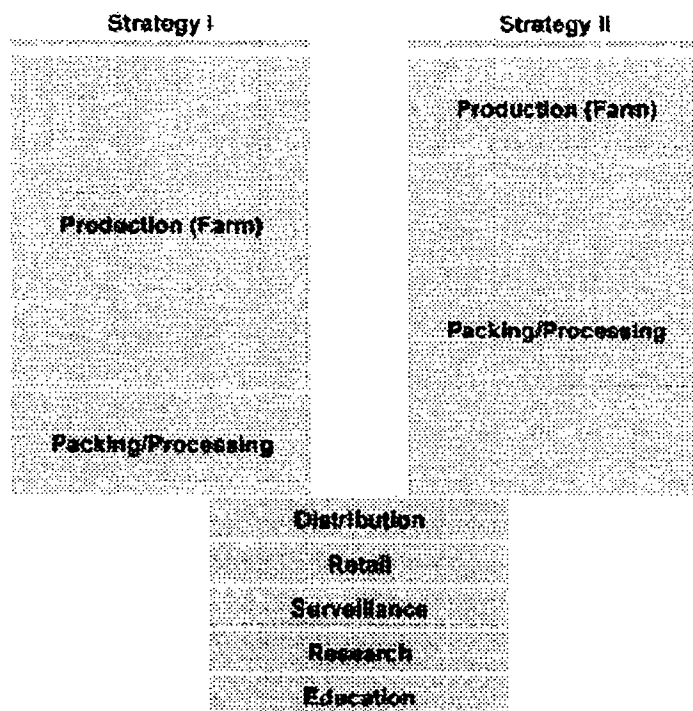


Table 1. Comparison of Program Strategies for Action Plan		
<i>Activity</i>	Strategy I	Strategy II
PRODUCTION (On-Farm): Objective 1.1		
Chicks from SE-free breeder flocks	X	X
SE Environmental Testing (chicks, pullets, layers)	X	
SE Environmental Testing (at depopulation)	X	X
SE Egg Testing (w/positive environmental results)	X	
Diversion of shell eggs to pasteurization	X	
Biosecurity	X	X
Rodent/Pest control	X	X
Decontamination (Cleaning & Disinfection)	X	X
PACKING¹: Objective 1.2		
Prerequisite programs	X	X
HACCP system with a "kill" step		X
PROCESSING¹: Objective 1.3		
Prerequisite programs	X	X
HACCP system with a "kill" step	X	X

DISTRIBUTION²: Objective 1.4		
Refrigeration during transport and storage	X	X
RETAIL: Objective 2		
Food Code (egg-relevant provisions)	X	X
SURVEILLANCE: Objectives 3-6		
Monitoring human and poultry SE infections	X	X
RESEARCH: Objective 7		
	X	X
EDUCATION: Objective 8		
	X	X
¹ Prerequisite programs must address: basic sanitation of facilities and premises; rodent and pest control; employee hygiene and health; safety of water and food packing materials; and washing, sanitizing, and packaging.		
² FSIS Final Rule; FDA Proposed Rule		



Presidential Initiative - Safety of Imported Food

Status Report

I. Background

American consumers enjoy one of the safest food supplies in the world. Enhancing the safety of the U.S. food supply is a high priority of the Clinton Administration as evidenced by funding requests for food safety initiatives, the establishment of the Food Safety Council, and directives to improve the safety of the food supply. On July 3, 1999, President Clinton expanded his food safety efforts by directing the Secretary of Health and Human Services and the Secretary of the Treasury to take additional action to further protect consumers from unsafe imported foods. While most imported foods are safe, and most importers comply with U.S. food safety requirements, a few importers try to sidestep U.S. laws to bring unsafe or contaminated food into the country. The President specifically directed the Food and Drug Administration (FDA), the agency responsible for the safety of most imported foods, and the United States Customs Service (Customs) to take all actions available to:

1. Prevent distribution of imported unsafe food by means such as requiring food to be held until reviewed by FDA;
2. Destroy imported food that poses a serious public health threat;
3. Prohibit the re-importation of food that has been previously refused admission and has not been brought into compliance with U.S. laws and regulations, and require the marking of shipping containers and/or papers of imported food that is refused admission for safety reasons;
4. Set standards for private laboratories for the collection and analysis of samples of imported food for the purpose of gaining entry into the United States;
5. Increase the amount of the bond posted for imported foods when necessary to deter premature and illegal entry into the United States; and
6. Enhance enforcement against violations of U.S. laws related to the importation of foods, including through the imposition of civil monetary penalties.

The President further directed the Secretary of Health and Human Services and the Secretary of the Treasury to consult with his Food Safety Council and relevant federal agencies, particularly the United States Department of Agriculture (USDA) and the United States Trade Representative (USTR), to develop steps in the above areas to protect consumers from unsafe imported foods.

II. This Report

The President asked the Secretary of Health and Human Services and the Secretary of the Treasury to

report on the steps they will take in each area identified in his directive to protect consumers from unsafe imported foods. This report presents the status of progress made in each area and a plan for accomplishing the President's "problem importers" directive.

To meet the President's goal of curtailing the effect that problem importers may have on the safety of the U.S. food supply, the Departments will exercise the full extent of their statutory authorities to:

1. Require controlled storage of merchandise entered by firms with a history of failing to hold products, of making false declaration, or of substituting products;
2. Seize and/or destroy merchandise that poses a serious health threat;
3. Promulgate regulations to require importers or consignees to mark food products that have been deemed unsafe and refused admission into the United States and prohibit the re-importation of any food product that has been previously refused entry;
4. Promulgate regulations to establish requirements pertaining to sample collection and private laboratories;
5. Assess liquidated damages equal to the domestic value of merchandise that has not been redelivered to Customs or that has not been exported or destroyed within the time period prescribed by law after refusal; and
6. Collaborate more effectively in enforcing the Customs program of assessing civil monetary penalties to importers who attempt to import any food by means of any material false statement, act or omission.

In his directive, the President recognized that there are limitations on the Departments' resources and statutory authorities to take measures to protect consumers against unsafe imported foods. Included in this report are discussions of proposed rulemaking and resource costs to FDA and Customs to enact the new procedures and implement new regulations.

Because public notice and/or comment is desirable and, in some instances, required for the implementation procedures, the Departments plan to invite discussion and comment on these initiatives. This report and its accompanying operational procedural guidance and regulatory enforcement programs will be posted on the Internet sites of FDA and Customs.

The actions outlined in this report are intended to deal with problem importers and unsafe food shipments. The proposed steps are fully in accord with World Trade Organization agreements and should not pose barriers to trade for importers who routinely follow U.S. regulations and procedures.

Food is defined as articles used for food or drink for man or other animals in section 201(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(f)(1)). Animal food or feed is also imported into this country. Unless stated otherwise, use of the word food in this report includes animal food or feed.