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Report to the Honorable
Richard J. Durbin, U.S. Senate

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FOOD SAFETY

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

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United States
General Accounting Office
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Resources, Community, and
Economic Development Division

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The Honorable Richard J. Durbin
United States Senate

Dear Senator Durbin:

Eggs contaminated by the *Salmonella* Enteritidis bacteria have been recognized as a public health problem since 1988. About 300,000 illnesses and between 115 and 229 deaths may have occurred in 1997 as a result of *Salmonella* Enteritidis, according to the Centers for Disease Control and Prevention. Illnesses and deaths from *Salmonella* Enteritidis cost the nation approximately $225 million to $3 billion in 1996, according to the most current estimates from the U.S. Department of Agriculture (USDA). Although not all *Salmonella* Enteritidis infections are linked to eggs, between 1985 and 1998, when a cause could be identified, over three-quarters of *Salmonella* Enteritidis outbreaks were linked to eggs, according to the Centers for Disease Control and Prevention.

No single federal agency has overall responsibility for the policies and activities needed to ensure the safety and quality of eggs and egg products. 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 U.S. Department of Health and Human Services. Responsibilities shift among these agencies as eggs make their way from the farm to the table. In particular, FDA has the primary responsibility for the safe production and processing of eggs still in the shell (known in the industry as shell eggs), and FSIS has the responsibility for food safety at the 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 system for ensuring the safety of eggs. Specifically, we examined whether (1) a prevention-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 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.

Results in Brief

The Food and Drug Administration has not established a prevention-based approach to shell egg production and processing that would reduce or eliminate *Salmonella* Enteritidis contamination by identifying, controlling, and monitoring known safety risks. At the state level, 13 states, responsible for about 38 percent of the nation's egg production, have established voluntary prevention-based programs for egg farms. However, because these programs use different approaches to testing for the presence of *Salmonella* Enteritidis and monitoring the farms, they do not provide a uniform level of risk reduction. Moreover, the Food Safety and Inspection Service does not require a prevention-based approach in processing plants where eggs are broken to create egg products.

The first national requirement to refrigerate eggs at 45 degrees Fahrenheit or below from the time they are packed until they reach the consumer may not be as effective as possible in reducing the risks from eggs contaminated with *Salmonella* Enteritidis. Responsibility for implementing the refrigeration requirement is split between two federal agencies. The Food Safety and Inspection Service has issued regulations that take effect in August 1999—8 years after the Congress passed the legislation—requiring that eggs be refrigerated after packing until they reach retail locations such as restaurants, institutions, and grocery stores. However, once eggs reach these locations, federal regulations will not require that they be refrigerated because the Food and Drug Administration has not yet issued the necessary regulations. In addition, many experts believe greater risk reduction could be achieved by cooling the internal contents of eggs more quickly than the law will require.

Inconsistent policies and practices in three areas have weakened the nation's egg safety efforts. Only about half the states have followed the Food and Drug Administration's recommendation that they require food service operators to use pasteurized eggs or egg products when serving populations, such as the elderly in nursing homes, that are more likely to suffer severe health consequences from eating contaminated eggs. In addition, inconsistent policies on returning eggs from grocery stores to processors to be repackaged, redated, and returned to the retail level and inconsistent practices for expiration dating on egg cartons can mislead consumers about the eggs' freshness and may pose a food safety risk.

The current organizational and regulatory framework for egg safety makes it difficult to ensure that resources are directed to the areas of highest risk and that policies are effectively coordinated. For example, the Food Safety and Inspection Service provides daily full-time inspection of egg products plants where eggs are pasteurized to kill harmful bacteria, whereas the Food and Drug Administration almost never inspects egg farms where eggs can be contaminated. In addition, although we reported in 1992 on the need for better coordination between the Food and Drug Administration and the Department of Agriculture on egg safety issues, each agency is developing its own labeling requirements for egg cartons that will become effective at different times, and the agencies have still not agreed on a comprehensive unified approach for improving egg safety.

We are offering a matter for congressional consideration and recommendations to the Secretary of Agriculture and the Commissioner of the Food and Drug Administration aimed at improving egg safety.

Background

When *Salmonella* is found in eggs, *Salmonella* Enteritidis (SE) is the strain most commonly identified. SE was first associated with clean, intact shell eggs in 1988. Since that time, in situations in which two or more people have become ill and a source could be found, shell eggs have been identified as the leading source of SE infection. From 1987 to 1997, reports of SE infections increased, as did the proportion of *Salmonella* cases involving SE. Although not necessarily indicative of a national trend, recent data from the Centers for Disease Control and Prevention for selected counties and states have shown a decrease in SE cases for 1996 through 1998. SE, as well as other strains of *Salmonella*, can cause such symptoms as abdominal pain, fever, headache, and vomiting and can also lead to more severe conditions, such as bloodstream infections, arthritis, and meningitis. And it sometimes kills, particularly elderly residents of nursing homes. SE in shell eggs is believed to originate from laying hens whose ovaries contain the bacteria. Proper refrigeration delays the breakdown of the yolk membrane, thereby retarding the growth of *Salmonella* in eggs, and pasteurization or thorough cooking can kill it. (See app. I for additional information on the prevalence, causes, and illnesses related to SE contamination in eggs.)

The marked growth in reported bacterial foodborne illnesses, including *Salmonella*, has led to changes in the federal food safety system. One notable change has been the introduction over the last few years of prevention-based hazard analysis and critical control point (HACCP)

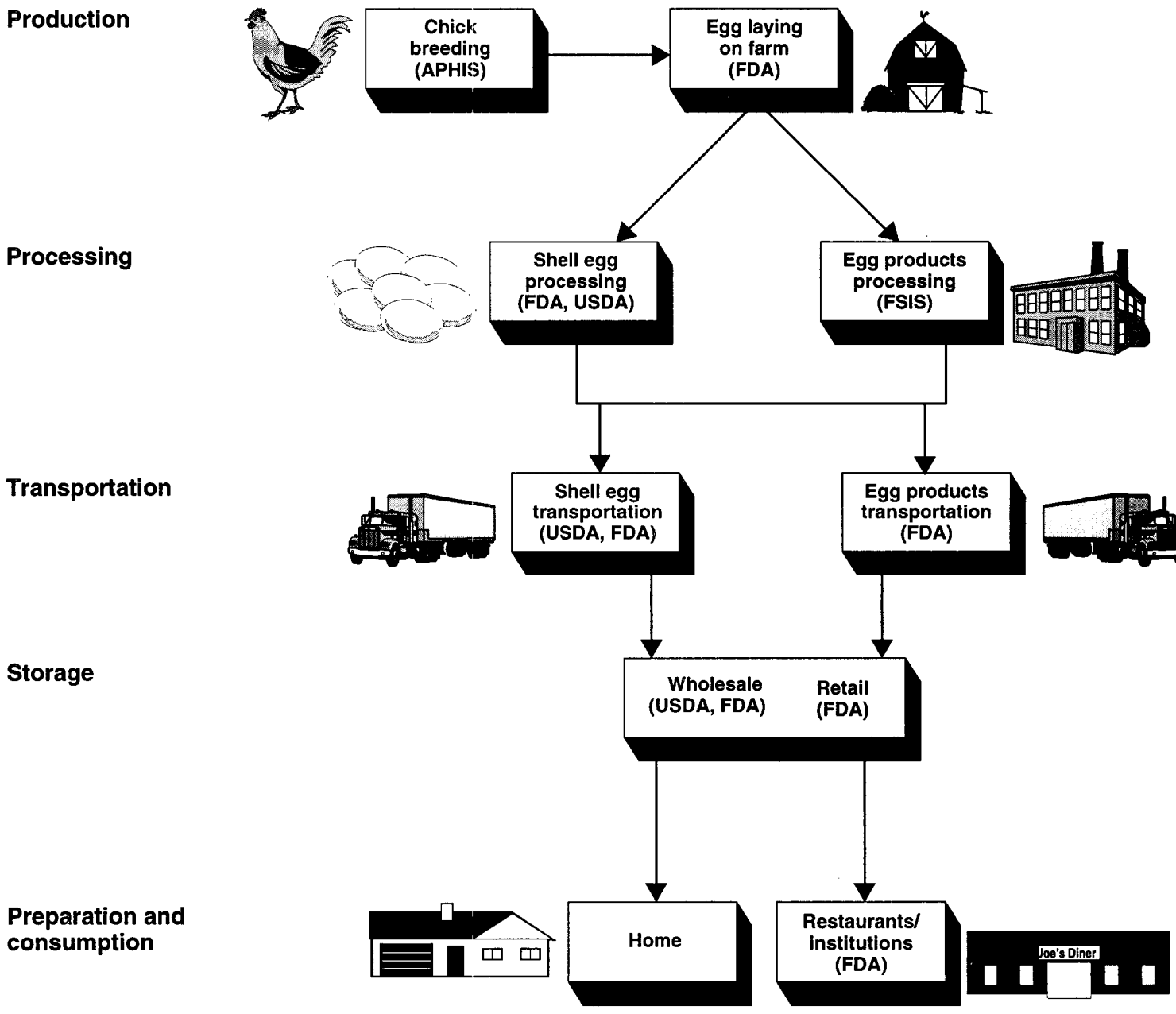
systems in meat, poultry, and seafood processing. HACCP systems are designed to actively monitor and control contamination throughout the food production process by identifying places where the greatest food safety risks exist, implementing methods to control the risks at those points, and then monitoring the efficacy of the controls. In May 1998, FDA and FSIS issued a joint advance notice of proposed rulemaking seeking to identify actions to decrease the food safety risks associated with eggs as they move from the farm to the table. This notice requested comments on several possible actions, including a proposal for a HACCP approach to shell egg production and processing. As of June 1999, no actions had been taken on this proposal.

The egg industry in the United States produced about 67 billion eggs in 1998. About 70 percent of those eggs were sold whole as shell eggs. The production and distribution of shell eggs from the farm to the table is a multistep process that involves (1) breeding laying hens; (2) producing eggs on farms; (3) cleaning and packing eggs at processing plants; (4) transporting eggs from processing facilities to wholesalers and retailers; and (5) handling and preparing eggs in restaurants, institutions, and homes. The remaining 30 percent of the eggs produced were broken, pasteurized, and processed into liquid, frozen, or dried egg products used, for instance, in commercial baked goods and ice cream. (For more information on egg production, processing, and distribution 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, as eggs move from the farm to the table, responsibility for egg safety shifts back and forth among several federal agencies and often two agencies in each state as well. (See fig. 1.) First, the Animal and Plant Health Inspection Service manages the National Poultry Improvement Plan that establishes breeding practices to ensure that at birth laying hens are free from SE. At the next stage, the farms where eggs are laid, FDA is responsible for egg safety. Once the eggs arrive at processing plants, where they are either packed as shell eggs or broken for egg products, the authority is split between two agencies—FDA for shell eggs and FSIS for egg products. While shell eggs are being processed, they may also be inspected by the Agricultural Marketing Service under a voluntary program to ensure shell egg quality. Once transported to the retail level, both shell eggs and egg products are under FDA's authority, but the millions of restaurants, institutions, and other retail food operations throughout the United States are generally inspected

by either a state agriculture or health department under state laws. FDA encourages uniformity among state laws by publishing the Food Code, which recommends model practices for ensuring safer food, and by encouraging states to adopt the code's provisions. (See app. III for additional information on the egg safety and quality responsibilities of federal and state agencies.)

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



(Figure notes on next page)

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

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

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

Outbreaks of egg-related illness are sometimes traced to egg production farms where laying flocks have become contaminated with SE. Although prevention-based approaches such as HACCP are generally recognized as the most effective method for identifying and reducing bacterial contamination, no federal program exists to reduce or eliminate this contamination during egg production and processing.

In our 1992 report on SE in eggs, we recommended that the Secretary of Agriculture and the Commissioner of FDA work together to develop a comprehensive program to control SE throughout the production, distribution, and consumption of eggs.[1] Six years later, in May 1998, USDA and FDA published an advance notice of proposed rulemaking in the Federal Register requesting comments by August 1998 on various proposals for improving farm-to-table egg safety, one of which concerned using the HACCP approach on egg farms. The agencies received comments from state agencies, egg industry associations, egg production farms, public interest groups, and individual citizens. Our analysis of the comments found strong support for a uniform, voluntary national HACCP-based program to reduce the risk associated with SE contamination during egg production. The state agencies 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 members own approximately 80 percent of all egg-laying hens in the country. As of June 1999, FDA, which has regulatory authority over shell egg production, had not taken any actions based on the comments received. An FDA official told us that the agency supports a HACCP-based approach for controlling SE but that taking action on this issue is currently not the agency's highest priority.

Some states, in cooperation with the egg industry, have established voluntary statewide HACCP-based programs to control or eliminate SE 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 states, which account for

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

about 38 percent of the nation's egg production, reported that they have voluntary quality assurance programs.[2] About half of these quality assurance programs began recently—7 of the 13 states reported starting their programs in 1997 or 1998. Producers may also choose to participate in other quality assurance programs, such as the one designed by the United Egg Producers, or establish HACCP programs 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.

Seven elements are commonly found in state quality assurance plans: (1) purchasing chicks from breeders approved by the National Poultry Improvement Plan, (2) controlling rodents and pests, (3) using bio-security procedures,[3] (4) cleaning and disinfecting henhouses, (5) conducting environmental testing for SE, (6) refrigerating eggs after packing, and (7) keeping records. Although the existing state programs for egg quality assurance include many of these elements, 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 SE. In some states, if SE is found in the environment, the eggs are immediately diverted to breaking facilities where they are pasteurized to kill the bacteria. In the other states, if environmental contamination is detected, the eggs are checked. If SE is found in any eggs, all the eggs are diverted to breaking facilities. Under about half of the plans, environmental testing is only done 8 weeks before the end of a flock's production cycle.[4] However, two states have more extensive testing regimens that start before a chicken begins to produce eggs and continue 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 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 the elements in the quality assurance programs are being performed. Many of the plans we reviewed,

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

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

[4]In commercial egg-laying operations, hens generally produce eggs until they are about 2 years old.

8 of 13, contained provisions for oversight. Under four of the plans, the oversight can be performed in part by groups associated with the industry, not by an independent third party. The frequency and procedures used to conduct the oversight also varied among the plans.

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

Eggs that are not sold as shell eggs are sent to egg products plants where they are washed, broken, separated, and pasteurized using automated processes. FSIS, which has regulatory authority over egg products, does not require HACCP programs 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] In public statements, FSIS officials have indicated that the implementation of HACCP programs at egg products plants is appropriate, and the agency has begun taking preliminary actions for a rulemaking to require HACCP, such as researching the scientific and economic issues. However, as of June 1999, the agency had not yet published a rule proposing such a requirement. 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 federal egg refrigeration requirement, the nation's first, is soon to be implemented but may not be as effective as possible in reducing the risks from SE contamination. In the multistep process used to bring eggs to consumers, egg safety can be jeopardized at many points by a lack of adequate refrigeration. Beginning in August 1999, FSIS will require that eggs destined for the ultimate consumer be refrigerated at an air temperature not to exceed 45 degrees. 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

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

appropriation if the agency did not issue implementing regulations. The 1991 amendments authorize USDA to inspect shell egg processors and packers, including transport vehicles, to ensure that shell eggs destined for the ultimate consumer, which FSIS has defined as households, restaurants, and institutions, meet the temperature requirement and that cartons are properly labeled to indicate that they require refrigeration. USDA is required to conduct these inspections on a quarterly basis.

Under the 1991 amendments, FDA is authorized to ensure compliance with the egg refrigeration and labeling requirements at locations not covered by FSIS, such as restaurants and institutions, as often as FDA determines inspections are appropriate. However, FDA has not yet issued regulations that would require eggs to be refrigerated at these locations or other retail locations such as grocery stores. In May 1998, FDA announced plans to propose regulations mandating that shell eggs be stored for retail sale at 45 degrees or less. Given FDA's limited inspection resources and the large number of retail establishments, it is not clear how FDA will enforce the refrigeration requirement at retail locations. 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 voluntary Food Code. An FDA official told us the agency plans to propose refrigeration regulations that will include provisions to encourage the states to enforce the refrigeration requirement. In the absence of a federal regulation requiring the refrigeration of eggs at retail locations, responsibility shifts to the states. Our survey of regulatory officials found that 43 states require that eggs be kept at 45 degrees or less in retail locations, 3 states have temperature limits above 45 degrees, and 4 states have no requirements.

While implementing the 1991 amendments is an important first step, FSIS and other experts have raised concerns about the effectiveness of an air temperature requirement in improving egg safety. According to FSIS, maintaining the internal temperature of eggs at 45 degrees or below throughout processing and distribution would result in a greater reduction in illnesses from SE than would result from an air temperature requirement.

In contaminated eggs, SE is unlikely to grow at temperatures under 45 degrees. However, when eggs are processed and packed, according to USDA, they are often in the 70- to 80-degree temperature range. Because of the way eggs are packed, even if they are immediately put into a cooler, research has shown that it may take from 3 to 6 days before the egg's

internal temperature is reduced to the air temperature. During this time, SE bacteria may replicate, and the more bacteria an egg contains, the more dangerous it will be if eaten raw or undercooked. A risk assessment study performed by USDA estimated, on average, an 8-percent reduction in human illness when eggs are maintained at an air temperature of 45 degrees.[6] In contrast, the study estimated, on average, a 12-percent reduction in illness if eggs are cooled to an internal temperature of 45 degrees immediately after being laid.

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 38 degrees within 12 minutes using cryogenic gases and that this approach would reduce the likelihood of *Salmonella* growth in or on eggs. One company has developed a prototype cooling method using cryogenic gases that will soon be tested in production. According to the company's estimates, 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 cool eggs faster, and a process of in-shell pasteurization that has recently begun to be used commercially also includes the rapid cooling of the eggs after they are pasteurized.

Inconsistent Policies and Practices Hamper Egg Safety Efforts

Once eggs reach consumers, federal and state efforts to ensure egg safety have been weakened by inconsistencies in three areas. First, provisions in FDA's voluntary Food Code designed to protect populations known to be particularly vulnerable to SE infections, such as the elderly in nursing homes, have not been adopted by all the states. Also, inconsistent federal policies on the repackaging of eggs and how expiration dates are used on egg cartons may mislead consumers and could pose a food safety risk. Although about 30 percent of the nation's eggs are graded for quality by USDA and, therefore, are subject to restrictions on repackaging, the remaining 70 percent are not subject to the same restrictions. In addition, while those eggs inspected by USDA cannot have expiration periods longer than 30 days, all other eggs may have longer expiration periods.

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 SE-contaminated eggs than the general population. For example, the Centers for Disease

[6]Salmonella Enteritidis Risk Assessment: Shell Eggs and Egg Products, Final Report (June 12, 1998).

Control and Prevention reported that 54 of the 79 deaths associated with outbreaks of SE between 1985 and 1998 were of individuals in nursing homes.[7] 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.

Because of the problems associated with SE-contaminated eggs, FDA's 1993 Food Code contained egg safety provisions for highly susceptible populations.[8] The provisions were revised and expanded in the 1995 and 1997 versions of the code. FDA's 1997 Food Code recommended that food service operators serving highly susceptible populations substitute pasteurized shell eggs or egg products for raw shell eggs (1) in Caesar salad dressing, mayonnaise, ice cream, and other foods that typically use raw or undercooked eggs and (2) when eggs are broken, combined in a container and not cooked immediately or are held for service after cooking, as with scrambled eggs on a buffet table. In the 1999 version of the Food Code, FDA modified its provisions for the protection of highly susceptible populations by allowing the use of shell eggs when eggs are combined and held for service only if they are prepared under a HACCP plan that ensures SE growth is controlled before and after cooking and is destroyed during cooking.

According to our survey of state regulatory officials, many states have not adopted the 1997 Food Code recommendations on serving pasteurized shell eggs or egg products to highly susceptible populations.[9] 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. In addition,

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

[8]Highly susceptible populations include the following persons who are in institutional or custodial care: (1) individuals with impaired immune systems, (2) the elderly in facilities such as nursing homes or hospitals, and (3) preschool children in facilities such as day care centers.

[9]When we conducted our survey of regulatory officials, the 1997 Food Code was the most current version.

according to a 1998 Dietary Managers Association[10] survey of 136 private nursing homes, hospitals, and other care facilities and 23 Air Force hospitals across the nation, 35 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.

Rules on Repackaging and Dating Egg Cartons Are Inconsistent

Two key risk factors can affect the growth of SE in eggs–age and temperature. Experts agree that an egg's natural defenses to SE can break down as an egg ages or is exposed to high or fluctuating temperatures. Therefore, ensuring that eggs are fresh and are maintained under a consistent, appropriate temperature from packing to the table are critical SE 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 dates. 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, industry representatives, and several state 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.

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 June 1999, had not taken any action to prohibit the practice. The inconsistency in the federal government's approach to repackaging may be misleading to consumers because USDA-graded and non-USDA-graded eggs sit side by side in grocery store coolers. The United Egg Producers has stated that a federal

[10]The association represents approximately 15,000 dietary managers and food protection professionals nationwide.

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 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 requires them on egg cartons. However, according to a Service official, many producers in its voluntary grading program take this optional step. If they do, the Service requires that the expiration date be no more than 30 days from the date the eggs were packed. Egg processors that do not participate in the agency's grading program typically include expiration dates of either 30 or 45 days, although some do not provide any expiration date. Hence, expiration-dating practices are inconsistent.

While the difference in safety between a 30-day-old egg and a 45-day-old egg may be negligible, according to some experts, inconsistent expiration dating practices can mislead consumers. For example, 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. But the eggs with the later date may actually be older than the USDA eggs in the cooler. FDA recognizes that this inconsistency may be misleading to consumers, and in a May 1998 notice in the Federal Register, the agency sought comments on whether this practice violates the Federal Food, Drug, and Cosmetic Act's provisions on misbranding. As of June 1999, FDA had not issued any rules on expiration dating.

Our survey of state regulatory officials found that only 17 of the 50 states require either an expiration or a sell-by date on egg cartons sold in their states. A National Egg Regulatory Officials' committee plans to develop guidelines for its members for uniform labeling of egg cartons because many eggs are transported interstate.[11] These officials believe that such uniformity would help ensure safety and quality.

[11]The 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.

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. The government does not assign egg safety resources to the different federal agencies with responsibilities for egg safety based on an overall assessment of risk. Furthermore, although FSIS and FDA are trying to work around the fragmented regulatory structure, the agencies have been unable to improve egg carton labeling or establish a comprehensive egg safety approach in a timely fashion.

Egg Safety Inspection Resources Are Not Allocated Based on Risk

The current regulatory and organizational framework does not provide an overall federal focus for ensuring that 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 on its own regulatory approach, priorities, and available funding for food safety activities.

Under the Federal Food, Drug, and Cosmetic Act, as amended, 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 because of limited resources, FDA almost never inspects shell egg production and processing operations. USDA, in contrast, follows a regulatory approach that generally 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 United States.

Egg safety inspection resources are not directed to the areas of highest risk under the current regulatory system. Most of the federal resources are directed toward egg products even though during processing, the eggs are pasteurized to kill harmful bacteria such as SE. In fiscal year 1998, FSIS had 102 full-time inspectors dedicated to daily continuous inspection at all 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 where eggs can be contaminated.

As we previously reported, this diverse regulatory approach results in inconsistent oversight and a system that does not base inspection

frequency on food safety risk.[12] If HACCP systems are implemented in all egg products plants, it may be possible to reduce or eliminate the current requirement for 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.[13]

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

Although USDA and FDA have worked together on various egg safety activities, including a consumer education campaign, an SE risk assessment study, and a foodborne disease monitoring network, progress on egg carton labeling and a comprehensive egg safety strategy has been slow. In our 1992 report, we found that USDA's and FDA's efforts to control illness from SE-contaminated eggs were stymied by questions about jurisdiction, among other things.[14] Because FSIS and FDA have jurisdiction over different aspects of egg safety, the agencies are each planning to establish egg carton labeling requirements.

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.[15] The regulations become effective a year later. In commenting on the proposed regulations, some respondents recommended additional food safety labeling requirements. In response, FSIS said that "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.

Our survey of the states found that while 23 states require at a minimum that egg containers be labeled "keep refrigerated," 27 other states have no

[12]Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992).

[13]Food Safety: Risk-Based Inspections and Microbial Monitoring Needed for Meat and Poultry (GAO/RCED-94-110, May 19, 1994).

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

[15]FSIS assumed responsibility from USDA's Agricultural Marketing Service in 1995 for the implementation of the 1991 amendments to the Egg Products Inspection Act.

such requirements. In the absence of federal or state requirements, some egg producers may voluntarily label egg cartons to show that eggs should be kept refrigerated. We asked state regulatory officials whether their states require egg cartons to carry words that tell the consumer not to eat eggs raw and to cook the eggs thoroughly. Only one state told us that either of these consumer warnings is required.

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

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 timetable for completing the strategy, and as of June 1999, they had not formed a team with FDA to work on the issues.

Conclusions

With responsibilities distributed among four federal agencies, the nation's egg safety efforts lack an organizational focus and contain gaps, inconsistencies, and inefficiencies. A prevention-based approach to food safety involving hazard analysis and critical control point (HACCP) principles has not been applied comprehensively to the production and processing of eggs and egg products. Moreover, while the states have begun to develop HACCP-based safety programs for egg farms, they are not based on a set of minimum national standards. A consistent national HACCP-based approach to safety on egg farms could reduce the frequency of *Salmonella* Enteritidis contamination in eggs and provide uniform risk reduction throughout the country. In addition, 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.

Controlling an egg's temperature is recognized as one of the most important steps in limiting the growth of *Salmonella* Enteritidis. However, federal regulations soon to be implemented on the refrigeration of eggs will not control this risk factor as effectively as possible because they address air temperature, not an egg's internal temperature. In addition, raw and undercooked eggs continue to be hazardous, particularly to highly susceptible populations such as those with impaired immune systems or the elderly in nursing homes. Finally, because of the fragmented federal regulatory approach to egg safety, decisions about how to allocate the nation's egg safety inspection resources are not based on risk. Although FDA and FSIS plan to take several actions in the near future to improve egg safety, the fragmented federal regulatory structure we identified in 1992 remains an obstacle to a comprehensive, consistent, and effective egg safety strategy.

Matter for Congressional Consideration

To provide an organizational focus for the nation's egg safety policies and activities, the Congress may wish to consider consolidating responsibility for egg safety in a single federal department.

Recommendations

To reduce the threat of *Salmonella* Enteritidis contamination during egg production and processing, we recommend that the Commissioner of the Food and Drug Administration develop a model HACCP-based program for egg farms and processing plants, that could be adopted by the states. This program should define the minimum national standards, including microbial testing, for egg safety at these locations.

To enhance safety protections in egg products processing plants, we recommend that the Secretary of Agriculture develop regulations to require these plants to implement HACCP systems.

To reduce the time needed to lower the internal temperature of eggs to 45 degrees, we recommend that the Secretary of Agriculture and the Commissioner of the Food and Drug Administration jointly study the costs and benefits of implementing rapid cooling techniques in egg processing and packing operations and, depending on the results, take appropriate action.

Agency Comments and Our Response

We provided USDA and FDA with a draft of this report for their review and comment. Both USDA and FDA provided a number of editorial and technical comments, which have been incorporated into the report as appropriate. The following summarizes their general comments and our responses. USDA's and FDA's letters are printed with our responses in appendixes IV and V, respectively.

In commenting on the draft report, USDA agreed with all three of our recommendations. While USDA concurred with the intent of our recommendation to implement hazard analysis and critical control point (HACCP) systems in plants, the Department suggested revising the wording of the recommendation. We have made some minor revisions based on the Department's suggestions. USDA also said that the report appeared unbalanced because USDA and FDA were criticized in the body of the report, whereas information about the agencies' positive actions was confined to the appendixes. We do not agree with USDA's view that the report is unbalanced. The body of the report presents the findings from our review, which identified a number of gaps, inconsistencies, and inefficiencies in the nation's egg safety efforts. Appendix III describes each agency's responsibilities and programs and is not a "listing of what is being done well," as stated by USDA.

In commenting on the draft report, FDA agreed with our recommendations. However, FDA said that before it can develop criteria for a HACCP-based program, it must first develop prevention controls for egg production because science has not yet established the optimal strategy to control *Salmonella* Enteritidis on farms. We agree with FDA that the scientific issues involved in designing and establishing the effectiveness of control measures for *Salmonella* Enteritidis are complex. However, we believe FDA can take immediate action to develop a model program that contains controls that are based on the best currently available scientific information and the experience of existing state programs. FDA also said that the draft report did not acknowledge that FDA has participated in various meetings and task forces regarding on-farm *Salmonella* Enteritidis prevention programs. Even though FDA states that it has participated in these activities, our concern remains that FDA has not established a national model program for reducing *Salmonella* Enteritidis on farms and that existing state programs vary significantly.

Both USDA and FDA commented that the draft report did not adequately acknowledge that they have been working together for many years on a coordinated approach to the problem of *Salmonella* Enteritidis in eggs. We

recognize that USDA and FDA have worked together and have added information to the report to reflect this. However, we continue to believe that progress on developing a comprehensive egg safety strategy has been slow. The problem of *Salmonella* Enteritidis in eggs was first identified in 1988. Eleven years later, USDA and FDA have yet to establish a comprehensive strategy to improve egg safety. Both USDA and FDA said that the report did not include any references to ongoing federal research efforts to better understand *Salmonella* Enteritidis. While we are aware that federal research on *Salmonella* Enteritidis is under way, reporting on that research was not one of the objectives of our review.

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 with several officials from different agencies responsible for egg safety in each state. We completed interviews with all 50 states for a response rate of 100 percent.

To determine whether the prevention-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 coordinate the

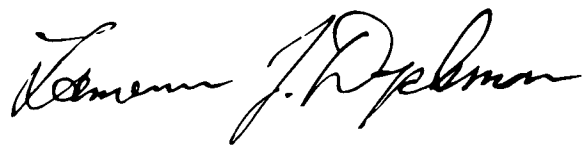
implementation of labeling requirements for egg cartons and to develop a farm-to-table egg safety strategy.

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

We will send copies of this report to the congressional committees with jurisdiction over food safety issues; Dan Glickman, Secretary of Agriculture; Jane Henney, Commissioner of the Food and Drug Administration; Jacob Lew, Director, Office of Management and Budget; 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 or Robert C. Summers at (404) 679-1839. Key contributors to this report are listed in appendix VI.

Sincerely yours,



Lawrence J. Dyckman
Director, Food and Agriculture Issues

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Abbreviations

AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
CDC	Centers for Disease Control and Prevention
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
HACCP	hazard analysis and critical control point
SE	*Salmonella* Enteritidis
USDA	U.S. Department of Agriculture

Salmonella Enteritidis Contamination in Eggs

Over the last decade, shell eggs contaminated with *Salmonella* Enteritidis (SE) 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, SE may have caused about 300,000 illnesses in 1997, resulting in 115 to 229 deaths. Significant economic costs result from SE illnesses and deaths, with estimates ranging from approximately $225 million to $3 billion in 1996. Although not all SE infections are linked to eggs, according to data from the Centers for Disease Control and Prevention, between 1985 and 1998, 82 percent of SE outbreaks[16] with an identified cause were associated with eggs.[17]

Increasing Reports of 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 outbreaks of SE-related foodborne illness 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, reported illnesses related to SE in eggs have been a growing problem through the mid-1990s. SE progressed from an infrequent cause of human illness to one of the most common strains, or serotypes, of *Salmonella*, growing from 5 percent of total *Salmonella* cases in 1977 to 15.6 percent in 1987 and 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 SE infections decreased by 44 percent in selected counties and states. SE also fell from being the most common strain of *Salmonella* from 1993 to 1996 to being 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 SE.

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, 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.

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

[17]In only 44 percent of cases could a responsible food be identified.

The transmission of SE from the farm environment, to egg-laying flocks, and then 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 populations, older flocks, and forced molting.[18] Once infected, chickens can pass the pathogen directly from their ovaries to the contents of the 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 the U.S. Department of Agriculture estimates that 1 in every 20,000 eggs is infected. This means that about 3.4 million of the approximately 67 billion shell eggs produced in 1998 were infected with SE.

Eating an egg infected with SE does not always result in illness, though, since proper refrigeration will limit bacterial growth and cooking can ultimately kill it. The site of SE contamination is normally in the egg white. The yolk membrane provides a barrier, which prevents SE from reaching the nutrient-rich yolk where it can quickly multiply. Refrigeration prolongs the life of the yolk membrane and thereby limits the growth of SE in contaminated eggs. Moreover, cooking food at 160 degrees Fahrenheit will rapidly kill SE 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. In addition, the commercial practice of pooling eggs has played a role in some outbreaks. When hundreds of eggs are pooled in a single bowl and are then used to make scrambled eggs or other dishes, one egg can contaminate the whole batch. For disease to occur, then, eggs usually must be contaminated at the farm or during processing and then be improperly handled, inadequately refrigerated, or undercooked or consumed raw.

Salmonella Enteritidis Outbreaks and Illnesses

Over the years, outbreaks of SE 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.)

[18]Forced molting is done to improve egg production. During a forced molt, chickens are generally deprived of feed or water for a period of time. Following the molt, the birds will produce more eggs than they would have without molting.

Table I.1: Examples of Salmonella Enteritidis Outbreaks and Egg-Associated Foods, 1990-98

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 and bearnaise sauces containing pooled raw eggs
	Sandwiches containing undercooked mayonnaise
1994	Hollandaise sauce containing raw eggs
1995	Jamaican malt beverage (a homemade drink of beer, raw eggs, milk, oatmeal, and ice)
	Caesar salad dressing containing raw eggs
	Baked eggs
1996	Coconut cream pie
	French toast using eggs
	Egg salad
1997	Crab fluff
	Bearnaise sauce
	Homemade cheesecake
1998	Cream pies
	Stuffing
	Homemade ice cream

Source: Centers for Disease Control and Prevention.

Human illnesses resulting from SE bacteria can cause a variety of serious health problems. Short-term reactions, usually beginning 12 to 72 hours after the contaminated food has been eaten, include abdominal pain, bloody stools, diarrhea, fever, headache, and vomiting. More severe conditions associated with *Salmonella* range from bloodstream infections to arthritis and meningitis. Patients' symptoms and the severity of their sickness can vary according to their personal characteristics and extent of exposure. Individuals with impaired immune systems, young children, and elderly patients in nursing homes are more susceptible to SE infections and have more severe symptoms and greater incidence of hospitalization and death. In SE outbreaks between 1985 and 1998, for example, approximately 68 percent of the deaths occurred among nursing home residents. Moreover, the death rate for SE outbreaks in nursing homes was approximately 13 times greater than the rate for all outbreaks. The higher

death rates among the elderly have been attributed to many causes, including preexisting illnesses and reduced immunity.

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 most 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	Number of eggs (millions)	Percentage of total U.S. egg production	Value of production (millions)
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
	Total	**50,260**	**63.1**	**$2,591**

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

Source: National Agricultural Statistics Service.

Egg production, processing, and distribution is a multistep process. For eggs that are sold whole, known in the industry 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. The 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 and stored on a farm before being transported to the processing facility at another location.

Upon arrival for processing, eggs are washed and may also be sanitized to remove dirt, feces, and bacteria collected in the laying house. Following washing, they are dried to remove the remaining moisture and may be oiled to seal the pores in the shells. Processing plant employees use a candling machine, which shines light through the eggs' shells, 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 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 multistep approach that defines shell egg processing. Upon arrival at an egg breaking plant, eggs are washed and candled, and eggs that are dirty, cracked, or have other problems 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, frozen, or dried. At the completion of the process, egg products are packed into containers or loaded as a chilled liquid directly into tankers.

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 U.S. Department of Agriculture (USDA), the Animal and Plant Health Inspection Service (APHIS), the Food Safety and Inspection Service (FSIS), and the Agricultural Marketing Service (AMS) and in the U.S. 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 multistep process. At the first step in this process, USDA offers a program that attempts to ensure chicks that will become egg-laying hens are born free of diseases, including *Salmonella* Enteritidis (SE). 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.

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. Participation is open to producers or sellers of poultry and poultry products that 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 that are compatible with the plan. The program is mandatory for those producers that ship interstate or internationally and voluntary for those that ship intrastate. Although the plan is voluntary for some producers, farms often cannot sell their birds without the plan's certification. According to an APHIS official, during 1998, 268 breeding flocks, comprising about 3 million birds, in 22 states participated in the program.

APHIS changes the plan's provisions from time to time as new information about poultry diseases becomes available from the industry. For example, in July 1989, APHIS added a component designed to reduce the incidence of SE organisms in egg-laying hens 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 ensures 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 henhouses every month for diseases throughout the life of the flock. If initial environmental test samples of the farm show the presence of SE, 60 birds are collected, and their heart, liver, and other organs are cultured for SE. 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 FDA and FSIS. FDA has traditionally been responsible for shell eggs[19] and FSIS for egg products. Changes soon to be implemented 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 requirements. Based on these requirements, FDA generally allows foods to enter the market without inspection, while USDA generally inspects products before they reach the market.

FDA's Responsibilities

FDA has regulatory authority for shell eggs throughout the farm-to-table process. The agency has responsibility for egg safety at egg farms, egg processing plants where eggs are washed and packed, during transportation, and at the retail level where eggs reach the consumer. The agency's power to regulate egg safety stems from 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 Cosmetic Act, as amended.

FDA has sole federal authority for regulating food safety on egg farms. The agency currently conducts two main activities at egg farms. First, it conducts egg farm inspections, known as traceback investigations, only when an outbreak of foodborne illness has been identified. Once the source of an outbreak is determined, FDA requires that eggs from SE-positive flocks be diverted from sale to the public and destroyed or sent to egg breaking plants for pasteurization. Second, to help prevent the introduction of SE 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 egg safety programs for farms based on hazard analysis and critical control point (HACCP) principles and known as quality assurance programs.

[19]Shell eggs include whole 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.

Under the Federal Food, Drug, and Cosmetic Act, as amended, FDA generally allows foods, including eggs, to leave the processing plant and 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 an FDA official, the agency almost never conducts inspections at the approximately 700 shell egg processing plants that wash, grade, and pack eggs in the United States. Under the act, FDA also has the authority to enforce provisions prohibiting the false or misleading labeling of foods, including the labels used on egg cartons. In addition, FDA has authority to regulate egg safety when eggs are transported.

The Public Health Service Act states that FDA will assist the states in the prevention and suppression of communicable diseases. 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 a 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 reported to FDA that they had adopted some or all of the provisions of the 1993 or more recent version of the code, and 23 states reported that they were 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 persons in institutional or custodial facilities who are highly susceptible to foodborne illness, such as preschool children, the elderly, and individuals with impaired immune systems.

The Egg Products Inspection Act, passed in 1970, also gives FDA authority over shell egg safety at the retail level. Although this act previously covered mainly egg product safety, the 1991 amendments included requirements for shell egg safety. The amendments give FDA responsibility at locations other than those that process and pack eggs, such as restaurants and institutions, for ensuring that eggs are stored at an air temperature not to exceed 45 degrees and are appropriately labeled to show they require refrigeration. This is a departure from FDA's traditional role at the retail level under the Public Health Service Act of promoting egg safety by encouraging states to adopt the Food Code. In addition,

although FDA previously had primary authority over shell eggs, the 1991 amendments split enforcement authority for the temperature and labeling requirements between FDA and USDA.

FSIS' Responsibilities

FSIS' responsibility for eggs begins when shell eggs are sent to a plant where they are broken to make egg products. When the Congress passed the Egg Products Inspection Act in 1970, it provided for the mandatory and continuous inspection of the liquid, frozen, and dried egg products of all U.S. egg products plants.[20] 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, FSIS 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 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 conduct inspections under technical supervision by 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 and facilities to ensure overall sanitation and cleanliness; (3) observe operations as the eggs are washed, sorted, broken, pasteurized, cooled for storage, and properly labeled; and (4) monitor the staff's personal hygiene practices. As a part of the inspection program, all plants must maintain an SE 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 *Salmonella*. If testing shows the presence of *Salmonella*, the

[20]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 other ingredients that are processed, pasteurized, and available in liquid, frozen, and dried forms.

product is repasteurized, 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 73 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 pasteurized egg products leave the plant, FDA has responsibility for the temperature requirements for the transportation and storage of these products as well as for inspections to ensure compliance with the requirements.

In the 1991 amendments to the Egg Products Inspection Act, the 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. FSIS and AMS will share responsibility for enforcing these regulations.

AMS Offers Programs for Egg Quality and Safety

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

The shell egg grading program assists 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 AA, A, or B based on internal and external quality factors. For example, the highest quality egg, Grade AA, must have a clean and unbroken shell, an air cell inside the egg of one-eighth 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 states, 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.[21] 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 inspection includes product sampling and a review of records, among other things.

AMS developed its new 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. Each participant is 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 SE. 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 the 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 producers' 5-Star

[21]Restricted eggs are defined as eggs with cracks or checks in their shells and as dirty, inedible, and leaking eggs, among others. Cracked and dirty eggs may be shipped to an official egg products plant for pasteurization; otherwise, restricted eggs must be either destroyed or diverted for use other than human consumption.

program. The United Egg Producers' 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's or packer's compliance with the 5-Star program and to 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 overall program.

States Share Responsibilities for Egg Safety and Quality

As eggs move from the farm to the 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 SE into egg-laying flocks. For instance, the Pennsylvania Department of Agriculture formed a partnership 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 have a minimal risk of causing foodborne disease from SE. 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 SE. 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, the agriculture and health departments. 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 Food and Agriculture is responsible for periodically spot-checking egg processing plants to ensure they are packing eggs that meet the state's quality standards. California's Department of Health Services, meanwhile, is primarily responsible for food safety inspections at the retail level as well as for working as a partner on quality assurance programs and conducting traceback investigations of foodborne illnesses.

Comments From the Department of Agriculture

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

JUN 17 1999

Mr. Lawrence J. Dyckman
Director, RCED Division
Food and Agriculture Issues
U.S. General Accounting Office
441 G Street, NW, Room 2T23
Washington, DC 20548

Dear Mr. Dyckman:

See comment 1.

Thank you for the opportunity to review and provide comments on the Draft Report RCED-99-184, "Food Safety: United States Lacks a Consistent, Farm-to-Table Approach to Egg Safety." We have a concern with the report as it is currently written with respect to the degree of coordination between the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA). Specifically, the report has not adequately acknowledged that USDA and FDA have been working together for many years on a coordinated approach to the problem of *Salmonella* Enteritidis (SE) in eggs. This coordinated approach is reflected in many joint activities of FDA and USDA such as: "FoodNet" a foodborne diseases active surveillance network begun in 1995 which also includes CDC and shows that the cases of illness due to SE are going down over recent years; Fight Bac! Education campaign begun in 1997 and which also includes EPA and provides information on the safe handling of eggs; quality assurance partnership agreements with several states in 1997 and 1998 which help to support the individual state's Egg Quality Assurance Plan in an animal production food safety program; Advance Notice of Proposed Rulemaking on SE in May 1998 to identify farm-to-table actions that will decrease the food safety risk associated with shell eggs; and an SE risk assessment on shell eggs and egg products in June 1998 to identify possible strategies for enhancing the safety of shell eggs.

See comment 2.

See comment 3.

In general, the report appears unbalanced with all of the criticisms of USDA and HHS in the body of the report and the actual listing of what is being done well by the Federal Government (positive things) more or less confined to the appendices. In addition, the report did not include any references to Federal research efforts, which are underway to better understand SE and improve control schemes. For example, the National Animal Health Monitoring System 1999 study was not mentioned and there was only limited reference to the fact that there are many unknowns in on-farm SE ecology.

GAO RECOMMENDATIONS:

Recommendation 1:

To reduce the threat of *Salmonella* Enteritidis contamination during egg production and processing, we recommend that the Commissioner of the Food and Drug Administration develop a model HACCP-based program for egg farms and processing plants, that could be adopted by the states. This program should define the minimum national standards, including microbial testing, for egg safety at these locations.

USDA response:

We concur.

Recommendation 2:

To enhance safety protections in plants that break eggs to create egg products, we recommend that the Secretary of Agriculture develop regulations to implement HACCP systems in these plants.

USDA response:

See comment 4.

We concur with the intent of the recommendation; however, the following is a suggested revision: The Secretary of Agriculture should develop and implement a HACCP-based inspection program in egg products processing plants.

Currently, the product inspection regulations specifically identify requirements to be followed by establishments during processing, packaging, and transport to assure that only wholesome egg products enter commerce for human consumption. These requirements, which are monitored by the FSIS food inspectors during processing, include facility and equipment sanitation, personnel hygiene practices, operating conditions, refrigerated storage, minimum pasteurization requirements and sampling pasteurization products for the presence of SE.

Recommendation 3:

To reduce the time needed to lower the internal temperature of eggs to 45 degrees, we recommend that the Secretary of Agriculture and the Commissioner of the Food and Drug Administration jointly study the costs and benefits of implementing rapid cooling techniques in egg processing and packing operations and, depending upon the results, take appropriate action.

USDA response:

We concur that USDA will work with FDA to jointly study the costs and benefits of implementing rapid cooling techniques in egg processing and packing operations, and

depending upon the results, take appropriate action. USDA and FDA are aware that the lowering of the internal temperature of the egg via methods faster than those currently in use are being studied by researchers in North Carolina and California.

TECHNICAL COMMENTS

Now on p. 2.

1. Page 2, second full paragraph:

The report states that the "first national requirement to refrigerate eggs at 45 degrees or below from the time they are packed until they reach the consumer may not be as effective as possible in reducing the risks for eggs contaminated with *Salmonella* Enteritidis". We agree that cooling will delay the onset of SE growth. However, the report does not explain that this mandatory temperature requirement is based on statutory language. We have made it clear that the Department has explained the technical weaknesses of this requirement in correspondence, public forums, etc.

See comment 5.

Passage deleted from the report.
See comment 6.

2. Page 2, last paragraph:

The report states that "the Food Safety and Inspection Service has not yet determined how compliance with the law will be monitored". The regulations are not effective until August 27, 1999. USDA resolved most of the implementation issues listed in the GAO report, and the implementation procedure (i.e., FSIS Directive) is expected to be issued before the end of June, well in advance of the August 27 effective date.

Now on p. 3.

3. Page 3, first paragraph:

The report states that "each agency (FDA and USDA) is developing its own egg carton labeling requirements that will become effective at different times". As noted in the August 27, 1999, final rule, FSIS published labeling requirements based on statute. The statute enacted by Congress required that section 5 of the Egg Products Inspection Act (21 U.S.C. 1034) be amended by adding the following:

> (e)(1) Subject to paragraphs (2) and (3), the Secretary shall make such inspection as the Secretary considers appropriate of a facility of an egg handler (including a transport vehicle) to determine if shell eggs destined for the ultimate consumer—
>
> > (A) are being held under refrigeration at an ambient temperature of no greater than 45 degrees Fahrenheit after packing; and
> >
> > (B) contain labeling that indicates that refrigeration is required.
>
> (2) In the case of a shell egg packer packing eggs for the ultimate consumer, the Secretary shall make an inspection in accordance with paragraph (1) at least once each calendar quarter.

(3) The Secretary of Health and Human Services shall cause such inspections to be made as the Secretary considers appropriate to ensure compliance with the requirements of paragraph (1) at food manufacturing establishments, institutions, and restaurants, other than plants packing eggs.

(4) A representative of the Secretary (of Agriculture) and the Secretary of Health and Human Services shall be afforded access to places of business referred to in this subsection, including transport vehicles, for purposes of making an inspection required under this subsection.

See comment 7.

Pursuant to this statutory mandate, and at the risk of losing $5.0 million, FSIS promulgated its final rule. FSIS' rule was coordinated with FDA and will in no way interfere or preclude FDA from developing future regulations. By meeting the FDA requirements, companies would also likely meet the FSIS requirements.

Now on p. 7.

4. Page 7, fourth sentence of the second paragraph:

See comment 6.

The focus of a HACCP-based program is to "reduce the risk associated with SE contamination during egg production" rather than "control SE".

Now on p. 11.

5. Page 12, fourth sentence of the first full paragraph:

See comment 6.

For clarification purposes, we suggest the fourth sentence of this paragraph be revised to read: Approximately 30 percent of the nation's eggs, marked for table use are graded by AMS, USDA, in accordance with U.S. Grade Standards, and therefore, subject to restrictions for repackaging. The remaining 70 percent are not subject to the same restrictions.

Now on p. 12.

6. Page 12, citation:

See comment 8.

There is continuing focus on the elderly as the primary group at greatest risk. The citation on page12 suggests that the definition of highly susceptible groups come from the Food Code. The first group cited is individuals with impaired immune systems. There should be an expanded definition of "individuals with impaired immune systems" in order to provide more transparency to the reader. Individuals with impaired immune systems include: the elderly, persons undergoing chemotherapy, people with chronic debilitating diseases (including but not limited to acquired immunodeficiency disease), and transplant recipients. Throughout this document, the elderly are cited inappropriately as the only at risk group.

Now on p. 17.

7. Page 18, first paragraph under conclusions:

See comment 9.

There is no mention of the effort by the United States Animal Health Association SE committee to develop the standardized template for all SE risk reduction/quality assurance programs.

Now on p. 24.

See comment 10.

8. Page 24, appendix I, first paragraph:

The statistics for number of illnesses and deaths should really be referenced. In recent years there have been several citations of these numbers and, as early as a year ago, CDC officials were publicly admitting that those figures were in need of recalculation. Also, the last sentence is rather alarmist in tone and leaves some of the most important information to the reader to lift out of a footnote. It would be more complete and more accurate to reword that last sentence to have all of the pertinent information in it. For example: "In the 44 percent of outbreaks where it was possible to identify a responsible food, 81.7 percent were linked to eggs." This translates to 35.9 percent of outbreaks were linked to egg consumption.

Now on p. 34.

See comment 6.

9. Page 36, last paragraph

" Regulations implementing the amendments become effective on August 27, 1999. As of April 1999, USDA had not announced whether FSIS or AMS will enforce these regulations." As noted in a previous meeting with you, FSIS and AMS share responsibility for enforcing these regulations. We are working with AMS to develop the enforcement protocols.

If you have any questions, please contact Mr. Ronald Hicks, Deputy Administrator for Management, at (202) 720-4425.

Sincerely,

Catherine E Woteki

CATHERINE E. WOTEKI, Ph.D., R.D.
Under Secretary
Food Safety

cc:

T. Billy, OA	J. Riggins, OPPDE	N. Blevins, AMS
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P. Thompson, TSC	M. McElvaine, ORACBA	A. Depman, FDA
R. Glasshoff, TSC		
P. Derfler, OPPDE	D. Lewis, AMS	

The following are GAO's comments on the Department of Agriculture's letter dated June 17, 1999.

GAO Comments

1. We agree that USDA and FDA have worked together on a variety of issues related to the problem of *Salmonella* Enteritidis in eggs and have revised the report to reflect this. However, we continue to believe that progress in developing and implementing a comprehensive strategy to improve egg safety has been slow. The problem of *Salmonella* Enteritidis in eggs was first identified in 1988. Eleven years later, USDA and FDA have yet to establish a comprehensive strategy to improve egg safety.

2. We do not agree with USDA's view that the report is unbalanced. The body of the report presents the findings from our review, which identified a number of gaps, inconsistencies, and inefficiencies in the nation's egg safety efforts. Appendix III describes agency responsibilities and programs and was not intended to be a "listing of what is being done well" as stated by USDA.

3. While we are aware that federal research on *Salmonella* Enteritidis is under way, reporting on that research was not one of the objectives of our review.

4. For purposes of clarification, we made minor revisions to the wording of this recommendation.

5. The draft report explained that a refrigeration requirement for eggs is required by statute; therefore, it was not necessary to make this change.

6. We revised the report to address USDA's remaining technical comments where appropriate.

7. The draft report did not say that FSIS' egg carton labeling requirements will interfere with or preclude FDA from developing future regulations. Therefore, we made no change in response to this comment.

8. The definition of highly susceptible populations used in the report comes from FDA's Food Code. Based on FDA's comments we have revised the report to make the definition fully consistent with the code. The report does not cite the elderly as the only risk group. Rather it uses the elderly in nursing homes as an example of a highly susceptible population that has been linked to outbreaks of *Salmonella* Enteritidis.

9. We are aware of the United States Animal Health Association's efforts to develop a standardized *Salmonella* Enteritidis risk reduction program. However, this does not change our conclusion that a uniform HACCP-based approach to egg safety has not been applied comprehensively to the production and processing of eggs.

10. We have revised the report to indicate that these data come from the Centers for Disease Control and Prevention. We have presented the data completely and accurately, and officials from the Centers concur with our presentation. We do not agree that the tone of the presentation is alarmist.

Comments From the Food and Drug Administration

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN [redacted]

Mr. Lawrence J. Dyckman
Director, RCED Division
Food and Agriculture Issues
U.S. General Accounting Office
441 G Street, N.W., Room 2T23
Washington, D.C. 20548

Dear Mr. Dyckman:

Enclosed are the Food and Drug Administration's proposed comments on the GAO draft report entitled, "FOOD SAFETY: U.S. Lacks a Consistent, Farm-to-Table Approach to Egg Safety," GAO/RCED-99-184.

If we can be of further assistance, please call Lois Adams at (301) 827-0125.

Sincerely,

Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

Enclosure

Comments of the Food and Drug Administration on the General Accounting Office Draft Report Entitled, FOOD SAFETY: U.S. Lacks a Consistent Farm-to-Table approach to Egg Safety (GAO/RCED 99-184)

GENERAL COMMENTS:

See comment 1.

The Food and Drug Administration (FDA) appreciates the opportunity to review and comment on the draft report. We have a concern with the report as it is currently written with respect to the degree of coordination between FDA and the United States Department of Agriculture (USDA). Specifically, the draft report fails to acknowledge that FDA and USDA have been working together for many years on a coordinated approach to the problem of *Salmonella* Enteritidis (SE) in eggs. This coordinated approach is reflected in many joint FDA and USDA activities such as: "Food Net," a foodborne diseases active surveillance network begun in 1995 which also includes the Centers for Disease Control and Prevention (CDC) and shows that cases of SE have decreased over recent years; the Fight Bac! education campaign begun in 1997 which also includes the Environmental Protection Administration (EPA) and provides information on the safe handling of eggs; quality assurance partnership agreements with several states in 1997 and 1998 which help to support individual state's Egg Quality Assurance Plan in an animal production food safety program; Advance Notice of Proposed Rulemaking on SE in May 1998 to identify farm-to-table actions that will decrease the food safety risks associated with shell eggs; and an SE risk assessment on shell eggs and egg products in June 1998 to identify possible strategies for enhancing the safety of shell eggs.

See comment 2.

In addition, the report did not include any references to Federal research efforts, which are underway tc better understand SE and improve control schemes. For example, the National Animal Health Monitoring System 1999 study was not mentioned and there was only limited reference to the fact that there are many unknowns in on-farm SE ecology.

GAO RECOMMENDATION:

To reduce the threat of *Salmonella* enteritidis contamination during egg production and processing, we recommend that the Commissioner of the Food and Drug Administration develop a model HACCP-based program for egg farms and processing plants, that could be adopted by the states. This program should define the minimum national standards, including microbial testing, for egg safety at these locations.

FDA COMMENT

See comment 3.

We concur. In principle, development of a model HACCP-based program for egg farms and processing plants that could be adopted by the states is a good approach. The first step will be to develop prevention controls for egg production. Then as the science progresses, FDA will develop criteria for a HACCP-type program.

GAO RECOMMENDATION:

To reduce the time needed to lower the internal temperature of eggs to 45 degrees, we recommend that the Secretary of Agriculture and the Commissioner of the Food and Drug administration jointly study the costs and benefits of implementing rapid cooling techniques in egg processing and packing operations and, depending upon the results, take appropriate action.

FDA COMMENT:

We concur. FDA will work jointly with USDA to study the costs and benefits of implementing rapid cooling techniques in egg processing and packing operations, and depending upon the results, take appropriate action. FDA is aware that researchers in North Carolina and California are studying methods for lowering the internal temperature of eggs that may be faster than those currently in use. The speed of cooling needs to be assessed in conjunction with its overall impact on egg safety.

TECHNICAL COMMENTS

Now on p. 2.
See comment 4.

Page 2, first full paragraph, line 1-2: FDA has initiated a number of preventative actions to reduce the risk of egg-associated *Salmonella* Enteritidis (SE) infections. Most FDA activities have been directed at controls on the farm and at the retail level. For example, FDA personnel have participated in public meetings to discuss and design proactive preventative programs. FDA has participated in the US Animal Health Association (USAHA) SE task force working on a program to replace the prior USAHA program, which had no testing component. FDA has presented speeches on SE updates and Egg Programs at all 1999 regional meetings of the USAHA, which have strong attendance from state veterinarians. FDA has also spoken with groups from the United Egg Producers (UEP) which resulted in inclusion of testing for the UEP program. FDA has worked with states that have expressed an interest in implementing a farm egg program.

Now on p. 2.
See comment 3.

Page 2, first full paragraph, lines 1-2: This sentence also suggests that the science FDA needs to establish a definitive control program is available. In fact, the difficulty with establishing specific preventive controls is the technical complexity of the issues and the difficulty in scientifically researching the effectiveness of controls in shell eggs. When a specific feasible universally applicable control (such as pasteurization for milk) is identified, the FDA will rapidly move to establish a performance standard linked to it. However, the optimal control strategy is not clear for shell eggs, thus FDA and USDA have worked to develop and promote the strongest on-farm "egg quality assurance" programs to develop safe production practices on the farm, in distribution, and at retail.

Now on p. 3.
See comment 5.

Page 3, first full paragraph, line 7: It is misleading to say that "each agency is developing its own egg carton labeling requirements..." While FDA labeling requirements that we intend to propose are designed for a different purpose than USDA's, i.e., to promote for consumers and retail end uses safe handling of eggs, they are completely consistent with USDA's labeling regulations that go into effect in August 1999.

Now on p. 3.
See comment 6.

Page 3, last paragraph, lines 4 and 7: There is a disconnect between the two sentences. The sentence starting on line 4 states that SE cases increased through 1997 but following sentence states the SE cases declined in 1996-1998.

Now on p. 7.
See comment 3.

Page 7, last paragraph, lines 1-3: Creating a HACCP program requires a seven element program including a hazard analysis and development of critical controls to prevent, eliminate or reduce the hazards to acceptable levels. As sound science is not available, credible HACCP or HACCP-based programs are difficult to conceive at this time.

Now on p. 10.
See comment 7.

Page 10, last paragraph, line 5: FDA also announced its intention to publish a proposed rule on refrigeration and labeling in a Joint FDA/FSIS Advance Notice of Proposed Rulemaking of May 19, 1998.

Now on p. 11.
See comment 8.

Page 11, second full paragraph, lines 5-7: Shell eggs have an internal defense against outgrowth of bacteria, which is dependent on temperature and time. Once this defense breaks down, significant multiplication can occur.

Passage deleted.

Page 12, second full paragraph, line 7: does the 82% relate to all outbreaks or only those involving highly susceptible populations?

For FDA's remaining comments, we modified the report as appropriate.

Page 12, last paragraph, line 3: after "Food Code" delete "recommended that food service operators serving highly susceptible" and replace with, "created a specific, additional section for highly susceptible populations to clearly establish the recommendation that facilities serving such"

Now on p. 12.

Page 12, footnote: after "include" add "the following persons who are in an institutional or custodial facility:"

Now on p. 12.

Page 13, carry over paragraph, line 1: after "cooking" delete "or" and replace with "and"

Now on p. 12.

Page 13, carry over paragraph, line 1: after "held" delete "for service" and replace with "before or"

Now on p. 12.

Page 13, carry over paragraph, line 4: after "combined" delete "or" and replace with "and"

Now on p. 12.

Page 13, carry over paragraph, line 4: after " plan" delete "which includes appropriate time and temperature controls" and replace with "that ensure SE growth is controlled before and after cooking and the organism is destroyed during cooking."

Passage deleted.

Page 16, second full paragraph, lines 5-8: FDA has not given high priority to inspection of egg packing facilities because these are frequently under AMS grading or comparable state grading inspection which assures basic sanitation and GMP controls as a condition of grading. FDA generally has not found significant problems with these facilities.

Now on p. 17.

Page 17, second full paragraph, line 4: after "refrigeration" delete "is required" and replace with "is necessary to assure safety."

Passage deleted.

Page 18, second full paragraph, line 5-6: could expand the reference to meat and poultry HACCP plans to include seafood, an FDA program. (See comparable reference to HACCP regulation for meat, poultry, and seafood on page 20, second paragraph, line 4.) Also, when referring to HACCP-type approach for meat and poultry, it must be remembered that this has only been implemented at the processing level – essentially equivalent to egg breaking establishments. HACCP for meat and poultry is not now in effect at farms producing USDA-regulated foods.

Now on p. 24.

Page 25, carry over paragraph, line 1: Traditional cooking practices had not previously had to contend with an SE organism on the inside of a whole intact shell egg, and culturally acceptable meal items contain raw or under-cooked eggs. It is correct to state that by implementing more rigorous cooking regimes, we may protect ourselves against this new threat; however the implication that the problem of increased illness due to SE in eggs is caused by changed cooking practices is not correct.

Now on p. 32.

Page 34, last paragraph, line 8: after sentence ending with "provisions." Add following sentence "Although states generally recognize shell eggs as potentially hazardous foods based on interpretive guidance from FDA in 1990, comprehensive and uniform requirements for shell eggs at retail are not in place nationwide."

Now on p. 32.

Page 34, last paragraph, line 9: after "the" delete "code," and replace with "1993 Food Code or a more recent edition"

Now on p. 32.

Page 34, last paragraph, line 13: after "to" delete "highly susceptible populations such as infants, the elderly and individuals with impaired immune systems." And replace with "persons who are in institutional or custodial facilities and are highly susceptible to foodborne illness such as the very young, the elderly, and individuals with impaired immune systems." This correction is very important from two respects. First, "very young," is not a term that can be pinned strictly to "infants" and those who are very young, elderly, or immunocompromised are only considered "highly susceptible" under the Code if they are in a facility to which their care is entrusted.

The following are GAO's comments on the Food and Drug Administration's letter dated June 10, 1999.

GAO Comments

1. We agree that USDA and FDA have worked together on a variety of issues related to the problem of *Salmonella* Enteritidis in eggs and have revised the report to reflect this. However, we continue to believe that progress in developing and implementing a comprehensive strategy to improve egg safety has been slow. The problem of *Salmonella* Enteritidis in eggs was first identified in 1988. Eleven years later, USDA and FDA have yet to establish a comprehensive strategy to improve egg safety.

2. While we are aware that federal research on *Salmonella* Enteritidis is under way, reporting on that research was not one of the objectives of our review.

3. In commenting on the recommendation to develop a model HACCP-based program for egg farms and processing plants and in its technical comments, FDA said that the science might not support developing prevention controls for egg production. We agree with FDA that the scientific issues involved in designing and establishing the effectiveness of *Salmonella* Enteritidis control measures are complex and that a single universally applicable control has not been identified. However, research and experience in the states have identified a set of controls that generally are agreed to help prevent *Salmonella* Enteritidis contamination on farms. We do not believe that FDA should wait to develop criteria for a model on-farm *Salmonella* Enteritidis reduction program until there are scientific advances. Rather, FDA can take immediate action to develop a model program that contains controls that are based on the best scientific information currently available and the experience of existing state programs. In addition, we have not recommended that the model program should include all the elements of a comprehensive HACCP program. Rather, the model should be HACCP-based in the sense that it follows the general HACCP principles of identifying the places where the greatest food safety risks exist, implementing methods to control the risks at those points, and monitoring the efficacy of the controls.

4. FDA states that the agency has participated in various meetings and task forces regarding on-farm *Salmonella* Enteritidis reduction programs. However, our concern remains that FDA has not established a model national prevention-based *Salmonella* Enteritidis reduction program for farms and existing state programs vary significantly.

5. FDA's proposed egg labeling regulations have not yet been made publicly available. Therefore, we are not in a position to comment on whether they are consistent with USDA's new labeling regulations. Because each agency is developing labeling regulations for different purposes and the regulations will become effective at different times, our report is accurate in saying that each agency is developing its own labeling requirements.

6. We do not agree with FDA that there is a conflict between the statements in the report referring to trends in reported *Salmonella* Enteritidis infections. The best national data available from the Centers for Disease Control and Prevention indicate that reports of *Salmonella* Enteritidis infections increased through 1997. We also cite new data from selected cities and counties that indicate a possible change in trends for 1996 through 1998. While these data are encouraging, they are not evidence of a nationwide reduction in *Salmonella* Enteritidis. Thus, we did not revise these statements.

7. We modified the report to address FDA's technical comment as appropriate.

8. We agree with FDA that eggs have an internal defense against the growth of bacteria. According to the results of one research study, an egg's internal defense against the growth of *Salmonella* Enteritidis would be intact beyond the 3 to 6 days it takes for an egg's internal temperature to be reduced to the air temperature. However, this research is based on the assumption that the *Salmonella* Enteritidis is deposited in the egg white and not the yolk. If *Salmonella* Enteritidis is deposited in the yolk, the bacteria could grow more quickly. In addition, even if *Salmonella* Enteritidis is deposited in the egg white, the research found significant growth during the first 24 hours after the egg was laid. Given the uncertainties about the extent of bacterial growth during the first few days after an egg has been laid, we did not revise the report in response to this comment. We also recommended that USDA and FDA jointly study the costs and benefits of implementing rapid cooling techniques.

GAO Contacts and Staff Acknowledgments

GAO Contacts

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Acknowledgments

In addition to those named above, Stephen D. Secrist, Kathy R. Alexander, Elyssa M. Back, Mary K. Colgrove-Stone, Fran A. Featherston, and John Nicholson made key contributions to this report.