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FOOD SAFETY

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

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Mr. Chairman and Members of the Subcommittee:

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

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

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

In summary, we found the following:

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

- FDA has not established prevention-based procedures on egg farms or at shell egg processing plants that would reduce or eliminate *Salmonella* Enteritidis contamination by identifying, controlling, and monitoring known safety risks. At the state level, 13 states, responsible for about 38 percent of the nation's egg production, have established voluntary prevention-based programs for egg farms.[2] However, these programs do not provide a uniform level of risk reduction because they take different approaches in critical areas such as the frequency of testing for the presence of *Salmonella* Enteritidis. Moreover, FSIS does not require a prevention-based approach in processing plants where eggs are broken to create egg products.
- The first national requirement to refrigerate eggs at 45 degrees Fahrenheit or below from the time they are packed until they reach the consumer may not, for a variety of reasons, effectively reduce egg safety risks.[3] Implementation and enforcement of the requirements will be split between FSIS and FDA. FSIS has issued regulations, which take effect in August, requiring that eggs be refrigerated during storage and transportation. However, FDA has not yet proposed regulations to require that eggs be refrigerated after they arrive at retail locations such as restaurants and grocery stores. In addition, many experts believe that greater risk reduction could be achieved by controlling the internal temperature of the egg, something that the new regulations will not require.
- Inconsistent policies and practices in three other areas have weakened the nation's egg safety efforts. Certain groups, including the elderly in nursing homes, are more likely to suffer severe health consequences from eating contaminated eggs. Yet, only about half the states have followed FDA's recommendation that they require food service operators to use pasteurized eggs or egg products when serving these groups. Also, federal policies allow some eggs to be returned from grocery stores to processors to be repackaged, redated, and returned to the retail level for sale. In addition, there are inconsistencies in how expiration dates are used on egg cartons. The inconsistencies in repackaging and expiration dating can mislead consumers about the eggs' freshness and may pose a food safety risk.
- The involvement of four federal agencies enforcing a variety of laws makes it difficult to direct resources to the areas of highest safety risk and to effectively coordinate egg safety policies. For example, FSIS is required by law to provide daily full-time inspection of egg products plants where

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

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

eggs are pasteurized to kill harmful bacteria, whereas FDA almost never inspects egg farms where eggs can be contaminated. In addition, although we reported in 1992 on the need for better coordination between FDA and the Department of Agriculture (USDA) on egg safety issues, the agencies have still not agreed on a comprehensive unified approach for improving egg safety.[4]

Background

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

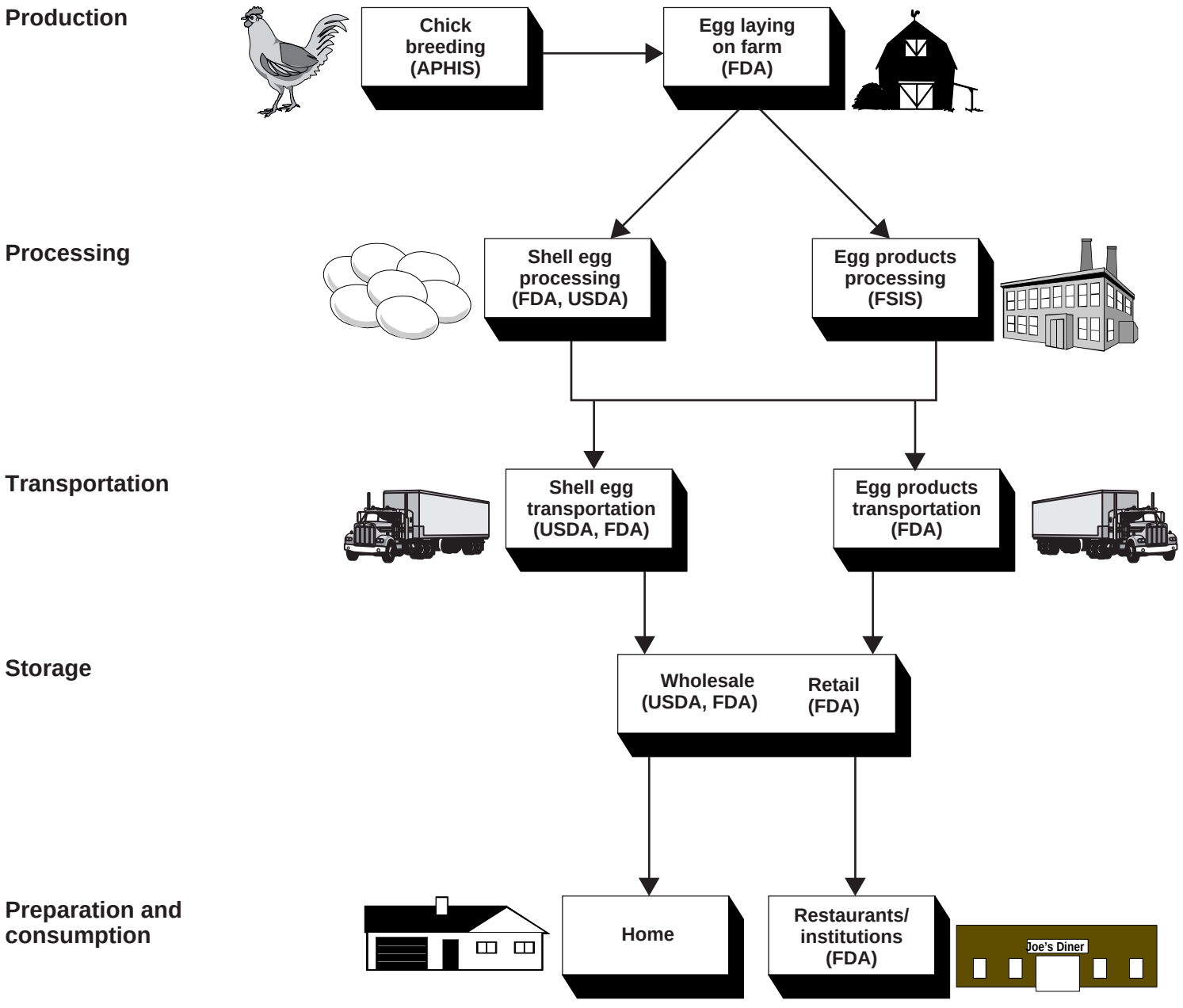
SE, as well as other strains of *Salmonella*, can cause such symptoms as abdominal pain, fever, headache, and vomiting, and can also lead to more severe conditions, such as blood stream infections, arthritis, and meningitis. It sometimes kills, particularly elderly residents of nursing homes. Refrigerating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

As eggs make their way from the farm to the table, responsibility for egg safety shifts back and forth among four federal agencies in two departments and often two agencies in each state. (See fig. 1.) First, USDA's Animal and Plant Health Inspection Service manages the National Poultry Improvement Plan that establishes breeding practices to ensure that laying hens are born free from SE. At the next stage, the farms where eggs are laid, the Department of Health and Human Services' FDA is responsible for egg safety. Once the eggs arrive at processing plants where they are either packed as shell eggs or broken for egg products, the authority is split between two agencies–FDA for shell eggs and USDA's Food Safety and Inspection Service for egg products. While shell eggs are being processed, they may also be inspected by the USDA's Agricultural Marketing Service under a voluntary program to ensure shell egg quality. Once transported to the retail level, both shell eggs and egg products are

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

under FDA's authority, but the millions of restaurants, institutions, and other retail food operations throughout the United States are generally inspected by either a state agriculture or health department under state laws. FDA encourages uniformity among state laws by publishing the Food Code, which recommends model practices for ensuring safer food, and by encouraging states to adopt its provisions.

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



(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 responsibility for egg products after they leave the processing plant.

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

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

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

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

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

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

environmental testing for SE, (6) refrigerating eggs after packing, and (7) keeping records to document the implementation and monitoring of plan requirements.

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

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

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

New Federal Refrigeration Requirements May Not Be as Effective as Possible

Beginning in August 1999, federal regulations will, for the first time, require that eggs for consumer use be refrigerated. But the new rules may not effectively reduce the risks from SE contamination in eggs. The Congress originally required egg refrigeration in the 1991 amendments to the Egg Products Inspection Act. Eight years later, USDA will begin implementing the requirement that eggs be refrigerated at an air

temperature not to exceed 45 degrees from the time they are packed until they reach grocery stores, restaurants, or households.

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

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

Inconsistent Policies and Practices Hamper Egg Safety Efforts

Individuals with impaired immune systems who are in institutional or custodial care, the elderly in facilities such as nursing homes or hospitals, and preschool children in facilities such as day care centers are more susceptible than the general population to severe health problems as a

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

result of eating eggs contaminated with SE. For example, the Centers for Disease Control and Prevention found that 54 of the 79 deaths associated with outbreaks of SE between 1985 and 1998 were of individuals in nursing homes.[8] Because of the problems associated with SE-contaminated eggs, FDA's Food Code recommends special procedures, such as substituting pasteurized eggs for raw eggs in certain situations, for food service operators serving highly susceptible populations. However, according to our survey of state regulatory officials, many states have not adopted the FDA's recommendations on serving pasteurized eggs to highly susceptible populations. For example, 24 of the 50 states told us that they did not require food service operators that serve highly susceptible populations to use pasteurized eggs for any food item that usually contains raw eggs, such as Caesar salad dressing. Furthermore, in 26 states, food service operators are not required to use pasteurized eggs when they crack, combine, and hold a number of eggs for subsequent cooking.

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

USDA and FDA have reacted differently to concerns about repackaging and redating. USDA's Agricultural Marketing Service announced that, as of April 27, 1998, the practice of repackaging and redating eggs would be temporarily prohibited for the one-third of the nation's eggs that are graded and packed under its voluntary grading program because the practice can mislead consumers about the eggs' freshness. The Service is currently developing regulations to make this prohibition permanent. FDA, which has regulatory authority over all shell eggs, announced in May 1998 that it was considering appropriate measures to address repackaging, but as of June 1999, had not taken any action to prohibit the practice. The

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

inconsistency in the federal government's approach to repackaging may be misleading to consumers because USDA-graded and non-USDA-graded eggs sit side by side in grocery store coolers. Our survey of state regulatory officials found that only 10 of the 50 states have laws prohibiting repackaging.

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

Fragmented Structure Makes Effective Resource Allocation and Policy Coordination Difficult

Under the current regulatory and organizational framework, egg safety resources are not directed to the areas of highest risk. FDA has limited inspection resources and under its regulatory authority foods are generally allowed to enter the market without preapproval. Consequently, the agency almost never inspects egg production farms even though outbreaks of egg-related illness are sometimes traced to these locations. In contrast, FSIS is required by law to conduct daily, continuous inspections of all egg products plants in the United States.[9] As a result, most federal resources for egg safety inspection are directed toward egg products even though during processing the eggs are pasteurized to kill harmful bacteria such as SE. In fiscal year 1998, FSIS had 102 full-time inspectors dedicated to daily, continuous inspection at all 73 egg products plants in the country. If HACCP systems are implemented in all egg products plants, it may be possible to reduce or eliminate the current practice of continuous inspection, which could allow inspection resources to be redirected to areas of higher risk.

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

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

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

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

The report we are issuing today contains a matter for congressional consideration and three recommendations aimed at improving egg safety. To provide an organizational focus for the nation's egg safety policies and

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

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

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

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

Contact and Acknowledgments

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

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