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Report to the Chairman, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

April 1992

FOOD SAFETY AND QUALITY

Salmonella Control Efforts Show Need for More Coordination

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GAO

United States
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Resources, Community, and
Economic Development Division

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April 21, 1992

The Honorable John D. Dingell
Chairman, Subcommittee on Oversight
and Investigations
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

This report responds to your request that we examine U.S. Department of Agriculture and Food and Drug Administration efforts to address the health threat posed by eggs contaminated with the salmonella enteritidis (S.e.) bacteria. This report makes recommendations for improving existing control efforts to the Secretary of Agriculture; the Commissioner, Food and Drug Administration; and the Director, Office of Management and Budget. It also presents measures that the Congress may wish to consider for improving coordination and cooperation between federal agencies in reacting to food safety issues and emergencies requiring joint action.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time we will provide copies to the Secretary of Agriculture; the Secretary of Health and Human Services; the Commissioner, Food and Drug Administration; the Director, Office of Management and Budget; and interested congressional committees. We will also make copies available to others upon request.

This work was done under the direction of John W. Harman, Director of Food and Agriculture Issues, who may be reached at (202) 275-5138 if you or your staff have any questions. Other major contributors to this report are listed in appendix II.

Sincerely yours,

J. Dexter Peach
Assistant Comptroller General

Executive Summary

Purpose

Between 1985 and 1990, at least 9,455 illnesses and 46 deaths were attributed to salmonella enteritidis (S.e.) food poisoning in the United States. S.e. is one of over 2,000 strains of the salmonella bacteria. The incidence of S.e. food poisoning has been steadily increasing since the 1970s and is now the most common type of salmonella food poisoning reported. According to U.S. Department of Agriculture (USDA) officials, S.e. food poisoning incidents cost the U.S. economy an estimated $118 million annually in lost productivity, medical and hospitalization expenses, and death. The Centers for Disease Control (CDC) found that many of the S.e. outbreaks reported were associated with eggs.

Concerned about the spread of S.e., particularly in eggs, and the federal response to it, the Chairman, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, asked GAO to review federal S.e. control efforts, including (1) how USDA and the Food and Drug Administration (FDA) coordinated efforts to address the S.e. problem and (2) what additional actions are needed to control S.e.

Background

USDA and FDA have the primary responsibility for dealing with the problem of S.e. in eggs. USDA is responsible for preventing the spread of communicable diseases in poultry. It also inspects egg handlers, processors, and pasteurizing plants. FDA is responsible for controlling communicable diseases that threaten human safety and the food supply. Where federal agency lines of authority overlap, such as in the control of S.e. in eggs, the Office of Management and Budget (OMB) is responsible for ensuring coordination and cooperation.

Results in Brief

USDA and FDA efforts to control the food poisoning outbreaks associated with S.e.-contaminated eggs were initially stymied by questions of jurisdiction, general lack of scientific data about the nature of the S.e. problem, FDA resource considerations, and disagreement and coordination problems between USDA and FDA about the actions to take. These coordination and cooperation difficulties, like other problems in the food safety area, result from the present regulatory structure of split and concurrent jurisdictions.

The continuing nature of these difficulties impedes food safety efforts. For instance, although USDA and FDA are striving to restore working relationships for S.e. control, the federal government has not yet agreed on a unified approach to address the S.e. problem, although 5 years have

elapsed since the problem was first identified. The coordination and cooperation problems between USDA and FDA over controlling S.e. are not unique in the food safety area. These difficulties, in GAO's view, essentially represent a case study of the types of problems that frequently arise among federal agencies responsible for food safety regulation because of split and concurrent jurisdictions.

Egg safety cannot be ensured without additional controls beyond USDA's current program to test chicken flocks. Flocks testing S.e.-free can subsequently become infected by contact with rodents and/or by other environmental conditions. Consequently, some infected eggs will still enter the marketplace, and the health threat can increase with improper handling as the bacteria continue to multiply. A comprehensive program is therefore needed to control S.e. throughout the egg production, distribution, and consumption process.

Principal Findings

Interagency Coordination/Cooperation Needs Improvement

In 1986, when S.e. in eggs was first recognized as a public health threat, USDA and FDA were unsure about their roles in addressing the problem. Within USDA, the Agricultural Marketing Service (AMS), which inspects egg handlers and egg-pasteurizing plants, initially had primary responsibility because S.e. was associated with eggs. However, when S.e. was subsequently seen as more of an animal health problem, leadership shifted to the Animal and Plant Health Inspection Service (APHIS), whose responsibilities include preventing the spread of communicable poultry diseases. Although USDA had the resources necessary to institute an S.e. testing and control program at the farm level, APHIS' legislative authority for such a program is intended to control animal, not human, diseases. Consequently, USDA officials decided they could not act until it was proven that S.e. was also making chickens sick. In contrast, FDA had the authority to ensure food safety and prevent the spread of diseases communicable to humans. However, FDA officials believed that they lacked the personnel and resources to deal with S.e. at the farm level or to implement a successful control program. Also, neither USDA nor FDA wanted to implement a federal program until more scientific information could be gathered about S.e. As a result, in August 1988, the agencies supported a voluntary industry program to test breeding flocks and began working

with industry and state governments for a solution to the growing problem.

When S.e. outbreaks continued despite the voluntary controls, USDA and FDA disagreed on what action to take next. USDA wanted to work within the existing voluntary program, while FDA favored a mandatory approach. When FDA developed a proposal for the mandatory testing of breeding and egg-laying chicken flocks implicated in S.e food poisonings, USDA surprised FDA by implementing its own mandatory program. Subsequently, coordination and cooperation between USDA and FDA broke down. At times this situation hampered FDA's ability to safeguard public health. For example, USDA did not notify FDA for almost 1 month of positive test results from a Pennsylvania chicken flock implicated in an outbreak of S.e. food poisoning in New York. Although USDA had stopped further shipment of eggs from the farm, it was too late for FDA to find and recall eggs already shipped to market. Also, neither USDA nor FDA took steps to ensure that all the S.e. research needs they had identified as important were addressed.

Additional Actions Are Needed to Protect the Public

USDA's S.e. control program focuses on sampling and testing at the farm level to identify and remove infected breeder and egg-laying chickens. However, these actions are not 100 percent effective. It may not be possible to completely disinfect previously S.e.-contaminated chicken houses and equipment and to prevent S.e.-free chickens from subsequently becoming infected from this environment, rodents, or other sources. As such, some S.e.-infected eggs will continue to enter distribution channels and reach consumers.

If control measures are taken at critical points throughout the egg production, distribution, and consumption stages, the health threat presented by eggs that contain S.e. can be minimized. Such an approach has been successfully used to control botulism in the low-acid canned food industry, and experts agree that a similar integrated approach would be effective for controlling S.e. in eggs. Furthermore, according to CDC, infants, the ill, the elderly, and pregnant women are more susceptible to S.e. Many S.e. outbreaks and almost all related deaths have occurred in nursing homes or institutions with elderly and/or ill patients. Health experts believe that the use of eggs that are pasteurized to kill bacteria would help control outbreaks among these individuals.

Recommendations

In view of the coordination and cooperation difficulties experienced by USDA and FDA, and given the recurring nature of these types of problems in the area of food safety regulation, GAO recommends that the Director, OMB, closely monitor USDA and FDA efforts to address S.e. contamination in eggs in order to facilitate continued interagency coordination and cooperation. Furthermore, GAO recommends that the Secretary of Agriculture and the Director, FDA, work together to develop a comprehensive program to control S.e. throughout the egg production, distribution, and consumption process. GAO also recommends that the Secretary of Agriculture and the Commissioner, FDA, take interim steps to protect more susceptible populations, such as infants, the elderly, the ill, and pregnant women from S.e-contaminated eggs.

Matters for Congressional Consideration

A better mechanism could ensure interagency coordination and cooperation and marshall federal resources to control S.e., as well as other food safety threats that require joint effort to address. Therefore, the Congress may wish to consider legislation establishing the structure for an interagency food safety task force that could be activated in response to specific food safety issues and emergencies and that could be staffed and financed by those federal agencies and organizations that have responsibilities for a given situation. Such a structure could include the position of chairperson, empowered with the authority to direct resources and ensure action by interagency members.

Agency Comments

GAO discussed the information in this report with responsible USDA, CDC, FDA, and OMB officials, who generally agreed with the facts as presented. Where appropriate, changes were made on the basis of these discussions to update and clarify some of the information. However, as requested, GAO did not obtain written agency comments on a draft of this report.

Contents

Abbreviations

AMS	Agricultural Marketing Service
ARS	Agricultural Research Service
APHIS	Animal and Plant Health Inspection Service
CDC	Centers for Disease Control
CFSAN	Center for Food Safety and Applied Nutrition
CSES	Cooperative State Extension Service
CSRS	Cooperative State Research Service
FDA	Food and Drug Administration
FSIS	Food Safety Inspection Service
GAO	General Accounting Office
HACCP	Hazard Analysis Critical Control Point
HHS	U.S. Department of Health and Human Services
NMFS	National Marine Fisheries Service
OMB	Office of Management and Budget
USDA	Department of Agriculture

Introduction

Salmonella are bacteria found virtually everywhere in the world—on farm buildings and equipment, fruits and vegetables, foods and feeds, humans, plants, and animals. Scientists have identified 2,000 different strains of salmonella, a few of which account for most human infections. The salmonella enteritidis (S.e.) strain can inhabit the gastrointestinal tracts of birds, reptiles, and farm animals, and may be present in their bedding, litter, feathers, and manure. The presence of S.e. in animals is not readily detectable, and animals infected with S.e. usually appear healthy.

Although no precise way of ranking food safety concerns exists, food scientists and regulators generally believe microbiological pathogens such as S.e. to be among the greater food safety risks. For instance, despite the overall safety of the domestic food supply, the Centers for Disease Control (CDC) and Food and Drug Administration (FDA) estimate that food-borne pathogens such as campylobacter, listeria, and S.e. cause between 6.5 million and 33 million illnesses and about 9,000 deaths in the United States each year. Food poisonings caused by S.e.-contaminated eggs are estimated to cost the U.S. economy $118 million each year in lost productivity, medical and hospitalization costs, and death.

Scientists became concerned about S.e. when CDC started receiving reports of increases in human food poisoning incidents caused by S.e.; illnesses traced to other salmonella types also increased, but less dramatically. S.e. has now become the most common strain associated with reported incidents of salmonella food poisoning in the United States. Delays in implementing mandatory federal programs to stop outbreaks of S.e. food poisoning raised concerns regarding the ability of the U.S. Department of Agriculture (USDA) and the FDA to effectively coordinate and cooperate in addressing the problem.

Increase in S.e. Outbreaks

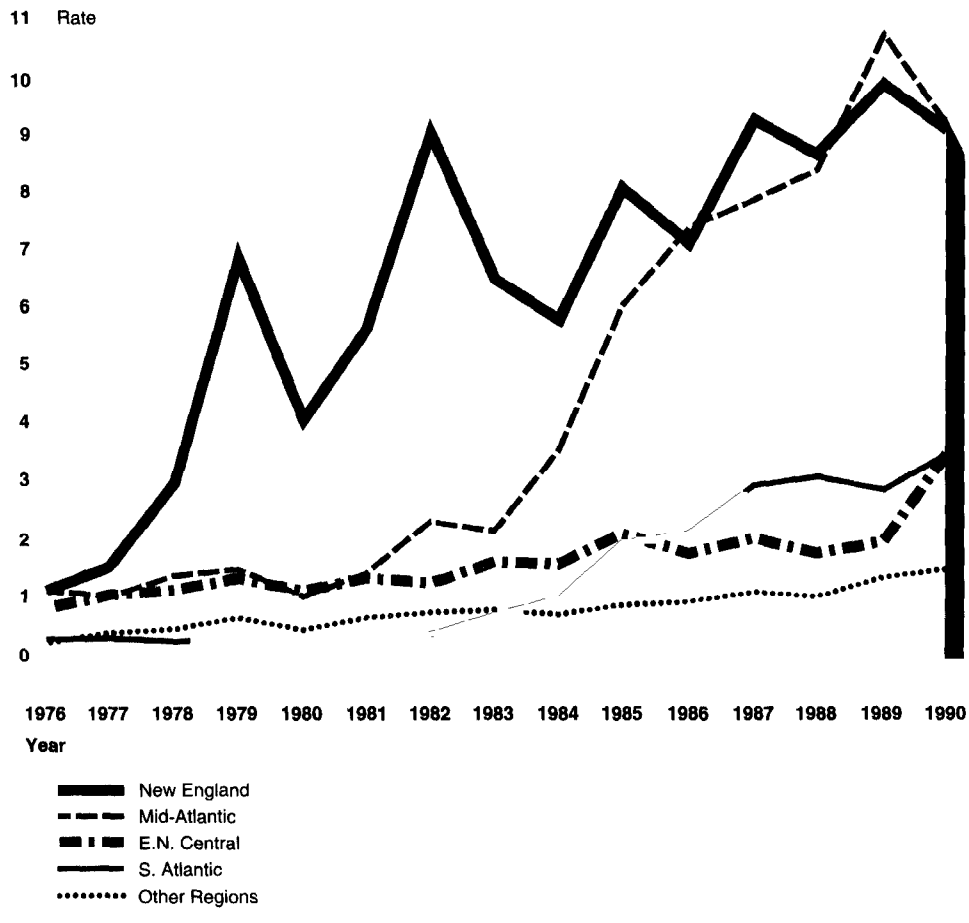
According to CDC, the number of salmonellosis (food poisoning) incidents attributable to S.e. in the northeastern United States increased sixfold between 1976 and 1987, compared with increases in other strains of this bacteria family. CDC data also show that since its emergence in New England, S.e. has spread to the Mid- and South Atlantic states. Outbreaks have also been reported in western states, including California, Colorado, Hawaii, and Idaho.

S.e. food poisoning is characterized by diarrhea, vomiting, fever, and pain. Some sectors of the population—the ill, the elderly, the very young, and

pregnant women—are more vulnerable to S.e. In these cases, S.e. may spread to the bloodstream, causing serious consequences, including death.

According to CDC, between 1985 and 1990, 9,455 illnesses and 46 deaths in the United States were attributable to 285 outbreaks of S.e. food poisoning. Between January and October 1991, 40 S.e. food poisoning outbreaks were reported, compared with 62 outbreaks for this period in 1990. However, authorities are not yet sure whether these numbers represent a real decrease in the incidence of S.e. Figure 1.1 shows the number of S.e.-caused illnesses by region for calendar years 1976 through 1990.

Figure 1.1: Salmonella Enteritidis Isolation Rate Per 100,000 Population by U.S. Region



Source: Centers for Disease Control.

Other countries have experienced similar problems, and the World Health Organization has described S.e. as an international epidemic. The United States' S.e. increase is small compared with those reported by Finland, France, Norway, Spain, Sweden, the United Kingdom, Yugoslavia, and others. In the United Kingdom, S.e. was responsible for over 75 percent of all reported salmonella food poisoning outbreaks. Many of these incidents were ultimately traced back to uncracked table-quality (grade A) eggs, previously thought to be an unlikely host to bacterial pathogens.

S.e. Outbreaks Linked to Table-Grade Eggs

Domestically, CDC scientists first connected human illness with grade A eggs in 1986, during an investigation of a large food poisoning outbreak afflicting about 3,300 people in at least 7 states. CDC investigators linked the illness to a commercially prepared pasta entree made with an incompletely cooked stuffing that included raw eggs. Investigators traced the grade A eggs used in the stuffing to several farms in the Northeast, and S.e. was isolated in specimens taken from those farms.

Scientists were initially reluctant to link eggs with human illness because they believed an existing USDA control program had eliminated egg-associated salmonella food poisoning. In the early 1960s, a food poisoning epidemic traced to several different salmonella strains (although not S.e.) was associated with eggs that had become contaminated by chicken feces on the outside of their shells. USDA instituted a control program in 1972 that eliminated this problem by requiring the pasteurization of all cracked or dirty eggs. By 1973 scientists considered uncracked, clean eggs (grade A) to be microbiologically safe, and FDA removed these eggs from its list of foods needing refrigeration during storage and transportation. After studying the S.e. situation, scientists hypothesized that S.e. was infecting the ovaries of healthy-looking chickens and contaminating the eggs before the shells were formed.

Regulatory Authorities

Federal laws assign authority for monitoring and controlling food safety and eggs to two federal agencies—USDA and the Department of Health and Human Services (HHS). In cases in which jurisdictional authorities and/or responsibilities of federal agencies overlap, such as the food safety area, the Office of Management and Budget (OMB) is responsible for ensuring that the efforts of the respective federal agencies are effectively coordinated. The federal government relies heavily on state regulatory agencies for the day-to-day monitoring necessary to ensure that the eggs

the public receives are safe. The egg industry is ultimately responsible for maintaining the safety of its product.

Currently, USDA is responsible for ensuring egg refrigeration in processing plants that use the Agricultural Marketing Service's (AMS) voluntary services for grading shell eggs, and USDA requires that these eggs be held at a 60 degrees Fahrenheit ambient temperature, or less. Although FDA is responsible for ensuring safety throughout the food chain, it can only advise state governments on refrigeration requirements. State governments establish requirements for refrigeration in retail stores, restaurants, and institutions, and local governments are frequently responsible for the enforcement of state regulations.

USDA

Within USDA, AMS continuously inspects all egg product, or egg-pasteurizing plants, and shell egg handlers every 3 months, under the Egg Products Inspection Act, as amended (21 U.S.C. 1031 et seq.). AMS is responsible for ensuring that cracked or dirty eggs or eggs from flocks involved in interstate commerce that have been implicated in human S.e. outbreaks go to egg-processing plants for pasteurization. In addition, USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for preventing the spread of communicable diseases of poultry. APHIS has the authority to seize, quarantine, and dispose of poultry to guard against the introduction or dissemination of communicable diseases (21 U.S.C. 134(a)). Interim regulations issued on February 16, 1990, and made final on January 30, 1991 (9 C.F.R. Parts 71 and 82), established APHIS's S.e. control program. Under this program, the APHIS S.e. Task Force tests laying flocks whose eggs are implicated in S.e. food poisoning incidents or are associated with infected breeding flocks. If initial tests on the flock's environment indicate the presence of S.e., the flock's owner cannot move the chickens or eggs outside of the state until more tests are done. The eggs may only be sent to processors for pasteurization or sold intrastate if permitted by state regulations. A flock's infected status cannot be lifted until extensive testing, including tests of the internal organs, fails to detect S.e. Poultry houses also must be rigorously cleaned and disinfected until free of signs of S.e. in further tests. USDA bears the costs of testing under this program. Producers bear the costs of cleaning and disinfecting their premises, as well as any destruction and repopulation that they may deem necessary. As of November 13, 1991, 19 laying flocks had been implicated in human outbreaks and had their eggs restricted. Restricted producers sold eggs to pasteurizing plants, usually at prices considerably lower than those for fresh, grade A eggs.

USDA has also developed, published, and distributed pamphlets to consumers, restaurants, and institutions on safe handling procedures for eggs. In addition, USDA's Food Safety and Inspection Service maintains a food safety hot line, which is available to answer consumer questions on egg preparation.

HHS

In addition to regulating drugs, cosmetics, and medical devices, FDA is responsible for ensuring the safety of the human food supply. It has broad authority to regulate eggs throughout the human food chain. FDA has developed, published, and distributed egg-handling pamphlets that provide safe egg-handling procedures to consumers, restaurants, and institutions. However, although it has the ultimate responsibility for regulating food safety for the public, FDA does not itself ensure that restaurants are adequately inspected. Regulation and inspection of restaurants and institutions is left to state governments. FDA prepares the Food Service, Sanitation and Retail Store Ordinances (model code), which recommends regulations and procedures to the states for the proper handling of eggs and other foods by restaurants and institutions and which suggests inspection requirements.[1] States, however, are not bound by the model code.

As part of HHS, CDC is charged with protecting the public health by providing leadership and direction in the prevention and control of diseases and other avoidable conditions. As part of its responsibilities, CDC tracks reports of individual S.e. food poisoning cases as well as of reported outbreaks of other food or water-borne diseases.

OMB

OMB was established as part of the Office of the President to, among other things, assist in the development of efficient coordinating mechanisms to implement government activities and expand interagency cooperation. OMB is also to ensure that work programs of agencies are coordinated and that moneys appropriated by the Congress are expended in the most economical manner, with the least possible overlap and duplication of effort.[2]

[1]CDC has also published guidelines for institutional food handlers.

[2]Executive Order 11541, subsequently amended by Reorganization Plan No. 1 of 1977 (5 U.S.C. App.).

State and Local Governments

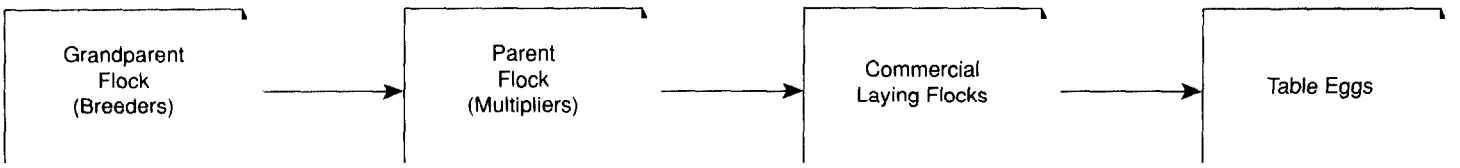
State and local governments are responsible for regulating and monitoring the handling and storage of eggs in retail stores and for the storage, preparation, and serving of eggs in restaurants, hotels, and institutions.

Industry Structure and Responsibilities

The U.S. egg industry is basically composed of three different flock levels: the "grandparent" or primary breeding flock level, the "parent" or multiplier flock, and pullets, which become the egg-laying flock. The primary flocks, consisting of about 700,000 chickens, produce the 3.2 million parent flocks, which in turn produce the 270 million commercial, egg-laying hens owned by about 3,500 producers. U.S. egg production farms tend to be large operations. For example, 1 producer owns about 20 million egg-laying hens.

Laying flocks produce about 68 billion eggs each year, of which about 47 billion are sold and consumed as whole, table-grade shell eggs (grade A). The remaining eggs may be used in hatcheries or pasteurized before they are distributed or exported. U.S. egg industry sales total about $3.2 billion a year. Figure 1.2 shows the structure of the domestic egg industry.

Figure 1.2: Structure of the Domestic Egg Industry



As a matter of good business practice, egg producers and industry officials are responsible for producing a safe, wholesome product. Prior to USDA's S.e. testing program, producers of breeding chickens participated in a voluntary program to certify that their hens were free of S.e. and other salmonella strains. Egg producers may also elect to utilize USDA's voluntary egg-grading services.

Objectives, Scope, and Methodology

On August 1, 1990, the Chairman, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, requested

that we review efforts to control S.e. As subsequently agreed, we focused our review on

- how FDA and USDA coordinated efforts to address the problem of S.e. contamination in eggs and
- what additional actions are needed to control the spread of S.e. in eggs in the United States.

To assess USDA and FDA coordination and cooperation on S.e., we reviewed USDA's and FDA's past, present, and planned S.e. control activities. We also discussed the management and coordination of control efforts with USDA and FDA officials, state officials involved with early control efforts, and egg industry representatives, and we examined the work of USDA's APHIS S.e. Task Force. We interviewed and gathered information from officials at CDC and at FDA's Center for Food Safety and Applied Nutrition (CFSAN).

To further assess how USDA and FDA coordinated S.e. control efforts, we interviewed and obtained documentation from Department of Health and Department of Agriculture officials in five states—California, Indiana, Maryland, New York, and Pennsylvania. We selected these states because they had the largest number of egg-laying flocks, the most flocks restricted as a result of being traced to human S.e. outbreaks, and/or the highest number of S.e. outbreaks. We also met with OMB officials to determine OMB's role in ensuring federal interagency cooperation.

We assessed federal cooperation in developing S.e. research by interviewing and gathering documents from USDA agency officials with major responsibilities for food safety, egg production, research, and education, including the AMS, Agricultural Research Service (ARS), APHIS, Cooperative State Extension Service (CSES), and Cooperative State Research Service (CSRS). We also interviewed experts at three major universities who are currently conducting research on S.e.

Because of problems that it experienced with S.e. contamination of eggs, the United Kingdom instituted a mandatory S.e. control program about 1 year before similar action was taken in the United States. We were asked by the Subcommittee to perform work in the United Kingdom to determine the comparability and success of U.S. and U.K. control efforts. Accordingly, we interviewed and obtained documentation from researchers, egg industry representatives, and officials of the U.K.'s Ministry of Agriculture, Fisheries and Food; the Department of Health; and the Public Health Laboratory Service.

In order to maximize audit coverage and minimize duplication of effort, we discussed our review objectives and coordinated our work with the USDA and HHS Offices of Inspector General.

Our review was principally conducted from July 1990 through May 1991, and some of the information was updated through February 1992. The review conformed to generally accepted government auditing standards. Information contained in the report was discussed with responsible USDA, CDC, FDA, and OMB officials, who generally agreed with the facts as presented. Where appropriate, changes were made on the basis of these discussions to update and clarify some of the information. However, as requested, GAO did not obtain written agency comments on a draft of this report.

Improved Mechanism Needed to Ensure Interagency Coordination and Cooperation

When USDA and FDA recognized that S.e.-contaminated eggs were causing human disease, they attempted to work together to address the problem. Because federal regulators were initially uncertain about which agency should assume the lead and what actions to take until more scientific knowledge could be gained, they encouraged producers to participate in voluntary control efforts. However, these efforts proved ineffective, and USDA and FDA could not agree on the next course of action. Interagency coordination and cooperation broke down. Although USDA and FDA are now attempting to restore interagency working relationships, efforts to control S.e. contamination in eggs have been hampered.

The problems USDA and FDA had working together to control the spread of S.e. in eggs are not unusual in the area of food safety regulation, nor are they necessarily limited to these two agencies. There are 12 federal agencies with various responsibilities under 35 different food safety laws, and similar problems have been reported in studies conducted over the years by congressional committees and agencies such as GAO and the Congressional Research Service. The continuing nature of these difficulties indicates that the present food safety regulatory structure—with federal agencies having acquired split and concurrent jurisdictions—has a systemic problem. Currently, no effective mechanism exists to marshall federal food safety resources, and agencies may be ill prepared to deal effectively with a major outbreak of food-borne disease requiring joint action.

Uncertainty Over Jurisdiction

Initially, neither USDA nor FDA were certain which agency should assume leadership in addressing S.e. contamination of eggs. Neither believed it could independently assume control of the S.e. problem because responsibilities and resources for eggs and the public health were split between the two agencies. Within USDA itself, AMS first took the lead in addressing the problem because of its association with eggs. However, because of S.e.'s implications for animal health, APHIS subsequently assumed responsibility.

While USDA has the expertise and personnel to deal with the S.e. problem, APHIS' legislative authority is directed toward the control of diseases affecting the health of animals, not humans. Therefore, on the basis of an internal legal opinion, USDA concluded that it could not assume responsibility for control until it had evidence that S.e. was making chickens sick. According to the Director of FDA's Center for Food Safety and Applied Nutrition (CFSAN) Microbiology Division, the Director of USDA's

AMS Poultry Division initially suggested that FDA assume control over the problem of S.e. in eggs. FDA could have initiated an S.e. control program to reduce human illness under the Public Health Act (42 U.S.C. 262 et seq.). However, CFSAN officials told us that their agency did not have the resources necessary to initiate a program to test poultry on the farm.

Similar problems regarding USDA and FDA uncertainties over divided regulatory authorities were previously noted by the Senate Committee on Governmental Affairs. In its 1977 report on the organization of federal regulatory authority over food, the Committee stated:

"where regulatory authority has been imprecisely—or concurrently—allocated, the result has been confusion and uncertainty as to the limits of each agency's jurisdiction . . . and the failure of either agency to act effectively in the face of a regulatory need."[1]

Federal Agencies Initially Worked Together

The federal government's S.e. control efforts began when researchers, industry representatives, and state public health authorities met in June 1987 with USDA and FDA officials to discuss the emerging S.e. issue. Subsequently, the agencies held a number of formal and informal meetings to identify the S.e. problem and to search for solutions.

Experts recognized that many questions about S.e. needed answers before an effective control program could be ensured. To gain this information, the Agricultural Research Service (ARS) and the Cooperative State Research Service (CSRS) sponsored the USDA Salmonella Enteritidis Task Force for Research in May 1988. This task force of 17 experts from USDA, FDA, CDC, and 7 universities worked together for about 6 months. The experts reviewed existing S.e. research and developed a list of about 12 research needs of the highest priority. In June 1988 the USDA/FDA S.e. Work Group was formed to address the problem of S.e. contamination in eggs. On September 15, 1988, FDA and USDA sponsored a national public meeting on S.e. at which participants from USDA, FDA, state agencies, academia, and industry identified issues and discussed possible solutions. Subsequently, USDA and FDA announced an extensive public awareness campaign, and thousands of safe egg-handling bulletins were distributed to the media, consumers, high-risk populations, and food service establishments.

A chronology of events concerning federal efforts to control S.e. is included in appendix I.

[1]U.S. Senate, Committee on Governmental Affairs, Study On Federal Regulation, Regulatory Organization, Vol. V (Dec. 1977).

Voluntary Program Endorsed

USDA and FDA did not immediately establish a mandatory federal program for S.e. control because much was unknown about the pathogen and its method of transmission. While the research needed to develop this information was being identified and conducted, USDA and FDA officials recommended that the egg industry participate in a voluntary testing program. This August 1988 program was based on a previous industry-supported voluntary effort that had effectively eliminated problems with a related type of salmonella in poultry.

The voluntary program recommended specific testing activities for breeding flocks. It also recommended testing commercial egg-laying flocks that were implicated in outbreaks of human illness or that were offspring of infected breeding flocks. However, compliance was incomplete. Furthermore, there were questions regarding the representativeness of the samples that had been collected by industry personnel, the lack of standardized criteria for culturing the samples, and the absence of a requirement for producers to report any S.e. findings. S.e. outbreaks continued, and controversy emerged over the effectiveness of the voluntary program. Calls increased for a mandatory federal control program from state officials, the table egg industry, and public health officials.

Interagency Coordination and Cooperation Deteriorated

Although USDA and FDA initially worked together to endorse the industry-initiated voluntary control program, the agencies disagreed on the next step to take when it appeared that the voluntary program was not working. USDA wanted to continue working within the existing voluntary approach. In contrast, FDA believed that a mandatory approach was needed. Working relationships between the two agencies started to change, and an element of interagency competition began to emerge. In a September 5, 1989, memo to the Deputy Administrator of Veterinary Services, APHIS officials stated that the role USDA adopted in addressing the S.e. issue could determine the future role of their agency in regulatory activities on food safety.

Duplicate Program Development

According to the Assistant Administrator of USDA's Food Safety and Inspection Service, who was a member of the USDA/FDA S.e. Work Group, working relationships began deteriorating when FDA officials told group members that FDA had independently developed a plan for S.e. control but was unwilling to share it. Although FDA planned to discuss its proposed S.e. control program with USDA in December 1989, it publicly announced

its plan earlier, at an October 31, 1989, meeting of the U.S. Animal Health Association. The plan would have required all flocks—breeding and laying—to be tested for S.e. and certified by the state of origin. However, when FDA officials finally met with USDA in December 1989, USDA officials surprised them by announcing a mandatory S.e. control program of their own. The USDA program required testing of breeding flocks, and egg-laying flocks implicated in S.e. food poisoning outbreaks, and placed restrictions on their interstate movement. In a January 12, 1990, weekly update for the Acting FDA Commissioner, FDA officials stated that allowing USDA to develop an S.e. control program risked FDA's status as the lead food safety agency.

However, FDA opted to support USDA's program rather than pursue implementation of its own proposal. FDA officials said they acceded to USDA's program because it could be implemented immediately under USDA's emergency authorities (21 U.S.C. section 134b) and because FDA would have had to go through a lengthy rule-making process before its program could have been initiated. USDA, FDA, state, and industry officials also told us that FDA did not have the resources to initiate its own program and that there were not enough veterinarians to take the required samples or laboratories to analyze all the samples that would have been involved. These officials also said that FDA's proposed program would have been expensive. USDA estimated that a mandatory program testing all commercial egg-laying flocks would cost between $6 million to $10 million a year.

USDA involved FDA in the development of USDA's February 16, 1990, interim regulations for the S.e. control program, and FDA insisted that the program include a statement of its authorities and its intentions to develop its own regulations to ensure the safety of fresh eggs in interstate commerce.

After USDA issued its interim regulations on February 16, 1990, FDA continued to develop its own contingency regulations for a mandatory program to control the spread of S.e. As planned, these regulations would be implemented if USDA's testing program was judged to be ineffective. However, FDA did not involve USDA or industry in this process, even though its regulations encompass many areas previously regulated by USDA and contain additional refrigeration requirements for eggs throughout the producer-to-consumer distribution chain.

USDA's Director of the AMS Poultry Division said that he surmised that FDA was developing regulations and that they included refrigeration

requirements because FDA staff members had occasionally called asking for specific information. However, he told us that FDA was unwilling to share a copy of the draft with him, despite his requests. Similarly, FDA officials refused to share a copy of the draft with us when we requested it, stating that they had not yet provided it to USDA. FDA officials told us that the Administrative Procedures Act prohibits the premature or privileged disclosure of proposed regulations, and they were concerned that we might share this information with USDA and that USDA might then reveal the details to the egg industry.[2]

Similarly, USDA did not inform FDA of its activities. Once USDA's interim regulations were issued, APHIS established its S.e. Task Force to oversee control procedures and to serve as a clearinghouse for S.e. information. FDA had no representation on this task force and was only occasionally invited to planning or evaluation meetings. In fact, USDA and FDA officials met only twice during 1990, once with industry officials and once as part of the USDA/FDA S.e. Work Group that had existed since June 1988.

This lack of coordination and cooperation meant that the food supply might not have been as safe as possible. FDA needed information the APHIS S.e. Task Force had on infected flocks to remove any infected eggs that remained in the food supply; lack of this information hampered the ability of FDA to fulfill its responsibilities. For example, USDA delayed notifying FDA of S.e.-positive test results that the APHIS S.e. Task Force obtained when it tested the environment of a Pennsylvania flock implicated in an outbreak of S.e. food poisoning in New York State. In this instance, the APHIS S.e. Task Force knew of the positive test results on April 27, 1990, but USDA did not notify FDA of the implicated farm until May 22, 1990. Although USDA stopped further shipment of eggs from the farm, it was too late for FDA to find and recall any suspect eggs already shipped to market. In another instance, USDA waited 12 days to notify FDA that it had determined another Pennsylvania flock was infected.

Different Refrigeration Requirements

To safeguard against human illness, it is important to refrigerate eggs as quickly as possible after they are laid and to keep them refrigerated until prepared and consumed. When eggs are held at room temperature, the number of S.e. bacteria present can divide every 15 to 30 minutes, sometimes increasing tenfold in an hour. The larger the number of salmonella present in the egg, the more likely consumption of the egg will

[2]FDA ultimately provided a copy of its proposal to USDA for coordination purposes early in March 1991, with the stipulation that the information not be shared outside the agency. However, the information found its way into industry's hands shortly thereafter.

cause illness. However, when eggs are refrigerated at an internal temperature of 45 degrees Fahrenheit or less, S.e. reproduction stops. Research by England's Public Health Laboratory also indicates that S.e. bacteria subjected to refrigeration are more sensitive to heat and die at lower cooking temperatures. Therefore, for food safety purposes, eggs and foods requiring raw eggs (e.g., caesar salad dressing) should always be kept adequately refrigerated until consumed.

However, poor coordination between USDA and FDA has resulted in dissimilar egg refrigeration requirements being proposed and/or established by the two agencies. For instance, in its proposed S.e. regulations, FDA wants eggs to be held at an ambient temperature of 45 degrees Fahrenheit or less during packing, storage, and transportation. However, under USDA regulations, producers electing to utilize USDA's voluntary grading service for shell eggs are only required to refrigerate eggs at ambient temperatures of 60 degrees Fahrenheit or less.

Also, poor coordination by FDA in proposing egg refrigeration requirements in its Food Service, Sanitation and Retail Store Ordinances (model code) has jeopardized state acceptance of actions needed to improve food safety. The model code serves as a guide for public health agencies and the food service industry. Although states may choose not to enforce the model code, FDA officials told us that it generally has been adopted by the states. In the changes proposed to the model code in April 1990, FDA recommended that eggs be added to the list of foods that are potentially hazardous without temperature control and that eggs be held at 45 degrees Fahrenheit or below until used or sold. FDA solicited comments on its draft proposal from USDA, states, and industry, who supported FDA's draft proposal because they understood that this refrigeration requirement meant eggs had to be stored and displayed in refrigerated units at ambient temperatures of 45 degrees Fahrenheit or below. But FDA's final model code differed from the draft: It required an internal egg temperature of 45 degrees Fahrenheit or below. The Director of AMS's Poultry Division, state officials from Indiana and Maryland, and the vice president of an egg industry group told us this difference is significant, unreasonable, and unattainable: Technology does not exist to quickly cool eggs to an internal temperature of 45 degrees Fahrenheit or below. In addition, since eggs usually move from warehouses to grocery stores within 2 days of laying, warehouses would have to hold eggs longer to achieve an internal temperature of 45 degrees Fahrenheit or below, and eggs in grocery stores would lose freshness. The Directors of Indiana's Consumer Protection Board and State Egg Board believe that FDA published its recommended

criteria on refrigerating eggs without performing the research necessary to determine if achieving such a temperature is even possible, given the manner in which eggs are currently processed.

According to the Director of FDA's CFSAN Microbiology Division and a science policy analyst for the Center's Executive Operations Staff, FDA had not intended to mislead commenters. While these officials agreed that the wording in the model code was changed when it was made final, they said that the model code requires all foods that are potentially hazardous without temperature control to be held at an internal temperature of 45 degrees Fahrenheit or below. Therefore, classifying eggs as potentially hazardous dictated that they too be held at this temperature.

FDA officials told us that they had subsequently advised state inspectors to be lenient in enforcing this requirement for eggs. However, some retail stores are already requiring producers to supply them with eggs cooled to an internal temperature of 45 degrees Fahrenheit or below. Also, some states, including Georgia, Indiana, and Maryland, have decided not to adopt FDA's model code refrigeration requirements for eggs because of the problems previously identified.

Research Efforts Need Better Coordination

USDA has allocated at least $3.2 million for the study of S.e. in eggs since 1988, and federally funded S.e. research has also been conducted by CDC and FDA scientists. In addition, state governments and the egg industry have funded S.e. research, although we could not readily determine the amount of funding provided. S.e. research needs were identified and prioritized by an ARS/CSRS task force in November 1988 and again by an expert panel assembled by the APHIS S.e. Task Force in August 1990. However, no one agency or individual was ever assigned the responsibility or authority for ensuring that this research was initiated, completed, and communicated to those who need it. As a result, some of the research requested by both USDA and FDA was not being performed—even though the research was considered important to ensuring the effectiveness of S.e. control efforts. For example, the expert evaluation panel assembled by the APHIS S.e. Task Force in August 1990 determined that research was needed to (1) evaluate different cleaning and disinfection methods for poultry buildings and equipment, (2) determine the prevalence of S.e., (3) develop sensitive and specific tests for S.e. in poultry, and (4) determine the role of rodents and flies in transmitting S.e. to chickens.

According to USDA and FDA officials, the ability to effectively clean and disinfect S.e.-contaminated poultry houses and equipment is very important to S.e. control. Unless effective methods are devised, producers who eradicate infected flocks and replenish their flocks with uninfected chickens run the risk of recurring S.e. problems. However, according to USDA and FDA regulators, even though USDA and the industry had repeatedly requested research on cleaning and disinfecting poultry houses, federal research agencies had not made this a priority or performed the research requested. The Director of the ARS S.e. Research Center said that he is not pursuing this area of research because, in his opinion, it is not a high priority.

According to the APHIS S.e. Task Force Director, although research on effective methods to clean and disinfect S.e.-contaminated poultry houses was not undertaken by ARS, this research is now being conducted at the University of Maryland. The Director also said that many of the other research needs identified as important by the task force's expert panel have now been undertaken by ARS and CSRS or by industry and other sources outside the federal government.

Interstate Trade May Be Restricted by Disparate State S.e. Control Programs

State officials as well as consumer and industry groups have criticized the federal government for a lack of leadership in addressing the problem of S.e. in eggs. Officials from Maryland's Departments of Agriculture and Health and Mental Hygiene said that USDA was slow to develop mandatory regulations—forcing the states to act on their own. New York State officials believe that USDA and FDA are not adequately protecting the consumer from S.e., and Pennsylvania state officials believe that USDA and FDA shifted responsibility for addressing the S.e. problem to the states.

Consequently, in 1989 Maryland began to require egg packers to document that their egg-laying flocks originated from parents who tested S.e.-free in order for the packers to sell eggs in Maryland. New York State also drafted regulations that require all producers who sell eggs in New York to ensure pullet flocks are derived from S.e.-free breeding flocks. However, New York also required that (1) pullet and commercial laying flocks' environments test S.e.-free, (2) commercial egg-laying flocks with S.e.-contaminated environments have their blood tested and their organs cultured, and (3) eggs from flocks with S.e. found in internal organs are sold only for pasteurization until the flocks are destroyed.

However, the development of individual state programs may adversely affect interstate trade because the egg market is a national rather than a state market. For example, packers representing about 900 flocks and 50 million chickens from about 15 states are registered in Maryland. In order for these packers to sell eggs in New York State, they will have to meet the more rigid requirements established there. Pennsylvania and New Jersey State officials have already notified their poultry industries and New York State that they will be unable to provide the sampling, laboratory service, or recordkeeping required to qualify eggs for shipment to New York. Pennsylvania officials also said that neither technology nor adequate resources are currently available to the poultry industry to eliminate salmonella from poultry production systems.

The egg industry presented its concerns about the possible trade implications of separate state S.e. control programs in a March 1989 position paper:

"Free access across state lines is an economic necessity . . . . Without federal coordination and enforcement of regulations that supersede the states, the egg industry will be fighting 50 local battles with public health entities that have no knowledge of the egg industry or its needs."

Efforts to Restore Federal Interagency Coordination/ Cooperation

In January 1991 the Office of Management and Budget (OMB) convened a meeting with USDA's Assistant Secretary of Agriculture for Marketing and Inspection Services and the Commissioner of FDA. Although we were told that the meeting was not held for the express purpose of ensuring interagency coordination and cooperation, relationships between the agencies improved soon thereafter. Also, according to officials at FDA's Center for Food Safety and Applied Nutrition, USDA's APHIS S.e. Task Force has improved its system for notifying FDA of farms implicated in S.e. outbreaks and now includes information on FDA's planned farm-related activities in its letters to the egg producers involved. In addition, the USDA/FDA S.e. Work Group was reactivated, with one of its main objectives being the establishment of mutually agreed-upon criteria for evaluating the effectiveness of USDA's control program. A section recognizing the need for coordination between USDA and FDA was also included in USDA's final rule for the Department's S.e. control program, and FDA provided copies of its proposed contingency regulations for a mandatory S.e. control program to USDA.

Although USDA and FDA have taken steps to reestablish coordination and cooperation on the S.e. issue, basic differences between these two agencies remain. Each agency has sharply contrasting regulatory philosophies, perspectives, and resources and is subject to oversight by different congressional committees. As such, problems could again surface in the S.e. area or with other food safety issues that similarly require action by more than one agency. Coordination and cooperation problems can also be exacerbated by the interest of each agency in maintaining its respective food safety role.

Food Safety Issues Typically Cut Across Federal Agency Lines of Authority

The responsibility for control of S.e. contamination in eggs crosses the jurisdictional lines and authorities of federal and state agencies. But the fragmented responsibilities and overlap in agency interests and efforts is not unique to the problem of S.e. contamination in eggs. Under the current structure, 12 federal agencies carry out their responsibilities under about 35 different laws related to food safety. As stated by the Senate Committee on Governmental Affairs in its 1977 report on the complicated nature of food safety regulation:

"Increasingly the human diet has come to consist of highly processed foods, some containing meat and some with no meat ingredients. Existence of divided responsibility for regulating production of these foods has resulted in a regulatory program which is often duplicative, sometimes contradictory, undeniably costly and unduly complex."[3]

Extensive coordination and cooperation is required between agencies under this regulatory patchwork in order to avoid duplication and/or gaps in regulatory coverage, and confusing or conflicting regulatory positions.[4] In addition, many of the same products inspected by federal agencies are regulated by state agencies at the retail level as well.

[3]U.S. Senate, Committee on Governmental Affairs, Study on Federal Regulation, Regulatory Organization, Vol. V (Dec. 1977).

[4]In Food Safety and Quality: Who Does What in the Federal Government (GAO/RCED-91-19A and B, Dec. 21, 1990), we identified over 50 different interagency agreements that were directed at preventing duplication of effort, gaps in coverage, and/or conflicting actions in the food safety and quality activities of the USDA's Agricultural Marketing Service, Federal Grain Inspection Service, and Food Safety and Inspection Service; the Environmental Protection Agency; the Department of Health and Human Service's FDA; and the Department of Commerce's National Marine Fisheries Service.

Agencies Still Use an Ad Hoc Approach to Address Coordination and Cooperation Problems

In its December 1977 report, the Senate Committee on Governmental Affairs noted that in the regulation of food safety, USDA and FDA generally treat recurrent problems of overlap, duplication, and split/concurrent jurisdiction on an ad hoc, case-by-case basis. Also, over the years, additional studies of the overall food regulation process have been conducted by congressional committees, a presidential project, congressional agencies, and other groups outside GAO. Changes recommended to correct the problems identified included increasing the use of interagency agreements and standing interagency committees to coordinate enforcement activities.

An Interagency Regulatory Liaison Group was formed in 1977 to facilitate agency interaction on matters concerning overlapping jurisdiction. However, the group was disbanded in 1981. Furthermore, although numerous interagency agreements have been formulated to prevent coordination/cooperation problems in the regulation of food safety, problems continue to occur. For example, in 1991 we reported that while USDA has made some progress in organizing its structure to address key issues in the food safety area, it has not developed an approach for managing these issues in a manner that facilitates a cohesive, departmentwide strategy.[5] Initiatives to establish coordinating mechanisms for managing multiagency issues have not been fully developed; instead, USDA management generally relies on ad hoc groups or USDA's individual agencies to develop policies and plans. Consequently, individual agencies within USDA implement and monitor their own specific responsibilities for cross-cutting food safety issues. This, in turn, hampers the development of an integrated, departmental perspective and makes effective coordination and cooperation both within USDA and with other federal departments and agencies more difficult to achieve. As a result, federal efforts to address food safety concerns can be delayed and/or duplicated, and opportunities to effectively deal with emerging food safety issues can be missed.

Also, in March 1991, the USDA Inspector General found that, despite the existence of interagency agreements to do so, AMS does not promptly notify FDA of unsanitary conditions found at dairy plants,[6] or at

[5]U.S. Department of Agriculture: Revitalizing Structure, Systems, and Strategies (GAO/RCED-91-168, Sept. 3, 1991).

[6]Agricultural Marketing Service—Dairy Grading and Inspection Activities (U.S. Department of Agriculture Office of Inspector General, Audit Report Number 01061-0012-Ch, Mar. 29, 1991).

egg-processing plants.[7] Coordination and cooperation problems involve agencies other than USDA and FDA as well. For instance,

- FDA has inspected seafood plants under inspection by the Department of Commerce's National Marine Fisheries Service (NMFS), without prior notification or coordination with the NMFS inspector.
- An official of the NMFS Southeast Regional Office told us that NMFS does not notify FDA of seafood plants that fail initial plant surveys because of poor sanitation, manufacturing practices, or other reasons.
- Because of different requirements governing the regulation of product health claims by FDA and the Federal Trade Commission, health claims banned from food labels by FDA are nonetheless allowed in food advertisements regulated by the Federal Trade Commission.

Conclusions

Despite initial attempts, USDA and FDA have not effectively coordinated their S.e. control efforts with state governments, the research community, industry, or each other. Consequently, although more than 5 years have elapsed since federal officials became concerned about S.e. contamination of eggs, the federal government has not yet agreed on a unified approach to solve the problem. In fact, breakdowns in coordination/cooperation resulted in USDA's and FDA's developing separate S.e. control proposals and in one case prevented FDA from removing S.e.-contaminated eggs from the marketplace.

An effective mechanism still does not exist to ensure that interagency coordination and cooperation takes place and that consistent progress is made toward a comprehensive approach to S.e. control. Although efforts are being made to improve interagency coordination and cooperation on the S.e. issue, the basic reasons for earlier difficulties remain—regulatory authorities concerning the problem of S.e. in eggs are split between USDA and FDA, and there are inherent differences in the institutional perspectives and objectives of these two agencies.

Furthermore, the coordination and cooperation problems that occurred between USDA and FDA in their attempts to address S.e.-contamination in eggs are not unique. We believe they are symptomatic of a larger, overall problem in the existing system of food safety regulation: That is, federal agencies acquired split and concurrent jurisdictions as food safety laws were enacted to address specific health risks.

[7]Agricultural Marketing Service—Federal Inspection Under the Egg Products Inspection Act (U.S. Department of Agriculture Office of Inspector General, Audit Report Number 01061-11-At, Aug. 9, 1989).

Although USDA and FDA are attempting to renew cooperative efforts for S.e. control, S.e. is not the only microbiological food-borne pathogen or food safety issue that will require interagency effort to be resolved. Because coordination and cooperation problems have had a history of reoccurring, and because they involve other agencies as well as USDA and FDA, a better mechanism could ensure interagency coordination and cooperation among federal agencies when food-related safety issues or emergencies arise that require joint action.

One possible option would be to put in place the structure for an interagency group, such as a task force or council, that could be quickly activated in order to respond to specific food safety issues and emergencies. To avoid problems that may arise from jurisdictional uncertainties and other concerns, such a structure could include the position of chairperson, empowered with the authority to direct resources and ensure action by interagency members. However, since 1971, a governmentwide restriction in annual appropriation acts has prohibited interagency financing of such organizations without prior and specific statutory approval. This action was taken by the Congress to ensure that funds appropriated to a federal agency would not be diverted to unauthorized interagency programs.

Recommendations

In view of the past coordination and cooperation difficulties experienced by USDA and FDA, and given the recurring nature of these types of problems in the area of food safety regulation, GAO recommends that the Director, OMB, closely monitor USDA and FDA efforts to address the S.e. problem in order to facilitate continued interagency coordination and cooperation and the efficient, effective, and economical expenditure of resources for S.e. control.

Matters for Consideration by the Congress

To better ensure effective interagency coordination and cooperation in cases where food safety issues and emergencies require joint agency action to address, the Congress may wish to consider legislation establishing the structure for an interagency food safety task force that could be activated to address specific food safety issues and emergencies and that would be staffed and financed by federal agencies and organizations appropriate to the given situation being addressed. Such a structure could include the position of chairperson, empowered with the authority to direct resources and ensure action by interagency members.

Additional Actions Are Needed to Protect the Public From S.e. in Eggs

Farm-level programs are necessary to help contain S.e., but they may not adequately limit the spread of S.e. in eggs to consumers. Flocks that test free of S.e. may subsequently contract the bacteria from rodents, the environment, or other sources, and may produce S.e.-infected eggs. After a few days, the S.e. in an infected egg can grow with improper handling at any point in the distribution chain—from the farm to the consumer's table—becoming a greater potential hazard to health. For example, an S.e. control program instituted by the United Kingdom is more extensive than USDA's, but because of similar program limitations, the U.K. program has not contained S.e.'s spread. Furthermore, a program similar to the United Kingdom's—which includes the destruction of infected egg-laying hens—could prove very costly if attempted in the United States, given the much larger size of domestic flocks.

An alternative method, endorsed by the National Research Council as a model for effectively addressing microbiological food safety hazards such as S.e., is known as the Hazard Analysis Critical Control Point (HACCP) approach. HACCP encompasses multiple control points—production, processing, distribution, and preparation—and has been used successfully by the low-acid canned food industry to eliminate botulism. Federal, state, and industry groups have identified control points in the egg production, distribution, and consumption process that could be used in a HACCP approach, but the authorities responsible for these points are dispersed. Therefore, coordination and cooperation among all cognizant groups will be needed for a HACCP program to be effective. Other measures are also available for protecting more vulnerable sectors of the population from S.e. in eggs.

USDA and U.K. Control Programs

In February 1990 USDA used its emergency authority over communicable diseases in poultry to establish a two-pronged approach for controlling S.e. in eggs. USDA's program requires the testing of all breeding flocks involved in interstate commerce, as well as egg-laying flocks implicated in S.e. outbreaks or associated with S.e.-infected breeder flocks. It also controls the interstate movement of poultry, eggs, and materials from positive and/or exposed flocks. USDA's program is based on scientific studies showing that the increase in egg-associated salmonellosis results from infected hens transmitting the disease through their ovaries. In theory, embryos in fertile eggs produced by such hens may also carry the infection and produce infected chicks. When an infected chick becomes an adult laying hen with infected ovaries, it can occasionally lay eggs infected with S.e.

Under USDA's program, a state-authorized lab tests breeding flocks for S.e. and certifies that hatching eggs and newly hatched chicks come from S.e.-free flocks. Interstate movement is prohibited without this certification. In addition, any offspring of a breeding flock found to be infected are traced and tested. State governments and producers bear almost all the testing costs of this program, as well as any eradication expenses.

In March 1989 the United Kingdom began a mandatory control program that tests all egg-laying and breeding flocks for the presence of S.e. The U.K. program requires producers to sample and test their own flocks and to send samples to laboratories. Laboratories are required to notify the Ministry of Agriculture, Fisheries, and Food of any positive results. If S.e. is confirmed in a poultry flock, the producer is required to slaughter that flock and clean and disinfect the premises before repopulating. The U.K. government compensates producers for the value of their slaughtered flocks,[1] but not for the costs of slaughtering, cleaning, and disinfecting.

Control Program Limitations

Most of the public health officials, regulators, and scientists we interviewed believe that while steps can be taken to control S.e., the bacteria will probably never be eradicated. Although USDA's program is proactive in ensuring that breeding flocks are S.e.-free, the pathogen can also be passed to egg-laying hens from rodents, the environment, and other conditions. Also, experts are not certain that hen houses can be adequately disinfected, and a repopulated flock may once again become infected with the bacteria. In the United States and the United Kingdom, S.e. incidents have recurred after laying flocks were destroyed, their environment disinfected, and the flocks repopulated.

USDA's program also does not address distribution and consumption, during which improper handling and preparation can seriously compound the S.e. threat to consumers. In addition, USDA's program depends on tracing S.e. food poisoning incidents, which must occur before control measures can be instituted for laying flocks. According to the Director of USDA's APHIS S.e. Task Force, the traceback program to date has not done enough to reduce the prevalence of S.e. in egg-laying flocks. The results of recent USDA surveys indicate that many more egg-laying flocks may be infected with S.e. than those identified to date by traceback procedures. USDA now estimates that up to 44 percent of flocks in the northeastern

[1]Initially the U.K. program paid 60 percent of the value of the flocks. However, some producers contested this level, and following arbitration the United Kingdom now pays the total value of the flock.

United States may be infected, as well as 23, 13, and 3 percent of the western, central, and southeastern flocks, respectively.

In addition to these issues, the legality of USDA's program has been questioned. Specifically, a producer whose eggs were restricted under USDA's program challenged the program's legality in a U.S. district court in Indiana. In June 1991 this court found USDA's regulations invalid because no compensation existed either for eggs sent for pasteurization or for chickens killed for testing or depopulation. USDA appealed to the U.S. Court of Appeals, 7th Circuit, and in February 1992 the decision of the U.S. district court was reversed. However, the issue of whether USDA must compensate the producers impacted by its S.e. regulations has not been resolved.

According to the APHIS S.e. Task Force, the potential consequences of an ineffective S.e. control program could include the following:

- Costs to the U.S. economy attributable to egg-related S.e. food poisoning could rise. Current estimates place these costs at about $118 million annually from lost productivity, medical and hospitalization bills, and death.
- Repetitive incidents of food poisoning from S.e.-contaminated eggs might result in a crisis like the "Alar-in-apples" scare. If so, egg producers could lose $300 million to $500 million—assuming a 3-month drop in consumer demand of 10 to 25 percent.
- Disparate control measures could increasingly be imposed on producers by federal agencies and individual states, leading to confusion and inefficiency for all.
- S.e. could become a more significant poultry pathogen, resulting in lost productivity and reduced economic performance of the national flock.

Other Proposals to Control S.e.

Early in 1991 USDA presented an alternate proposal for additional S.e. controls, including a program of voluntary certification for egg-laying flocks. As proposed, producers would test hen house environments for S.e. at the end of laying cycles, and APHIS would then certify flocks as S.e.-free. Restaurants and other food service institutions would be encouraged to purchase certified eggs.

FDA has proposed a contingency plan for S.e. control, to be implemented if USDA's program is judged ineffective by government officials. In addition to other requirements, the plan calls for producers and distributors to certify

that all eggs in interstate commerce come from state-tested, S.e-free environments and provides for FDA's detention and destruction of eggs without valid certification.

Most of the egg industry supports neither USDA's nor FDA's proposed certification plans. According to the APHIS S.e. Task Force Director, some segments of the egg industry centered in New England and the Mid-Atlantic states support USDA's proposal because they are more affected by S.e. and have already initiated similar testing programs. However, members of the egg industry in other areas of the country who are less affected by S.e. are unwilling to engage in a program that they view as unnecessary and potentially costly. Some egg industry groups also believe that USDA's proposal contains disincentives and penalties for producers, and they will not support it without an indemnification provision. As of November 1991, the egg industry had neither endorsed nor accepted USDA's voluntary certification proposal, although discussions were still ongoing. Another approach, possibly incorporating indemnity payments financed by the egg industry itself through an insurance program, is currently being considered. Also, the industry has historically opposed FDA's control of the problem.

A mandatory domestic program requiring the testing and eradication of S.e.-infected chickens could prove costly. For instance, as of October 1990, the United Kingdom had destroyed 173 flocks (about 1.6 million chickens) and had paid 1.6 million pounds (or $3.3 million in U.S. dollars),[2] to compensate producers. U.K. producers estimate that the compensation paid actually covered only about one-third of their losses since it covered only flock-replacement costs. A British Ministry of Agriculture Under Secretary told us that egg production losses also occurred after the destruction of the flock because immediate replacement of slaughtered flocks is not always possible, and when replaced, the flock may be too young to produce eggs at once. In addition, a British egg industry representative said that required testing added about 12-1/2 percent to farmers' production costs. There are about 270 million laying hens in the United States, compared with approximately 46 million in the United Kingdom. Also, individual U.S. flocks are typically large operations. The slaughter of just one of the larger U.S. producer flocks could involve almost as many chickens as were killed in the U.K. S.e. program from its inception in March 1989 through October 1990.

[2]Based on the exchange rate as of Nov. 1990.

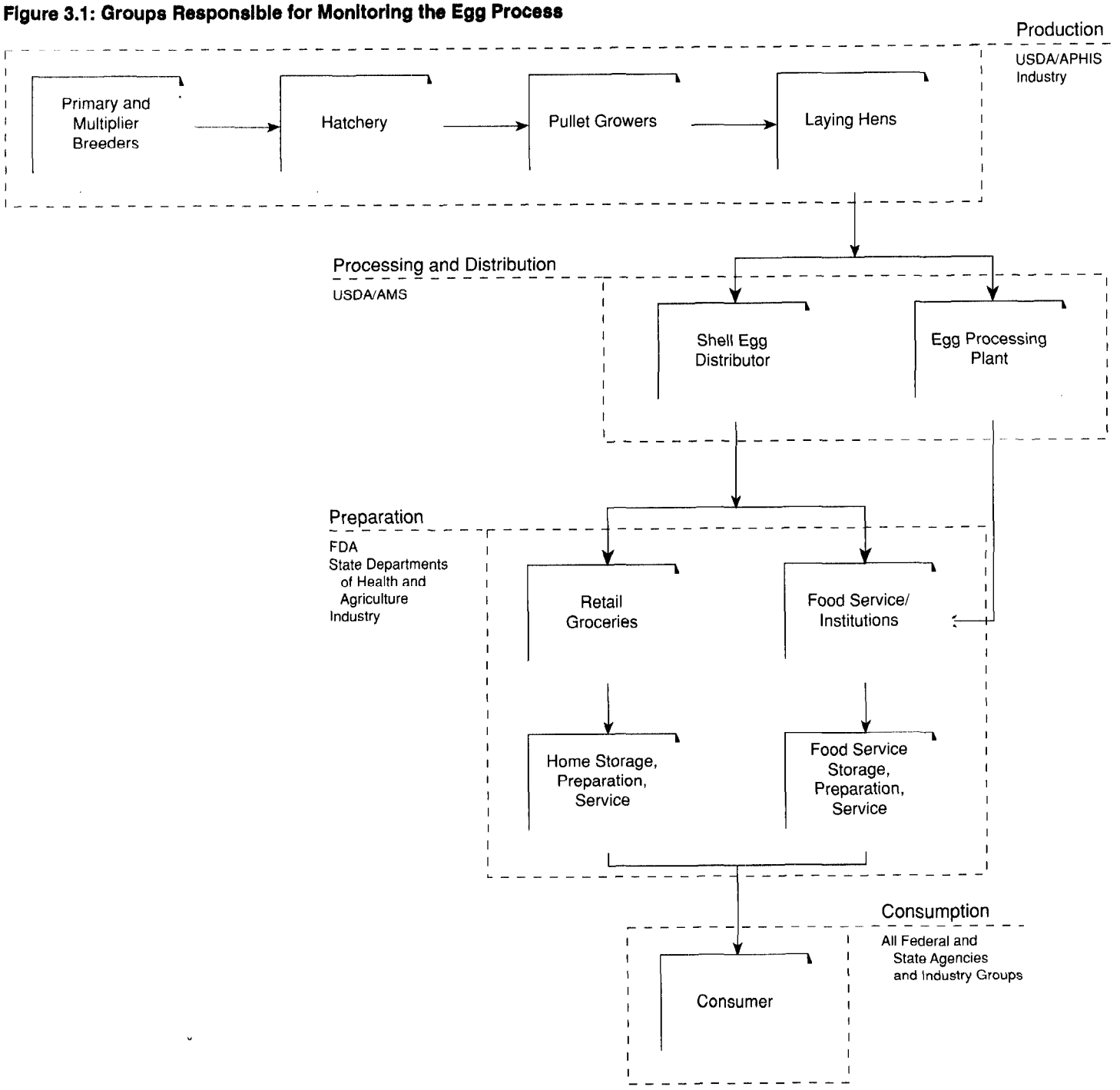
According to the Director of USDA's APHIS S.e. Task Force, if S.e. was found to be prevalent in the environments of 13 percent of egg-layer houses, producer losses under a mandatory testing and eradication program could range from $30 million to $136 million. In addition, the resulting supply deficits could increase consumer prices by as much as 75 percent.

A Unified Approach With Multiple Control Points May Better Protect Consumers From S.e. in Eggs

While sampling, testing, and controlling S.e. at the farm level is necessary, it is not 100 percent effective. A number of questions also exist regarding disinfecting the environments of S.e.-contaminated flocks or preventing recontamination from rodents or other sources. Therefore, some S.e.-infected eggs will continue to enter distribution channels and reach consumers despite the control measures currently available at the farm level.

Additionally, even if all those responsible for eggs, from the farmer to the retailer, were successful in controlling S.e., consumers could still mishandle the product, nullifying the earlier controls and exposing themselves and others to the bacteria. On the other hand, eggs, like meat, poultry, milk, and other foods of animal origin, are safe when handled and prepared properly. A program that encompasses all the critical points in the total egg process could reduce the number of S.e. food poisoning incidents associated with eggs. However, regulatory authority over many points in the egg production-to-consumption process are divided among federal agencies, while others lie outside federal regulatory jurisdiction. Figure 3.1 illustrates the domestic egg production-to-consumption network and the groups responsible for various points in it.

Figure 3.1: Groups Responsible for Monitoring the Egg Process



Source: APHIS S.e. Task Force, as modified by GAO.

An approach that coordinates the efforts of all federal, state, and industry groups involved in the egg process is needed. Such a concept, known as the HACCP system, has been endorsed by the National Research Council[3] for reducing or eliminating microbiological food hazards like S.e.

HACCP Has Been Used Successfully

The HACCP concept unites government and industry groups to ensure food safety. Using HACCP,

- hazards associated with growing, harvesting, processing, marketing, preparing, and using a given raw material or food product are identified and assessed;
- critical points for controlling any identifiable hazard are determined; and
- systems to monitor those critical control points are established.

In 1973, after FDA had used a limited HACCP approach, federal regulations mandated that the HACCP approach be applied to control microbiological hazards in low-acid canned foods, which are subject to contamination by clostridium botulinum. If spores of this bacteria survive the canning process, and if toxin is subsequently produced, consumption of the contaminated product may lead to botulism, an often fatal disease. Testing for the presence of this bacteria in processed food is difficult because it occurs so infrequently. However, the low-acid canned food industry successfully ensured the safety and stability of its products using a HACCP system. This success required cooperation between the canning industry and responsible government agencies.

According to the National Research Council, the HACCP system for low-acid canned foods should serve as a model for the rest of the food industry. If joint government/industry efforts identified critical control points and established effective monitoring systems, food safety and stability could be achieved in other areas. A HACCP approach is now being developed for the seafood industry, and USDA's Food Safety and Inspection Service has also proposed a HACCP approach for the inspection of meat and poultry operations. USDA, FDA, and state officials, agreed that a HACCP approach could also be used to reduce the threat from S.e.-contaminated eggs.

[3]The Council's membership consists of representatives from the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

Some Critical Control Points Have Been Identified

When scientists realized that S.e. had infected some of the nation's egg-laying flocks, researchers and regulators began identifying possible control points and methods for the bacteria. USDA's program to test breeding flocks for the presence of S.e. provides a first control point for the production phase. USDA also restricts egg-laying flocks after they have been implicated in S.e. food poisoning incidents. More proactive programs that would routinely monitor and test all egg-laying flocks for S.e. have also been proposed by some experts.

Precautionary measures, such as refrigeration, have also been identified for controlling S.e. in eggs during the processing and distribution phase. Additional measures to be taken during the preparation phase include ensuring that eggs are kept at the proper temperature and/or cooked thoroughly, so that they do not become a health hazard. Another way to avoid egg-related S.e. problems is to use pasteurized eggs. According to USDA, pasteurized eggs are S.e.-free. During the pasteurization process, the liquid egg is removed from the shell and heated to temperatures that kill most bacteria. Pasteurized eggs are sold as liquid, frozen, or dried products and can be used in omelets and scrambled eggs, or as an ingredient in various recipes. Experts agree that the use of pasteurized instead of whole eggs would reduce human illness from S.e.—especially for the ill, the elderly, infants, and pregnant women. In fact, according to CDC, many large S.e. outbreaks and almost all related deaths have occurred in nursing homes or institutions where the patients are elderly or have impaired immune systems. CDC has recommended that institutions serve only pasteurized eggs to the elderly or to patients in hospitals. In addition, some restaurants have begun to substitute pasteurized eggs in their recipes in order to avoid problems associated with egg-related S.e. food poisoning incidents.

Many of the human S.e. outbreaks and deaths that have occurred in institutions and restaurants have involved mishandling of the products. Although an egg may be contaminated when laid, it becomes increasingly dangerous when the bacteria multiply because of improper handling. Therefore, it is particularly important that chefs and food handlers in institutions and restaurants follow safe egg-handling procedures because of the large number of people they serve. Basic food hygiene requirements must be adhered to, particularly washing hands and utensils to avoid cross-contamination of foods, including other eggs. Eggs should also be cooked thoroughly in order to kill any bacteria that might be present. Cooked eggs should be held at serving temperatures of 140 degrees Fahrenheit or higher until consumed.

About 61 of 69 S.e. outbreaks investigated by APHIS during 1990 resulted from foods prepared in institutions and restaurants, or by caterers. Mishandling of food in restaurants and institutions frequently involved the pooling of eggs before preparing such menu items as scrambled eggs or French toast, and holding the combined product at warm room temperatures. This practice allows one S.e.-infected egg to infect a quantity of other eggs, enables the bacteria to multiply before consumption, and increases the potential for human illness. For example, 65 people became ill with S.e. food poisoning following a restaurant brunch for a wedding party. CDC determined that this illness resulted from a hollandaise sauce made from eggs that had been pooled, incompletely cooked, and served over an hour after preparation.

In another instance at least 435 persons who attended a convention banquet became ill after eating a bread pudding with vanilla sauce. Public health investigators determined that the shell eggs used in this dessert might have been undercooked and that the dessert was left at room temperature for 1 to 4 hours before serving.

Most states have incorporated FDA's model code suggestions for regulating the food service industry and retail food stores into their state regulations. However, some states may lack the resources needed to effectively inspect restaurants. For instance, one Pennsylvania official said his agency only has one restaurant inspector for every 750 food service facilities under its jurisdiction. Consequently, regulations may not be adequately enforced and safe food handling procedures—including those for eggs—may not always be followed.

Conclusions

Regulators, researchers, and other experts agree that while steps to control the spread of S.e. are possible, it is doubtful that the bacteria will ever be eliminated. U.S. and U.K. actions to address egg-related S.e. at the farm level have had limited effectiveness. Also, some proposed actions, like the slaughter of domestic laying flocks, could become very costly.

Farm-level control measures alone will not alleviate the public health threat posed by S.e. in eggs. Some S.e.-infected eggs will continue to enter distribution channels and reach consumers. However, if control measures are taken at critical points throughout the egg process—production, distribution, and consumption—the health threat presented by eggs that contain S.e. can be minimized. This approach may do more to protect consumers than proposals to eradicate domestic egg-laying flocks. Such

an approach has already proven itself effective in addressing other microbiological hazards, and experts agree that it could be effectively employed to address the S.e. problem with eggs.

A concerted effort of federal and state government officials; industry; restaurants and institutions; and, ultimately, consumers themselves is required to achieve such control. The structure necessary to facilitate this approach exists in the USDA/FDA S.e. Work Group. With adequate representation from all the regulatory and marketplace sectors involved, the work group could gain the comprehensive perspective and cooperation necessary to ensure that needed controls for a successful HACCP program are identified, enacted, and enforced. However, this will take time to accomplish. Until the work group has successfully implemented the HACCP approach to protect all consumers, additional measures—such as requiring that pasteurized eggs be used to the extent possible in hospitals, institutions, restaurants, and food assistance programs—could be taken to protect the more S.e.-vulnerable population sectors, such as the ill, the elderly, the very young, or pregnant.

Recommendations

To better ensure that the public health threat presented by S.e.-contaminated eggs is minimized throughout production, distribution, and consumption, we recommend that the Secretary of Agriculture and the Commissioner of the Food and Drug Administration require the USDA/FDA S.e. Work Group to develop a comprehensive S.e. control program for eggs that employs HACCP principles to identify and encompass all possible areas of bacterial contamination, and that implements methods to ensure control.

In the interim, to better protect more S.e.-susceptible sectors of the population, such as the ill, the elderly, infants, and pregnant women, we recommend the following:

- The Secretary of Agriculture and the Commissioner, FDA, should work with other federal agencies, including OMB, and state governments to encourage the use of pasteurized eggs, to the extent possible, in food assistance programs and in institutions such as hospitals and elderly care facilities where the more S.e.-susceptible population sectors are served and to encourage the use of pasteurized eggs by restaurants and the food service industry.
- The Commissioner, FDA, should direct that FDA's Food Service, Sanitation and Retail Store Ordinances (model code), which are provided to the

states as a guide for public health agencies in regulating the food service industry, be amended to recommend the use of pasteurized eggs by the food service industry.

- At a minimum, and as an example, USDA and FDA, should encourage the refrigeration of fresh eggs, and where possible the substitution of pasteurized egg products, in recipes at all federally operated hospitals, institutions (such as prisons), restaurants, and in federal food assistance programs.

Selected Chronology of S.e. Epidemic and Control Efforts

Date	Event
1986	
June	CDC, several state health departments, and FDA began investigating a S.e. food poisoning outbreak involving about 3,300 people, caused by a commercially prepared stuffed pasta that was labeled as "fully cooked" but that actually contained raw eggs.
1987	
January	A CDC weekly report noted the increasing rate of S.e. in New England and the Mid-Atlantic states.
March	A poultry industry group alerted USDA to the rising number of S.e. food poisoning incidents associated with eggs.
June	CDC sent provisional guidelines for preventing S.e. infections and deaths to state and territorial epidemiologists. USDA hosted an interagency meeting to discuss S.e. infections in the Northeast. The meeting was attended by about 40 people, including federal and state officials, researchers, and industry representatives.
December	New York State sponsored an S.e. symposium that included representatives from CDC, FDA, and USDA, state health and agriculture agencies, and university scientists. The purpose of the symposium was to foster information exchange and encourage definitive leadership action by the federal government and other states regarding the rising S.e. problem.
1988	
April	An article in the Journal of the American Medical Association reported on the increase in S.e. food poisoning incidents, associating the infections with the transmission of S.e. bacteria from poultry to eggs.
May	USDA's CSRS convened the S.e. Task Force for Research, whose membership included representatives from CDC and FDA, and university scientists.
June	An organization of poultry disease specialists drafted the first version of the Voluntary Model State Program for S.e. control. The program was subsequently revised 10 times as knowledge was gained and the need for new information recognized. The program began S.e. field research and developed the initial tests used to detect the bacteria. An industry group called the National Poultry Improvement Plan endorsed a plan to prevent the transmission of S.e. bacteria from egg-type breeding chickens to their progeny. The program was implemented in June 1989. New York State embargoed eggs from Maryland and Maine producers implicated in S.e. food poisoning incidents in New York. The USDA/FDA S.e. Work Group was formed and held its first meeting in Washington, D.C. Additional meetings followed.
August	USDA and FDA approved the industry-developed voluntary program for S.e. quality assurance and sent copies to state officials and industry organizations. This program was revised in November 1988.

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Date	Event
September	USDA and FDA sponsored a National Public Meeting on egg-associated S.e. in Washington, D.C. USDA and FDA announced an extensive public awareness campaign and over 50,000 safe egg-handling bulletins were distributed to consumers, high-risk populations, and food service establishments.
November	USDA S.e. Task Force for Research published the results of its 6 months of work, identifying ongoing S.e. research and additional research needs.
December	USDA/FDA S.e. Work Group held a final meeting before individual control programs were proposed.
1989	
January	USDA's ARS allocated new 1989 funds for S.e. research and redirected in-house S.e. research programs.
March	An egg industry group called USDA's response to S.e. in eggs "insufficient." The group requested that USDA establish a nationally coordinated program to identify and eradicate S.e.-infected flocks with or without an indemnification provision and stated that free access across state lines is an economic necessity.
April	USDA issued regulations governing restrictions on the importation of eggs from all countries where S.e. in eggs is considered to be a problem.
June	The U.S. Sanitation Monitored Program to control S.e. in breeding flocks was published in the Federal Register. This program was a part of the National Poultry Improvement Program, but participation was voluntary.
September	APHIS officials alerted upper management that the role they adopt in addressing S.e. could determine the future role of their agency in regulatory activities relating to food safety.
October	FDA proposed a program to require S.e. testing of both breeder and commercial layer flocks.
December	Assistant Secretary of Agriculture met with industry representatives to discuss USDA mandatory testing program for breeding flocks. USDA surprised FDA by announcing a mandatory S.e. control program for breeder flocks and commercial layer flocks implicated in S.e. food poisoning incidents.
1990	
January	FDA officials alerted their Acting Commissioner that allowing USDA to develop an S.e. control program may jeopardize FDA's status as the lead food safety agency. Representatives from USDA and FDA met to discuss APHIS's proposed control program. FDA officials agreed to APHIS's program but retained the authority to evaluate it and develop a contingency plan.

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Date	Event
February	USDA's interim regulations to control and monitor S.e. were published in the Federal Register. FDA notified USDA of a technical problem with a test specified by interim regulations. USDA later indicated the problem had been fixed without notifying FDA. An APHIS S.e. Task Force was established to implement USDA's S.e. program and coordinate associated field activities.
March	APHIS received its first public health report linking an S.e. food poisoning outbreak to eggs.
April	A USDA/FDA S.e. Work Group meeting was held. First traceback of an S.e. food poisoning incident to a Maryland commercial egg-laying flock occurred. Environmental, blood, and organ tests were conducted and restrictions placed on movement of eggs from this farm.
May	In order to determine if FDA actions were warranted, FDA attempted to obtain information on S.e.-infected eggs already in distribution from the Maryland flock. USDA notified FDA that a Pennsylvania flock was S.e. infected, 25 days after positive environmental test results were obtained. FDA issued a draft for comments that proposed returning eggs to the list of potentially hazardous foods in its model code of recommendations for state governments.
June	APHIS S.e. Task Force convened four regional work conferences to introduce USDA's control program to state officials. Extended comment period for APHIS interim regulations was closed.
July	USDA waited 12 days to notify FDA that another Pennsylvania egg-laying flock was S.e.-infected. The Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce held a hearing on salmonella poisoning in food.

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Date	Event
August	This Subcommittee requested that GAO investigate the efforts of FDA, USDA, and other federal agencies concerned with food safety and food-borne pathogens, especially S.e. APHIS S.e. Task Force assembled an expert panel to evaluate the APHIS program and to discuss S.e. research needs. Representatives from CDC, FDA, and industry, as well as university scientists participated. FDA issued a model code recommendation that redesignated shell eggs as a "potentially hazardous" food and recommended that states require refrigeration of eggs. USDA, states and industry groups subsequently stated that a wording change from proposed interpretation makes implementation difficult.
September	FDA requested that USDA's nctification letter to restricted egg producers be modified to include information on FDA's responsibilities and pending actions related to the farm. USDA complied with this request. New York State published and requested comments on S.e. regulations requiring that all producers selling eggs in that state test their egg-laying flocks for S.e.
October	USDA initiated a "spent hen" survey to determine the extent of S.e. infection in the egg-laying flock. New Jersey Department of Agriculture notified New York State that New Jersey did not have the resources to assist New Jersey producers in complying with New York State's S.e. testing program.
1991	
January	Joint meeting between USDA, FDA, and OMB.
March	FDA draft regulations for proposed contingency S.e. control program shared with USDA. Pennsylvania Department of Agriculture notified New York State that it does not have the resources to comply with New York's S.e. testing program. Commissioner of FDA corresponded with Assistant Secretary of USDA to reestablish the USDA/FDA S.e. Work Group. USDA/FDA S.e. Work Group met in Washington, D.C. Primary task of the group was to develop mutually agreeable criteria for evaluating the effectiveness of USDA's S.e. control program.
June	U.S. district court in Indiana found USDA's S.e. regulations invalid because no compensation existed for losses incurred by producers. APHIS S.e. Task Force and HHS/FDA officials met in Washington, D.C., to discuss S.e. objectives in HHS document entitled "Healthy People 2000."

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Date	Event
July	Georgia General Assembly required that shell eggs be transported, stored, and displayed at an ambient temperature of 45 degrees Fahrenheit.
September	ARS meeting in Athens, Georgia, to discuss current status of the USDA's S.e. control program. Officials from APHIS S.e Task force, CDC, FDA, and 35 technical consultants and staff personnel attended. Meeting between APHIS S.e. Task Force and FDA officials regarding USDA S.e. control program.
October	Special meeting with United Egg Producers regional representatives. Officials of APHIS S.e. Task Force and CDC attended. Meeting in Stroudsburg, Pennsylvania, between APHIS S.e. Task Force representatives and state epidemiologists from the Northeastern Region.
Oct./Nov.	U.S. Animal Health Association Meeting in San Diego, California. Officials from USDA, CDC, FDA, and other federal agencies, as well as state and industry attended. Meeting between APHIS S.e Task Force personnel and staff from the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce.
February	U.S. Court of Appeals, 7th district, reversed U.S. district court decision that USDA's S.e. regulations were invalid.

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