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Prevention of *Salmonella* Enteritidis in Shell Eggs During Production; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 118

[Docket Nos. 1996P–0418, 1997P–0197, 1998P–0203, and 2000N–0504]

RIN 0910–AC14

Prevention of *Salmonella* Enteritidis in Shell Eggs During Production

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require shell egg producers to implement measures to prevent *Salmonella* Enteritidis (SE) from contaminating eggs on the farm. We are taking this action because of the number of outbreaks of foodborne illnesses and deaths caused by SE that are associated with the consumption of shell eggs that have not been treated to destroy this pathogen. We expect that the requirements that we are proposing in this rule, if finalized as proposed, will result in a significant decrease in the number of SE-contaminated eggs produced on farms. Ultimately, we expect that the proposed requirements in this rule will generate public health benefits through a decrease in the numbers of SE-associated illnesses and deaths caused by consumption of shell eggs.

DATES: Submit written or electronic comments by December 21, 2004.

Submit written comments on the information collection provisions by October 22, 2004. See sections III.C and VI.C of this document for the proposed compliance dates of a final rule based on this document.

ADDRESSES: You may submit comments, identified by [Docket Nos. 1996P–0418, 1997P–0197, 1998P–0203, and 2000N–0504], by any of the following methods:

• Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

• Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

• E-mail: *fdadockets@oc.fda.gov*. Include [Docket Nos. 1996P–0418, 1997P–0197, 1998P–0203, and 2000N–0504 and RIN number 0910–AC14] in the subject line of your e-mail message.

• FAX: 301–827–6870.

• Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/dockets/ecomments*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/dockets/ecomments* and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rebecca Buckner, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy. College Park, MD 20740, 301–436–1486.

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I. Highlights of the Proposed Rule

In this proposed rulemaking, FDA is proposing egg safety SE prevention measures for egg production. This proposal is significant because a farm-to-table risk assessment of *Salmonella* Enteritidis (SE) in eggs identified implementation of on-farm prevention measures as a very important step that could be taken to reduce the occurrence of SE infections from eggs. Voluntary quality assurance programs for egg production have led to meaningful reductions in SE illnesses already. However, these programs are not always uniformly administered or uniformly comprehensive in their prevention measures.

Moreover, the most recent data from the Centers for Disease Control and Prevention (CDC) show that SE illnesses have essentially remained steady for the past several years. In 2001, CDC estimated that 118,000 illnesses were caused by consumption of SE-contaminated eggs. Accordingly, we believe that additional interventions are warranted. The proposed on-farm SE prevention measures and a more detailed rationale for these measures are found in section III of this document.

Following are the proposed SE prevention measures: (1) Provisions for procurement of chicks and pullets, (2) a biosecurity program, (3) a pest and rodent control program, (4) cleaning and disinfection of poultry houses that have had an environmental sample or egg test positive for SE, and (5) refrigerated storage of eggs at the farm. Moreover, a cornerstone of the proposal is a requirement that producers test the environment for SE in poultry houses. If the environmental test is positive, we are proposing that egg testing for SE be undertaken, and that if an egg test is positive, eggs be diverted from the table egg market to a technology or process that achieves at least a 5-log destruction of SE for shell eggs, or the processing of egg products in accordance with the Egg Products Inspection Act. As part of the SE prevention measures, we are proposing that producers identify a responsible person to administer the prevention measures at each farm. We also are proposing recordkeeping requirements for environmental and egg sampling and testing and for egg diversion. Finally, we are proposing that if a producer has 3,000 or more laying hens and all eggs at a farm are to be given a treatment that will achieve at least a 5-log destruction of SE or processed into egg products, then only the proposed refrigeration requirements would apply. The proposed rule would not apply to producers who sell all of their eggs directly to consumers or producers with fewer than 3,000 laying hens.

We also are soliciting comment on whether we should include additional requirements in the final rule, particularly in two areas. First, should we expand the recordkeeping requirements to include a written SE prevention plan and records for compliance with the SE prevention measures? Second, should the safe egg handling and preparation practices in FDA's 2001 Model Food Code (as outlined in section IV.D of this document) be federally mandated for retail establishments that specifically serve a highly susceptible population (e.g., nursing homes, hospitals, day care centers)? These issues are discussed in more detail in the following relevant sections of this document.

II. Background

A. Salmonella and SE Infection

1. Salmonellosis

Salmonella microorganisms are ubiquitous and are commonly found in the digestive tracts of animals, especially birds and reptiles. Human illnesses are usually associated with ingesting food or drink contaminated with *Salmonella*, although infection also may be transmitted person to person through the fecal-oral route where personal hygiene is poor or by the animal-to-man route (Ref. 1).

The disease salmonellosis is the result of an intestinal infection with *Salmonella* and is characterized by diarrhea, fever, abdominal cramps, headache, nausea, and vomiting. Symptoms of salmonellosis usually begin within 6 to 72 hours after consuming a contaminated food or liquid and last for 4 to 7 days. Most healthy people recover without antibiotic treatment; however, the infection can spread into the bloodstream, then to other areas of the body such as the bone marrow or the meningeal linings of the brain. This infection can lead to a severe and fatal illness (Ref. 2). The complications associated with an infection are more likely to occur in children, the elderly, and persons with weakened immune systems. In addition, about 2 percent of those who recover from salmonellosis may later develop recurring joint pains and arthritis (Ref. 3).

Salmonellosis is a serious health concern. It is a notifiable disease, i.e., physicians and health laboratories are required to report cases (single occurrences of illness) to local health departments in accordance with procedures established by each State. These cases are then, in turn, reported to State health departments, and the *Salmonella* isolates[1] are referred to State Public Health laboratories for serotyping. Each case and each serotyped isolate is reported to CDC. These reports are made only for diagnosed cases of *Salmonella* infection.

A case of illness is confirmed as salmonellosis only if an isolate is confirmed by a laboratory as being

[1] When a physician sees a patient and suspects that the patient has a case of salmonellosis, the physician may obtain a patient's specimen (e.g. stool) for analysis. The specimen is sent to the laboratory to be tested to identify and confirm any *Salmonella* that may be present. Thus, the laboratory obtains the actual specimen of *Salmonella*.

Salmonella. Although all cases may not be confirmed, all confirmed cases are associated with isolates of *Salmonella*. Reported cases are likely to represent only a small portion of the actual number of illnesses that occurred because of the following reasons: (1) Ill individuals do not always seek care by medical professionals, especially if the symptoms are not severe; (2) medical professionals may not establish the cause of the illness but may simply treat the symptoms; and (3) medical professionals do not always report *Salmonella* cases to public health officials. CDC used updated information and data from a FoodNet population study to estimate that there are 38 cases of salmonellosis for every one that is reported (Ref. 4). This estimate was central to updating an estimate of the burden of salmonellosis. The overall burden of salmonellosis in 2001 was estimated to be 1,203,650 cases, including 14,000 hospitalizations, and 494 deaths (Refs. 4 and 5).

CDC surveillance data list close to 600 different *Salmonella* serotypes (a group of related microorganisms distinguished by their antigens) that have caused illness in the United States. Following are the four serotypes most frequently reported as causing illness: (1) *Salmonella enterica* serotype Typhimurium, (2) *Salmonella enterica* serotype Enteritidis (*Salmonella* Enteritidis or SE), (3) *Salmonella enterica* serotype Newport, and (4) *Salmonella enterica* serotype Heidelberg (Ref. 6). These microorganisms are found in poultry, eggs, and other foods.

2. SE

Currently, SE is one of the most commonly reported serotypes of *Salmonella*. SE accounted for only about 5 percent of the number of all reported *Salmonella* isolates in 1976. However, in 1985, 1990, 1994, and 1999, SE constituted 9.8 percent, 20.6 percent, 26.3 percent, and 16.3 percent, respectively, of all *Salmonella* isolates (Ref. 6). The rate of SE isolates reported to CDC increased from 0.6 per 100,000 population in 1976 to 3.6 per 100,000 in 1996 (Ref. 7). In 2001, the isolation rate of SE was 2.0 per 100,000 population and the contribution of SE (corrected for underreporting) to total salmonellosis was estimated to have been 213,046 illnesses, including 2,478 hospitalizations, and 87 deaths (Refs. 4 and 5).

In 1985, the States reported 26 SE-related outbreaks (i.e., occurrences of 2 or more cases of a disease related to a common source) to CDC; by 1990 the number of SE-related outbreaks reported to CDC had increased to 85. In 1995 there were 56 confirmed outbreaks of SE infection, in 2000 there were 50 and in 2002 there were 32 (Ref. 8).

3. SE and Eggs

In the mid-1980s, CDC made an epidemiological and laboratory association between eggs and *Salmonella* outbreaks. Shell eggs are now the predominant source of SE-related cases of salmonellosis in the United States where a food vehicle is identified. A food vehicle is identified in approximately half of the outbreaks of illness associated with SE. Between 1990 and 2001, an average of 78 percent of vehicle-confirmed SE outbreaks were egg associated (Ref. 9). These eggs were typically raw or undercooked. Although CDC can estimate the number of egg-associated SE illnesses as a percentage of all SE illnesses, the proportion of domestically acquired salmonellosis that is attributable to SE in eggs is difficult to estimate. The estimates have a broad range of uncertainty around them because of the variable nature of both foodborne disease outbreaks and investigations. However, the basic surveillance information on the number of reported SE cases and outbreaks is readily available and does not require further estimation. Although there are other sources of SE, actions to improve egg safety are the single most effective way to reduce the overall number of SE infections and outbreaks.

CDC has described several SE outbreaks that occurred between 1996 and 1998 and were associated with raw or undercooked eggs (Ref. 7).

- In November 1997, 91 persons who consumed broccoli with Hollandaise sauce at a Las Vegas restaurant became ill. Investigation showed that the Hollandaise sauce was prepared with pooled shell eggs, cooked to a temperature inadequate to kill SE, and then held at room temperature for several hours prior to service.
- In August 1997, 12 persons developed culture-confirmed cases of SE after consuming cheesecake prepared in a private residence in Los Angeles, CA. The cheesecake contained raw egg whites and egg yolks that were heated in a double boiler until slightly thickened. The California Department of Health Services and Department of Food and Agriculture investigated the farm that supplied the eggs and isolated SE from manure samples and from pooled egg samples.
- In October 1997, 75 persons at 7 different events in the District of Columbia developed salmonellosis after consuming lasagna supplied by the same commercial manufacturer. Cultures of leftover lasagna yielded SE. Investigation revealed that all of the lasagnas consumed at the different events were prepared from the same egg-cheese mixture. A traceback investigation led to farms at which 5 of 13 poultry houses had environmental samples positive for SE.

From 1990 to 2001, 14,319 illnesses were attributed to SE associated with shell eggs. Of those illnesses, 10,406 occurred during 1990 through 1995 and 3,913 occurred during 1996 through 2001 (Ref. 9). In 2002, there were 32 outbreaks of SE illness, and the SE isolation rate (illnesses per 100,000 population) was 1.77 (Ref. 8). Progress has been made and there has been a decrease in SE incidence since the mid-1990s, in part due to egg quality assurance (QA) programs, informing and educating consumers and retailers on proper handling, and nationwide regulations to keep eggs refrigerated. However, these gains are still far short of the public health and foodborne illness gains required to meet Healthy People 2010 goals. Healthy People 2010 sets forth significant and achievable goals, namely a 50 percent reduction in both outbreaks and salmonellosis from foodborne contamination (corresponding to a 50 percent reduction from the 2000 goals for SE outbreak reduction and a 50 percent reduction in salmonellosis in general) (Ref. 10). We estimate that the largest gains towards our public health goals will be achieved through implementation of this rule. The incidence of SE in the United States remains much higher than in the 1970s (1976 SE isolation rate = 0.56) (Ref. 11), and the decrease in reported cases of SE illness since 1999 has appeared to slow or stop compared to decreases seen in the mid-1990s (Ref. 9). Because progress in reducing the number of illnesses and outbreaks appears to have greatly slowed or stopped, we believe the additional preventive measures, proposed herein, for shell eggs may be needed to reduce further the incidence of SE illnesses and meet our public health goals.

4. Mechanism of *Salmonella* Contamination in Eggs

Previously, *Salmonella* contamination of shell eggs was thought most likely to be caused by trans-shell penetration of bacteria present in the egg's environment. The surface of an egg can become contaminated with any microorganism that is excreted by the laying hens. In addition, contact with nesting materials, dust, feedstuff, shipping and storage containers, human beings and other animals may be a source of shell contamination. The

likelihood of trans-shell penetration increases with the length of time that the eggs are in contact with contaminating materials.

While environmental contamination is still a route for *Salmonella* contamination, SE experts now believe that the predominant route through which eggs become contaminated with SE is the ''transovarian'' route. Though the mechanism is still not well understood, SE will infect the ovaries and oviducts of some egg-laying hens, permitting transovarian contamination of the interior of the egg while the egg is still inside the hen (Refs. 12 and 13). The site of contamination is usually the albumen (the egg white).

It is believed that only a small number of hens in an infected flock shed SE at any given time and that an infected hen may lay many uncontaminated eggs (Ref. 14). Nonetheless, it has been estimated that of the 47 billion shell eggs consumed annually as table eggs (eggs consumed as shell eggs, as opposed to eggs that are used to make egg products), 2.3 million are SE-positive, exposing a large number of people to the risk of illness (Ref. 15).

5. Infectious Dose

In general, the greater the numbers of microorganisms ingested, the greater the likelihood of disease. The likelihood of disease also is contingent on the virulence of the microorganism and the susceptibility of the host (Ref. 16). However, there is evidence that the infectious dose (i.e., amount of microorganisms capable of causing disease) for SE can be very low. For example, in a 1994 outbreak attributed to consumption of SE-contaminated ice cream, the highest level of contamination found in the implicated ice cream was only six microorganisms per half-cup (65 gram) serving (Ref. 17). Another report, using a different method of measurement, determined that the infective dose per serving was 25 microorganisms (Ref. 18). These reports indicate that low-level contamination of some foods with SE can lead to illness. It is generally believed that SE-contaminated eggs initially contain only a few SE microorganisms (less than 20 (Ref. 19)), which may be sufficient to cause illness.

B. U.S. Egg Industry

On a per capita basis, Americans consume about 234 eggs per year (Ref. 20). U.S. production is relatively stable and has increased only slightly, from about 60 billion eggs in 1984 to 67.3 billion eggs in 1998 (Ref. 21). Generally, about 70 percent of the edible shell eggs produced are sold as table eggs while the remainder are processed into liquid, frozen or dried pasteurized egg products. The majority of egg products are destined for institutional use or further processing into foods such as cake mixes, pasta, ice cream, mayonnaise, and bakery goods.

Geographically, commercial egg production in the western United States is concentrated in California, and in the eastern United States is centered in Ohio, Indiana, Iowa, and Pennsylvania. Other States in which major producers are located include Texas, Minnesota, and Georgia. Over 4,000 farm sites have 3,000 or more egg-laying hens, representing 99 percent of all domestic egg-laying hens and accounting for 99 percent of total egg production. There are an additional 65,000 farms with fewer than 3,000 egg-laying hens, accounting for the balance of eggs produced (Ref. 22).

C. Federal Egg Safety Regulatory Agencies and Authorities

Federal authority to regulate egg safety is shared by FDA and the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA's FSIS). In addition, USDA's Animal and Plant Health Inspection Service (APHIS) conducts a control program that certifies poultry breeding stock and hatcheries as SE-monitored and USDA's Agricultural Marketing Service (AMS) conducts a surveillance program to ensure proper disposition of restricted shell eggs.

FDA has jurisdiction over the safety of foods generally, including shell eggs, under section 201 of the Federal Food, Drug, and Cosmetic Act (the FFDCA) (21 U.S.C. 321). The Public Health Service Act (the PHS Act) (42 U.S.C. 201 *et seq.*) authorizes the FDA to make and enforce such regulations as ''are necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the States * * * or from one State * * * into any other State'' (section 361(a) of the PHS Act (42 U.S.C. 264(a)). Thus, under the FFDCA and the PHS Act, FDA has the authority to regulate a food when the food may act as a vector of disease, as in the case of SE-contaminated eggs.

USDA has primary responsibility for implementing the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*). Under the EPIA, FSIS has primary responsibility for the inspection of processed egg products to prevent the distribution of adulterated or misbranded egg products.

This proposed rule is part of a joint and coordinated strategy by FDA and FSIS to more effectively address egg safety. Pursuant to this coordinated strategy, FDA is focusing its efforts on farm practices, and on food manufacturing plants, institutions, and restaurants. FSIS, in turn, is focusing its efforts on egg products plants and egg handlers. Both agencies are evaluating additional measures to improve egg safety, and FSIS intends to issue proposed rules in the near future for egg products plants and egg handlers, including egg handlers who operate in-shell pasteurization treatments. FDA and FSIS will continue to work closely together to ensure that our egg safety measures are consistent, coordinated, and complementary.

D. Current Federal Egg Safety Measures for Shell Egg Production and Retail

Currently, there are no Federal regulations to reduce the presence of SE in eggs during production. However, we recognize that some State or local agencies may have requirements in place addressing egg safety during production.

There are several Federal activities related to egg safety at the retail level. FSIS issued a final rule for refrigeration and labeling of eggs during transport and storage when packed for the ultimate consumer (63 FR 45663, August 27, 1998). In addition, FDA issued a final rule that requires labeling of eggs and refrigeration of eggs at retail establishments (65 FR 76092, December 5, 2000). Further, FDA's Food Code provides guidance to retail establishments on the handling and storage of potentially hazardous foods, such as shell eggs. Also, there have been egg safety education campaigns specifically tailored for the retail sector. The following sections describe these egg safety measures.

1. Refrigeration of Shell Eggs

The EPIA was amended in 1991 (Public Law 102–237) to require that shell eggs packed for the ultimate consumer be stored and transported under refrigeration at an ambient temperature (i.e., the air temperature maintained in an egg storage facility or transport vehicle) not to exceed 45 °F. The 1991 Amendments to the EPIA also require that labels on egg containers indicate that refrigeration of eggs is required. Subsequently, USDA's FSIS amended its regulations to require shell egg handlers to store and transport shell eggs packed in containers destined for the ultimate consumer under refrigeration at an ambient temperature of no greater than 45 °F (7.2 °C) (63 FR 45663). In the FSIS regulation, an egg handler is defined as any person, excluding the ultimate consumer, who engages in any business in commerce that involves buying or selling any eggs

(as a poultry producer or otherwise), or processing any egg products, or otherwise using any eggs in the preparation of human food. In 9 CFR 590.5, FSIS defines an ultimate consumer as any household consumer, restaurant, institution, or other party who has purchased or received shell eggs or egg products for consumption. This regulation became effective August 27, 1999.

FSIS' regulation does not require the ultimate consumer, including restaurants and institutions, to maintain shell eggs under refrigeration. Consequently, we concluded that it was necessary to require that shell eggs be kept refrigerated throughout retail distribution. On December 5, 2000, we published a final rule requiring that retail establishments, such as grocery stores, farm stands, restaurants, schools, and nursing homes, promptly refrigerate eggs upon receipt and store and display eggs at an ambient temperature of 45 °F (7.2 °C) or less (65 FR 76092).

2. Labeling of Shell Eggs

In an effort to inform consumers of the risks associated with consuming raw or undercooked eggs, we require that egg cartons carry safe handling instructions (21 CFR 101.17(h)). All eggs not specifically processed to destroy *Salmonella* must carry the following safe handling statement: ''SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly.''

3. The FDA Food Code

Through the Food Code, FDA endeavors to assist those local, State, tribal, and Federal governmental jurisdictions assuming primary responsibility for preventing foodborne illness and for licensing and inspecting establishments within the retail segment of the food industry. The Food Code, published by FDA, is not Federal law or regulation, and is not preemptive. Rather, it represents our best advice to States and local authorities to ensure that food at the retail level is safe, properly protected, and properly represented (i.e., is what it is purported to be). The Food Code provides guidance on food safety, sanitation, and fair dealing that can be uniformly adopted for the retail segment of the food industry. The document is the cumulative result of the efforts and recommendations of many contributing individuals with years of experience. These individuals represent a diverse group of regulators, educators, industry leaders, and consumer representatives acting through their agencies, companies, professional groups, or trade organizations.

Although the Food Code provisions are not Federal requirements, they are designed to be consistent with Federal food laws and regulations. The Food Code is written so that all levels of government can easily adopt the language of the Food Code into a legal requirement.

All segments of the food industry and Federal, State, and local governments share the responsibility to ensure food provided to the consumer is safe and does not become a vehicle for a disease outbreak or the transmission of communicable disease. By sharing in this responsibility, government and industry can ensure consumer expectations are met, and food is prepared in a sanitary environment, properly presented, and not adulterated.

The Food Code provides advice on how to prevent foodborne illness based on information obtained from CDC investigations. CDC has identified risk factors, such as unsafe sources, inadequate cooking, improper holding, contaminated equipment, and poor personal hygiene, which may lead to foodborne outbreaks. CDC further established five key public health interventions to protect consumer health: (1) Demonstration of knowledge, (2) employee health controls, (3) controlling hands as a vehicle of contamination, (4) time and temperature parameters for controlling pathogens, and (5) consumer advisories.

FDA revises sections of the Food Code every 2 years, and publishes the revision either as a supplement (most recently in 2003) to the existing edition or as a new edition (most recently in 2001), based on the extent of revision. Each new edition incorporates the provisions of supplements issued between editions. The next revision of the Food Code will be in 2005. Provisions relevant to egg safety can be found in the 2001 Food Code in sections 3–202.11, 3–202.13, 3–202.14, 3–302.13, 3–401.11, 3–603.11, and 3–801.11.

4. Egg Safety Education Efforts

Consumer food safety surveys conducted in 1993, 1998, and 2001 by FDA and FSIS suggested that consumers are less aware of or concerned about risks associated with eggs than they are of risks associated with other foods (Refs. 23 and 24). The data indicate that people are most likely to follow recommended practices when handling fish, somewhat less likely when handling meat or chicken, and much less likely to follow recommended practices when breaking eggs. In fact, the majority of people (65 percent) do not wash their hands with soap after breaking raw eggs (Refs. 23 and 24).

Comparing the 1998 survey findings with those of 1993, improvement in the safe handling of eggs by people 61 and older lagged considerably behind that of people 18 to 25 years old. The younger group showed a 42 percent improvement versus 9 percent for the older group. The 2001 survey showed no significant difference in consumers' egg-handling behavior from 1998 (Ref. 24).

In consideration of the survey findings, we developed a strategy for an education campaign on egg safety that targeted both the general public and at-risk populations. We began the campaign with the July 1, 1999, release of FDA's egg labeling and refrigeration proposed rule to take advantage of media and public interest in safe handling instructions for shell egg labels and refrigeration requirements for eggs at retail establishments. We prepared a video news release (VNR) to inform consumers of the proposed regulations and to alert them to the potential risks of, and steps to take to avoid, undercooked eggs. The VNR was released in conjunction with the July 1999 announcement of the proposed egg labeling and refrigeration rule.

To provide a basic source of print information for consumers on eggs and egg safety, we developed a fact sheet, ''Food Safety Facts for Consumers: Playing It Safe With Eggs,'' which was released in July 1999. The fact sheet covers safe buying, handling, preparation, and storage of eggs and egg dishes, as well as information on how to avoid the hidden risks in foods that contain raw or lightly cooked eggs. A corresponding fact sheet was developed for food service personnel, entitled ''Food Service Safety Facts: Assuring the Safety of Eggs and Egg Dishes Made From Raw, Shell Eggs,'' and was released in September 1999.

The consumer fact sheet was targeted to general consumers, especially parents of young children and older Americans. The food service fact sheet was targeted to institutional preparers of food for children, the elderly, and immunocompromised individuals. To reach the target audience, the fact sheets were distributed to the print and electronic media, 83,000 day care centers, 13,000 nursing home directors, school nurses, FDA field staff, extension agents, State and local health agencies, and food preparation trade associations. Both fact sheets are posted on FDA's Web site *www.foodsafety.gov*.

Egg safety information also is incorporated into other food safety

education initiatives. For example, the widely distributed English and Spanish Fight BAC! brochures produced by the public-private Partnership for Food Safety Education, of which FDA is a member, include safe egg cooking information. The Partnership's Virtual Toolbox, available on the *fightbac.org* Web site, features egg safety information prominently among a wide range of other education materials for use by health educators.

We initiated a second phase of the egg safety education campaign after publishing the final rules on safe handling labels and refrigeration at retail. Our strategy remained unchanged; we targeted the general public and at-risk populations. Our campaign message focused attention on the new labels on eggs, the potential for human sickness caused by bacteria from fresh eggs from any source, and the safety of eggs if selected, stored, and prepared properly.

In addition to the press information FDA distributed about the regulations, we prepared and distributed a range of consumer education materials, including a video news release; a public service announcement/flier sent to 600 publications specializing in health, food, elderly issues and parenting, as well as specialized health information providers, such as the National AIDS Clearinghouse and Hotline, the American Cancer Society and National Cancer Hotline, and the Arthritis Foundation; a consumer brochure; and a drop-in feature article in English and Spanish. All consumer education materials are available on our Web site.

We currently are distributing educational materials we developed for food service and food retail personnel incorporating existing FDA regulations and recommendations pertaining to egg safety. These materials consist of a brochure entitled ''Assuring the Safety of Eggs and Menu and Deli Items Made From Raw, Shell Eggs—Information for Retail Food Stores and Food Service Operations,'' and a poster, ''Key Temperatures for Egg Safety in Food Service Operations and Retail Food Stores.'' Initially, 250 copies each of the brochure and the poster were sent to State Egg Program Directors, State Food Service Program Directors, FDA Regional Food Specialists, and FDA Public Affairs Specialists in the field to use in generating demand for the information.

Since the initial mailing, orders have been steady. As of August 2004, approximately 202,000 posters and 246,000 brochures had been distributed. At least one State, Kentucky, ordered enough (22,000) to provide copies to each retail food store, food service establishment and food manufacturing firm in the State. In addition, the brochure, ''Assuring the Safety of Eggs and Menu and Deli Items Made from Raw Shell Eggs—Information for Retail Food Stores and Food Service Operations,'' was mailed to 70,300 restaurants in September 2002.

Consumer information on safe handling of eggs is also included in two widely distributed FDA consumer publications, To Your Health: Food Safety for Seniors and the Fight BAC! Flyer (originally developed as a patient handout for the AMA/ANA/FDA/CDC/USDA health professional education kit, Kiagnosis and Management of Foodborne Illnesses). Distribution of consumer and foodservice educational materials continues at professional meetings and conferences, most recently the 2003–2004 meetings of the American Dietetic Association, American Public Health Association, Food Safety Summit, National WIC Association, American College of Physicians, National Restaurant Association, American Nurses Association, National Association of Area Agencies on Aging, National Wellness Conference, and International Association for Food Protection.

E. The SE Risk Assessment

In December 1996, FSIS and FDA, with representatives from other government agencies and academia, began a comprehensive risk assessment in response to an increasing number of human illnesses associated with the consumption of eggs (Ref. 15). Following are the objectives of the risk assessment: (1) Establish the unmitigated (without any SE-prevention measures risk of foodborne illness from SE, (2) identify and evaluate potential prevention strategies, (3) identify data needs, and (4) prioritize future data collection efforts.

A team of scientists developed a quantitative model to characterize the risks associated with the consumption of eggs contaminated internally with SE, using information obtained from academic, government, and industry sources, along with scientific literature. The risk assessment model consists of five discrete modules (Egg Production Module, Shell Egg Module, Egg Products Module, Preparation and Consumption Module, and Public Health Module) that may be used independently to evaluate the effect of variable changes during a particular stage of the farm-to-table continuum. However, the overall model encompasses the entire continuum, from the chicken through egg production, to egg consumption and human illness. The model predicted that using any one intervention (e.g., egg refrigeration or consumer egg safety education) could achieve a modest reduction in human SE illnesses, while using multiple interventions could achieve a more substantial reduction for those interventions tested (Ref. 15). Though on-farm mitigations, as such, were not specified in the risk assessment, various inputs to the model were tested for cooling and refrigeration of eggs, including cooling eggs immediately after lay. The SE risk assessment concluded that a broad-based policy, encompassing interventions from farm to table, is likely to be more effective in eliminating egg-associated SE illnesses than a policy directed solely at one stage of the egg production-to-consumption continuum.

F. Advance Notice of Proposed Rulemaking on Salmonella Enteritidis in Eggs

In the **Federal Register** of May 19, 1998 (63 FR 27502), FDA and USDA jointly published an advance notice of proposed rulemaking (ANPRM) seeking to identify farm-to-table actions that would decrease the food safety risks associated with eggs. The agencies requested comment on these egg safety actions. In section III.M of this document, we respond to comments related to on-farm measures to prevent SE contamination of eggs. We respond to comments related to retail standards to reduce the risk of egg-associated SE illnesses in section IV.E of this document.

G. Egg Safety Public Meetings

To address the public health problem of SE, FDA and FSIS decided to coordinate efforts in a farm-to-table approach. Consistent with each agency's legislative authority, FDA would address egg safety issues at the producer and retail levels and FSIS would address these issues at egg packers and processors. On March 30, 2000, and April 6, 2000, FDA and FSIS held public meetings in Columbus, OH, and Sacramento, CA, respectively, to gather information for reducing or eliminating the risk of SE in eggs. Comments on specific egg safety questions were solicited in a **Federal Register** document (65 FR 15119, March 21, 2000). Interested persons were given until April 20, 2000, to comment.

In an effort to expand the public process and build upon the two public meetings, FDA and FSIS held a public meeting (65 FR 42707, July 11, 2000) on July 31, 2000, in Washington, DC. The purpose of this meeting was to obtain

comments on the agencies' current thinking on approaches to ensure egg safety from farm to table. A document outlining the agencies' current thinking on on-farm egg safety standards, packer/processor egg safety standards, and retail egg safety standards was made available at the public meeting and on the agencies' food safety Web site *www.foodsafety.gov*. Interested persons were given until August 14, 2000, to comment.

We are responding to comments from the public meetings in Columbus, OH, and Sacramento, CA, and the current thinking meeting in Washington, DC in this document. We have responded to comments related to on-farm measures to prevent SE contamination of eggs in section III.M of this document and to comments on retail standards to prevent egg-associated SE illnesses in section IV.E of this document.

H. Current On-Farm Practices

Most of the information on current on-farm practices comes from the APHIS National Animal Health Monitoring System (NAHMS) Layers '99 Study (the Layers study) and information on voluntary egg QA programs.

1. The Layers Study

In 1999, NAHMS conducted a study addressing national table egg layers and SE (Refs. 25, 26, and 27). The aim of the study was to include information from States that account for at least 70 percent of the animal and farm population in the United States. Fifteen States (Alabama, Arkansas, California, Florida, Georgia, Indiana, Iowa, Minnesota, Missouri, Nebraska, North Carolina, Ohio, Pennsylvania, Texas, and Washington) were chosen to participate in the study. These 15 States represented 82 percent of the 1997 U.S. table egg layers. The States, and the operations surveyed within those States, were chosen from a ranking of table egg layers summarized in a 1997 National Agricultural Statistics Service (NASS) survey of egg layers and egg production. NASS maintains information on laying operations that have more than 30,000 hens; therefore, each operation participating in the Layers study had more than 30,000 laying hens, although all hens may not have been on one farm.

a. Production facilities. Egg laying operations varied considerably in size and style of poultry house. Of the farm sites surveyed by the Layers study, approximately 34 percent had fewer than 50,000 layers, 29 percent had 50,000 to 99,999 layers, 20 percent had 100,000 to 199,999 layers, and 17 percent had 200,000 or more layers. One-third of farm sites surveyed had only one layer house, while 16.5 percent had 6 or more layer houses.

Within a poultry house, style also varied. Approximately one-third of all poultry houses had six or more banks of cages. A bank is all cages between two walkways or between a walkway and a wall. Approximately 40 percent of houses had 4 or more vertical levels of cages, while approximately 25 percent had only one level. Less than 1 percent of all poultry houses were cage-free.

Manure handling varied with house style and also varied regionally. Houses with a manure pit at ground level with the house above (high rise) accounted for 63 percent of houses in the Great Lakes region and 48 percent of houses in the Central region. In the Southeast, 40 percent of farm sites flushed manure to a lagoon. Nonflush scraper systems were used on 44 percent of farms in the West region.

b. Chicks and pullets. When a poultry house is repopulated with new laying hens, most of the new layers come from a pullet raising facility. A pullet is defined in the Layers study as a chicken less than 20 weeks of age. Less than 10 percent of layer farms raised pullets at the layer farm site, although some layer farms had their own pullet raising facilities at other locations.

The vast majority (95 percent) of pullets in pullet raising facilities came as chicks from National Poultry Improvement Plan (NPIP) monitored breeder flocks. USDA's NPIP is a cooperative Federal-State-industry mechanism intended to prevent and control egg-transmitted, hatchery-disseminated poultry diseases. NPIP has different monitoring programs for many avian diseases and pathogens, including SE, and all flocks in the program must meet the qualifications for ''U.S. Pullorum-Typhoid Clean'' classification (9 CFR 145.23(b)). Therefore, the fact that the chicks were from NPIP-monitored breeder flocks does not mean that they were from certified ''U.S. *S.* Enteritidis Monitored'' breeder flocks (9 CFR 145.23(d)).

Many pullet raising facilities in the Layers Study had their own programs for SE monitoring. In the West region, 83 percent of farms obtained layers from SE-monitored pullet facilities, and 70 percent of layers on all farms came from SE-monitored pullet facilities. Pullet facilities used one or more of the following methods to monitor SE: (1) Dead chick/chick paper testing, (2) environmental culture, (3) bird culture, and (4) serology. Some pullet facilities used competitive exclusion products[2] and/or vaccines to protect pullets against SE.

c. Production. In 1997, the average flock was placed for its first production cycle at 17.5 weeks of age. Flocks in their first production cycle reached peak production around 29 weeks of age. At peak production, the average maximum number of eggs produced was 90 eggs per 100 hens per day. Induced molting was used on many farms (83 percent of farm sites) to increase the laying cycles of the hens. In the West and Southeast regions, 95 percent or more of farms molted birds, while in the central region just over half (57 percent) of the farms molted birds. On average, molted flocks ended production at 111 weeks of age, while nonmolted flocks ended production at 74 weeks of age.

d. Feed and water. Approximately half (48 percent) of layer houses used a chain feed delivery system. Well water was used for watering birds by 66 percent of farms. The percentage of farms that tested feed for SE varied regionally. For example, finished feed was tested for SE by 26 percent of farms in the central region, and 68 percent of farms in the West. Approximately 75 percent of farms in both the West and Southeast regions tested feed ingredients for SE.

e. Biosecurity. Approximately two-thirds of farms instituted biosecurity measures that did not allow visitors without a business reason to enter poultry houses. Sixty-two percent of farms allowed business visitors provided they had not been on another poultry farm that day. Most farms (76 percent) required that visitors wear clean boots. At the majority of farms, employees were required not to be around other poultry and not to own their own birds.

f. Pest control. The Layers study estimated that rodents and flies had access to feed in feed troughs on nearly all farms. Fly control was practiced on 90 percent of all farms; baiting was the most common form of fly control (72 percent of farms). Essentially all farms used some type of rodent control. Chemicals and baits were used by 93 percent of farms for rodent control. Professional exterminators were used on less than 15 percent of farms that used rodent control. Producers rated almost 30 percent of farms as having a moderate or severe problem with mice and almost 9 percent as having a moderate or severe problem with rats.

[2] Competitive exclusion is a strategy in which benign bacteria are introduced into the gut to prevent a pathogen from colonizing the gut by blocking all of the sites on the walls of the intestines where the pathogen would attach.

g. Depopulation practices. Depopulation of a poultry house is the most opportune time for a producer to thoroughly clean and disinfect the house. Most farms did some sort of cleaning between flocks. Essentially all farms emptied feeders, 91 percent emptied feed hoppers, 81 percent flushed water lines, 79 percent dry cleaned cages, walls, and ceilings, and 71 percent cleaned fans and ventilation systems. Approximately one-third of farm sites never cleaned or disinfected egg belts/elevators between flocks. Down time between flocks varied regionally; most farms had a down time of more than 11 days, although some were down for less than 4 days.

h. Testing for SE. A 1994 NAHMS survey of farms revealed that almost 16 percent of farms tested for SE. The Layers study showed that, in 1997, 58 percent of farms tested for SE. The number of farms testing for SE varied by region. In the Southeast, almost 84 percent of farms had an SE testing program, while in the West only 26 percent had an SE testing program. The number and regional distribution of farms doing testing for SE is very similar to the number and distribution of farms participating in an egg quality assurance (QA) program.

i. NAHMS Study Testing for SE. In 1994, NAHMS undertook its own survey for SE in layer houses. It found that 7 percent of layer houses were positive for SE, based on environmental sampling. Only 4 percent of houses with fewer than 100,000 laying hens were positive for SE, while 16 percent of houses with greater than 100,000 laying hens were SE-positive. The study indicated that the number of rodents, cleaning and disinfection procedures, biosecurity, and the age of the flock were all related to the SE status of the layer house.

2. Voluntary Egg QA Programs

The Layers study found that 51 percent of all farm sites participated in an egg QA program sponsored by a State or commodity group (e.g., United Egg Producers (UEP)). Based on this information, we estimate that approximately 50 percent of the eggs in the United States are produced under an egg QA program.

In 1992, Congress provided special funding to USDA to begin the SE Pilot Project (SEPP). The SEPP was one of the first egg QA programs in the United States. The pilot project phase operated for 2 years and then, in 1994, the SEPP became the PA Egg QA Program (PEQAP). Currently, there are several voluntary egg QA programs operated and administered by states or other organizations (Refs. 28, 29, 30, 31, and 32). The states that have programs include PA, MD, NY, OH, SC, AL, OR, CA and the New England region. The UEP has a program called the UEP ''Five Star'' Total QA Program (Ref. 33) and the United States Animal Health Association has a protocol entitled ''National Standardized *Salmonella* Enteritidis Reduction Program for Eggs'' (Ref. 34). In addition, certain egg companies operate an egg QA program within their own facilities (Ref. 26).

Currently the egg QA programs that exist are voluntary for producers. All programs have similar requirements but vary in how they implement these requirements. All programs require use of chicks from NPIP ''U.S. *S.* Enteritidis Monitored'' breeders or equivalent, biosecurity, rodent control, and cleaning and disinfection of poultry houses. Most programs require some environmental testing; the amount varies among programs from once to four or five times during the life of a flock. If an environmental test is SE-positive, several programs require egg testing, with diversion if the egg testing is SE positive. Several programs also have State government oversight and recordkeeping requirements. All existing QA programs have some educational programs for participants. There is data indicating that QA programs have been effective in reducing SE contamination in poultry houses (see discussion in section III) and the provisions in this proposal are modeled on those successful programs.

I. Petitions to the Agency

FDA has received several citizen petitions relevant to this proposed rulemaking.

1. Center for Science in the Public Interest

We received a petition from the Center for Science in the Public Interest (CSPI) (filed May 14, 1997, Docket No. 97P–0197) requesting, among other things, that FDA require programs to reduce the risk of SE for all egg producers. In support of its request, CSPI stated that SE in eggs is a serious health problem, illnesses caused by SE in the United States have increased, and consumers are at risk of illness from SE in raw or undercooked eggs. CSPI requested that producers be required to implement on-farm SE prevention programs using Hazard Analysis and Critical Control Point (HACCP) principles and modeled after the PEQAP program. CSPI also requested the following program components: (1) Chicks from SE-monitored breeder flocks, (2) environmental sampling for SE of chicks, pullets, and twice during the life of layers, (3) cleaning and disinfection of poultry houses if environmental tests are SE positive, (4) egg testing if the environment is positive with diversion of SE-positive eggs to pasteurization plants, (5) biosecurity, (6) rodent control program, (7) program to control SE in feed, and (8) refrigerated storage of eggs at 41°F to ensure that SE cannot multiply. In addition, CSPI requested that producers be required to keep records that would be verified by FDA to indicate compliance with SE prevention programs.

2. Rose Acre Farms, Inc.

We received a petition from Rose Acre Farms, Inc. (filed November 4, 1996, Docket No. 96P–0418) requesting, among other things, that we issue a regulation requiring ''Best Practices'' of egg producers. The petitioner stated that ''best practices'' are a set of procedures used by egg producers to control the presence of SE to the lowest level practical. Rose Acre Farms, Inc. suggested that the ''best practices'' might include: (1) Environmental testing of a poultry house for SE, (2) egg testing if the environmental testing is SE-positive, (3) cleaning and disinfection of poultry houses, (4) a program to reduce SE in feed, (5) vaccines, (6) rodent control, (7) biosecurity, (8) egg washing, (9) recordkeeping requirements, and (10) use of appropriate third parties to audit compliance with program elements. The petitioner requested that ''best practices'' programs be accredited individually by FDA and USDA. The petitioner also requested that eggs produced under an accredited program could never be deemed adulterated, regardless of the outcome of environmental testing or implication of a flock in a traceback.

In addition, Rose Acre Farms, Inc. requested that the agency place greater emphasis on consumer education and retail foodservice. The petitioner suggested that FDA revise the FDA Food Code to prohibit pooling of more than three shell eggs by any restaurant or foodservice institution. For egg dishes requiring pooling of more than three eggs, pasteurized product would have to be used.

3. United Poultry Concerns, Inc. and the Association of Veterinarians for Animal Rights

We received a petition from United Poultry Concerns, Inc., and the Association of Veterinarians for Animal Rights (filed April 14, 1998, Docket No. 98P–0203/CP1) requesting that FDA eliminate forced molting of laying birds in the United States. The petitioners requested that forced molting be

stopped because it is cruel. The petitioners also stated that the stress of forced molting promotes a systemic disease in birds in the form of SE that renders products derived from these birds a health risk to consumers.

In support of the request to stop forced molting because it promotes SE-infection in layers and renders products from these birds a health risk to consumers, the petitioners stated that forced molting impairs the immune response of laying hens, which invites colonization of the intestine and other organs by SE. The petitioners also cited studies that they believe demonstrate SE is shed in large numbers in the feces of infected, molted birds and spreads more rapidly among molted laying hens than among nonmolted ones. The petitioners stated that molted birds are more susceptible to SE infection from rodents, which have been shown to harbor SE in the poultry house environment. The petitioners also cited information that indicates feathers can carry SE and that molted birds engage in abnormal feather pecking because of the molting conditions.

United Poultry Concerns, Inc. and the Association of Veterinarians for Animal Rights also requested that forced molting be eliminated because the living conditions under which forced molting is conducted are inherently disease producing. The petitioners cited studies that indicate that concentrated confinement of birds in cages allows 48 square inches of living space per bird. The petitioners stated that the confined living space puts an additional stress on birds that lowers immune response and exacerbates an SE infection if present.

III. The Proposal to Require SE Prevention Measures for Egg Production

A. Rationale for Proposal

The incidence and geographical distribution of egg-associated SE illnesses have made SE a significant public health concern. Although there are Federal rules requiring refrigeration of shell eggs packed for the ultimate consumer (FSIS) and at retail (FDA) to limit the growth of SE that may be present, there are no Federal requirements to address the introduction of SE into the egg during production. The *Salmonella* Enteritidis Risk Assessment Team (Ref. 15) estimated that 1 in 20,000 eggs are contaminated with SE. Based on annual egg production (Ref. 20), this means that 3.3 million SE-contaminated shell eggs may be produced annually. Thirty percent of total egg production is used in egg products (Ref. 20), leaving an estimated 2.3 million SE-contaminated shell eggs that may reach the consumer. Therefore, interventions that can reduce the number of SE-contaminated eggs produced are warranted from a public health standpoint.

As discussed in section II.I of this document, several States and organizations have established voluntary egg QA programs that show great promise in reducing the incidence of egg-associated SE illnesses in specific regions of the country. Data from the PEQAP program show that after three years on the program the number of poultry houses that had environmental samples positive for SE decreased from 38 percent in 1992 to 13 percent in 1995 (Refs. 35 and 36). PEQAP data initially indicated that approximately 50 percent of the flocks in the program had environmental samples positive for SE at some time during flock life, whereas in 1996 approximately 15 percent of PEQAP flocks had environmental samples positive for SE at some time during flock life (Ref. 36). From 1992 to 1995, there was a decrease in the SE isolation rate in humans in the three-State region (NY, NJ, PA) that constitutes the market for PA's eggs. This decrease in isolation rate has been attributed to the PEQAP program and consumer education (Refs. 35 and 36).

Currently in the United States, only 50 percent (Ref. 26) of shell eggs are produced under voluntary egg QA programs and the regions that have voluntary egg QA programs are not necessarily the regions that have had recent outbreaks of SE illnesses (Ref. 9). Therefore, we have tentatively concluded that a proposal to require that producers of shell eggs for the table market, other than those producers whose eggs are treated or sold directly to consumers or who have fewer than 3000 laying hens, comply with all of the proposed SE prevention measures would exclude SE on the farm and, thus, remove sources of SE contamination of shell eggs.

B. Shell Egg Producers Covered by Proposed 21 CFR Part 118

The proposed requirements for SE prevention measures do not apply to producers who sell all of their eggs directly to consumers (e.g., roadside stand operators) or producers with fewer than 3,000 laying hens. Although we could have proposed to require these producers to implement SE prevention measures, we opted not to do so because the sales by these producers do not contribute significantly to the table egg market. In addition, we have no information indicating that an outbreak of SE illness has ever been caused by eggs sold directly from farmer to consumer or from a producer with fewer than 3,000 laying hens. We are soliciting comment on the exemption for producers with fewer than 3,000 laying hens and producers who sell all of their eggs directly to consumers. Specifically, should these producers be covered by some or all of the SE prevention measures?

We are proposing in § 118.1(a) (21 CFR 118.1(a)) that if you are a producer with 3,000 or more laying hens at a particular farm whose eggs are going to the table egg market (eggs consumed as shell eggs, rather than eggs used in egg products), and not all of your eggs receive a treatment as defined in § 118.3, then you must comply with all of the requirements in proposed part 118 for eggs produced on that farm. You may be selling your eggs to restaurants or other foodservice establishments where the presence of SE-contaminated eggs could cause a severe public health threat by striking many people at one time. In establishments where eggs are combined to make food items, one SE-contaminated egg can contaminate a dish that will be served to many people. Thus, it is necessary for you to use SE prevention measures on your farm to prevent SE contamination of your eggs and illness in consumers.

It is our understanding that it would be difficult for a producer to keep eggs produced from individual poultry houses on a farm separate from other eggs that may be handled differently. For example, a producer could not easily segregate eggs destined for a breaking plant from three poultry houses, which would not have to comply with the SE prevention measures, from eggs not destined for a breaking plant from two other poultry houses, which would have to follow all of the SE prevention measures. Furthermore, it would be difficult for the producer to maintain proper biosecurity for the two poultry houses subject to all of the SE prevention measures if there were three other poultry houses on the farm not employing the same biosecurity measures. Therefore, we have tentatively concluded that, unless all of the eggs from a particular farm receive a treatment as defined in § 118.3 or are sold directly to consumers, producers who have 3000 or more laying hens on that farm must comply with all of the requirements of proposed part 118 if the eggs are produced for the table egg market.

We are proposing in § 118.1(b) that if you are a producer who produces eggs on a farm that will all receive a treatment as defined in § 118.3 and you

have 3,000 or more laying hens, you must comply only with the refrigeration requirements for on-farm storage found in proposed § 118.4(e). As defined in proposed § 118.3, ''treatment'' means a technology or process that achieves at least a 5-log destruction of SE for shell eggs, or the processing of egg products in accordance with the Egg Products Inspection Act. It is important that the load of SE within a contaminated egg be kept low prior to treatment so that the level of kill given to that egg by the treatment will be sufficient. For example, if the in-shell pasteurization process for eggs is designed to reduce the level of SE in an egg by ''x'' logs, then the incoming SE load of that egg must be less than ''x'' logs for the treatment to be successful.

Refrigeration at 45 °F within 36 hours of laying has been shown to slow the multiplication of SE within an egg substantially and is discussed in section III.E.5 of this document. We have tentatively concluded that, prior to treatment for SE destruction, producers who have 3,000 or more laying hens must keep eggs under refrigeration at 45 °F maximum if they are held at the farm for more than 36 hours. Although we are not proposing to require that producers who treat all of their eggs to achieve the required destruction of SE comply with all of the SE prevention measures, we strongly encourage all egg producers to follow non-mandatory SE prevention measures during egg production.

C. Proposed Compliance Dates for Shell Egg Producers of Various Sizes

We are proposing that, if a producer has 50,000 or more laying hens, according to the requirements of proposed part 118, compliance would be required 1 year after the date of publication of the final rule in the **Federal Register**. Although producers who currently participate in voluntary QA programs may already have some of the provisions in place, we recognize that producers will need time to implement SE prevention measures, train individuals to implement the measures, and begin to incorporate them in their farm practices. We believe that 1 year from the date that any final rule is published is a realistic timeframe for producers that have 50,000 or more laying hens on farm to put measures in place.

We recognize that smaller producers (those with fewer than 50,000 but at least 3,000 laying hens) may need more time to comply with the requirements of proposed part 118. We tentatively have concluded that it is reasonable to allow for extended compliance periods for smaller producers. For smaller producers, compliance would be required 2 years after the date of publication of the final rule in the **Federal Register**.

D. Definitions

We are proposing in the introductory paragraph of § 118.3 that the definitions and interpretations of terms in section 201 of the FFDCA, unless these terms are redefined in this part, are applicable to these terms when used in proposed part 118.

We are proposing in § 118.3 that the term ''biosecurity'' means a program to ensure that there is no introduction or transfer of SE onto a farm or among poultry houses. As specified in proposed § 118.4(b), a biosecurity program includes, but is not limited to, limiting visitors to a farm, keeping animals and wild birds out of poultry houses, requiring personnel to wear protective clothing, and ensuring that equipment is not moved among poultry houses or, if it is so moved, that it is adequately cleaned before it is moved.

We are proposing in § 118.3 that the term ''farm'' means all poultry houses and the grounds immediately surrounding the poultry houses covered under a single biosecurity program. We intend the term ''farm'' to encompass an entire farming operation at a single geographic location. We do not intend to allow, by this definition, multiple ''farms'' covered by multiple biosecurity programs at a particular geographic site. If we did allow multiple farms at a geographic location, a producer could have part of the operation under SE prevention measures for eggs going to the table egg market and part of the operation under no such measures for eggs going to treatment. Such an outcome is contrary to our rationale set forth for proposed § 118.1(a).

We are proposing in § 118.3 that the term ''flock'' means all laying hens within one poultry house. We recognize that laying hens of different ages sometimes are placed in the same poultry house. Research has indicated that once SE is introduced into a poultry house it spreads among the laying hens in that house (Refs. 37 and 38).

We are proposing in § 118.3 that the term ''group'' means all laying hens of the same age within one poultry house. This term particularly applies to laying hens of the same age that comprise part of a multi-aged flock of laying hens within one poultry house.

We are proposing in § 118.3 that the term ''induced molting'' means molting that is artificially initiated. Induced molting is done to improve egg production and egg quality.

We are proposing in § 118.3 that the term ''laying cycle'' means: (1) The period of time that a hen begins to produce eggs until it undergoes induced molting or is permanently taken out of production; and (2) the period of time that a hen produces eggs between successive induced molting periods or between induced molting and the time that the hen is permanently taken out of production.

We are proposing in § 118.3 that the term ''molting'' means a life stage during which a hen stops laying eggs and sheds its feathers.

We are proposing in § 118.3 that the term ''pest'' means any objectionable animals or insects, including, but not limited to, birds, rodents, flies, and larvae. This is also the definition of ''pest'' found in 21 CFR part 110.

We are proposing in § 118.3 that the term ''positive flock'' means a flock that produced eggs that tested positive for SE and applies until that flock meets the egg testing requirements in proposed § 118.6 to return to table egg production.

We are proposing in § 118.3 that the term ''positive poultry house'' means a poultry house from which there has been an environmental test that was positive for SE during a laying cycle. A poultry house would be considered positive until it had been cleaned and disinfected, even if an environmental test is positive for SE prior to a molt and then is SE-negative at the post-molt environmental test. A negative environmental test after a molt does not invalidate the initial positive environmental test or necessarily indicate that SE is no longer present. Data from the PEQAP program have indicated that cleaning and disinfection procedures can decontaminate an SE-positive poultry house (Ref.39). Therefore, we have tentatively concluded that a poultry house that has had an SE-positive environmental test must be considered positive until it has been cleaned and disinfected according to proposed § 118.4(d).

We are proposing in § 118.3 that the term ''poultry house'' means a building, other structure, or separate section within one structure used to house poultry. We have also tentatively concluded that, for structures comprising more than one section containing poultry, each section must have biosecurity procedures in place to ensure that there is no introduction or transfer of SE from one section to another. In addition, each section must be enclosed and separated from the other sections. We interpret ''enclosed and separated'' to mean that sections must be separated from one another by walls. Thus, under this proposed

definition, producers would have to limit their designation of ''sections'' representing separate poultry houses to areas that are physically separate from one another. It would not be acceptable under this proposed rule to designate areas that are separated, for example, only by a walkway or a gate as separate poultry houses.

We are proposing in § 118.3 that the term ''producer'' means a person who maintains laying hens for the purpose of producing shell eggs for human consumption.

We are proposing in § 118.3 that the term ''shell egg (or egg)'' means the egg of the domesticated chicken. This differs from the definition of ''shell egg'' in the EPIA, because, unlike the EPIA definition, FDA's definition does not cover shell eggs of the domesticated turkey, duck, goose, or guinea. FDA is focusing its resources on domesticated chicken eggs because they have been associated with numerous outbreaks of foodborne illness.

We are proposing in § 118.3 that the term ''treatment'' means technologies or processes that achieve at least a 5-log destruction of SE for shell eggs or the processing of egg products in accordance with the EPIA. In 1997, we recommended to AMS, in response to an AMS request to FDA on criteria for shell egg pasteurization, that processors attain a 5-log reduction in *Salmonella* in shell eggs in order for the eggs to be considered ''pasteurized.'' We recommended the 5-log lethality based on literature available at the time on naturally infected shell eggs that indicated, under most storage conditions, an intact shell egg could contain between 10^2 and 10^3 *Salmonella* organisms (Ref. 19). FDA then added a 2-log safety factor to arrive at the recommendation for a 5-log lethality. AMS published this standard in its **Federal Register** notice on official identification of pasteurized shell eggs (62 FR 49955, September 24, 1997).

We are soliciting comment on whether a 5-log reduction or an alternative approach to achieve an equivalent level of protection is still appropriate to ensure the safety of shell eggs. We intend to work with USDA to ensure that shell eggs and egg products are given adequate treatments to destroy SE.

E. The SE Prevention Measures

Data indicate that voluntary egg QA programs have contributed to a decrease in SE in poultry houses and a decrease in SE illnesses. The particular program (PEQAP) from which the data were gathered includes provisions for chick and pullet procurement, biosecurity, rodent control, refrigeration, cleaning and disinfection of poultry houses, and monitoring of the poultry house environment through testing for SE (Ref. 28). Although the individual provisions were not evaluated for their relative importance, the PEQAP results indicate that, when used together, the provisions resulted in a decrease in the prevalence of SE within a poultry house (Ref. 35). Thus, the agency tentatively concludes that SE prevention measures are necessary to reduce the incidence of SE illness from consumption of shell eggs, when the eggs are not treated to destroy SE.

All of the provisions of proposed § 118.4 apply to you if you are a producer with at least 3,000 laying hens, you produce shell eggs for the table market, and you do not sell all of your eggs directly to consumers or treat all of your eggs to destroy SE as defined in proposed § 118.3 (§ 118.1(a)). We are proposing in § 118.4 that shell egg producers described in § 118.1(a) develop and implement the following SE prevention measures: Provisions for procurement of chicks and pullets, a biosecurity program, rodent, fly and other pest control, cleaning and disinfection of poultry houses that have had an environmental or egg test positive for SE, and refrigerated storage of eggs at the farm.

We also are proposing in § 118.4 that the particular form that SE prevention measures take be specific to each farm and poultry house where eggs are produced. Depending upon whether there are multiple poultry houses on a farm and whether the poultry houses vary in house style and location, the SE prevention measures may vary among poultry houses. For example, one poultry house may require certain rodent and pest control measures that another poultry house may not require.

Further, we are proposing that if you are a producer under section § 118.1(a), you must comply with the environmental and egg testing requirements in §§ 118.5 and 118.6, the sampling and testing methodology requirements in §§ 118.7 and 118.8, the administration requirements in § 118.9, and the recordkeeping requirements in § 118.10. We will discuss our rationale for compliance with these requirements in the relevant sections of this proposed rule.

1. Chicks and Pullets

We are proposing in § 118.4(a) that you must procure chicks and pullets that came as chicks from breeder flocks that meet NPIP's standards for ''U.S. *S.* Enteritidis Monitored'' status or equivalent standards. The fact that SE can be transmitted via the transovarian route means that chicks can be born SE-positive (Refs. 35 and 40). Therefore, they may remain infected as pullets and be placed into poultry houses as layers already carrying SE and then contaminate their eggs and, in addition, pass SE on to other layers within the poultry house (Refs. 38, 41, and 42). We tentatively have concluded that it is necessary for you to procure chicks and pullets that came as chicks from breeding flocks that meet NPIP's standards for ''U.S. *S.* Enteritidis Monitored'' status (9 CFR 145.23(d)) or equivalent standards in order to prevent SE contamination of shell eggs from SE-positive chicks. Producers that procure pullets from a pullet-raising facility need to have an assurance that those pullets came as chicks from a breeder flock that meets NPIP's standards for ''U.S. *S.* Enteritidis Monitored'' status or equivalent standards.

USDA's NPIP is a cooperative Federal-State-industry mechanism for controlling certain pathogens and poultry diseases. NPIP has established ''U.S. *S.* Enteritidis Monitored'' standards (9 CFR 145.23(d)) from which the breeding-hatching industry may conduct a program for the prevention and control of SE. Participation in the plan is voluntary, except under 9 CFR part 82, subpart C, no hatching eggs or newly-hatched chicks from egg-type chicken breeding flocks may be moved interstate unless they are classified ''U.S. *S.* Enteritidis Monitored'' under NPIP or meet equivalent standards.

To be classified ''U.S. *S.* Enteritidis Monitored,'' under 9 CFR 145.23(d), a flock and the hatching eggs and chicks produced must come from a ''U.S. S. Enteritidis Monitored'' flock, or meconium (first bowel movement) from chick boxes and a sample of chicks that died within 7 days after hatching must be examined and test negative for *Salmonella*. Throughout the life of a ''U.S. *S.* Enteritidis Monitored'' flock, environmental and blood samples are taken at specified times and examined for group D *Salmonella* (the group that includes SE). Breeder flocks may be vaccinated with an SE bacterin, provided that 350 birds remain unvaccinated until the flock is at least 4 months of age. Hatching eggs produced by the flock are collected as quickly as possible, sanitized or fumigated, and incubated in an approved hatchery. The flock must also meet feed, facilities, and transport requirements.

A flock is not eligible for the ''U.S. *S.* Enteritidis Monitored'' classification if SE is isolated from a specimen taken from a bird in the flock. Isolation of SE

from an environmental sample of a vaccinated or nonvaccinated flock necessitates bird testing. If bird testing reveals no SE contamination, then the flock qualifies for the classification. The classification may be revoked at any time if procedures are not followed.

We are aware that most producers purchase pullets from a pullet-raising facility to repopulate a poultry house. Some of these pullet-raising facilities have SE-monitoring programs (Ref. 25). We specifically request comment on whether we should include in any final rule based on this proposal, a requirement that producers certify that pullets they procure have come from a facility that has an SE-monitoring program. If so, what requirements should producers certify that a pullet-raising facility has met in order to ensure that the pullet raising facility has an adequate SE-monitoring program?

2. Biosecurity

We are proposing in § 118.4(b) that you develop and implement a biosecurity program. Biosecurity refers to procedures that must be instituted on farms to prevent SE from being transferred from the environment into the poultry house or among poultry houses. Biosecurity is a routine part of all existing egg QA programs and is aimed at preventing the horizontal spread of SE. According to the Layers study (Ref. 26), 66 percent of farm sites already practice some form of biosecurity, and poultry houses where visitors were not allowed were less likely to test positive for SE. The Swiss have identified control of the horizontal spread (i.e., cross contamination from layer to layer or poultry house to poultry house) of SE as a major success of their SE control program (Ref. 42). We have tentatively concluded that producers need to develop and implement a biosecurity program covering the grounds and all facilities, including poultry houses, for each egg farm in order to prevent the horizontal spread of SE.

As part of your biosecurity program, you must take measures to prevent cross-contamination among poultry houses and contamination of poultry houses from the environment. This includes, where practical, purchasing separate equipment for each poultry house within a farm because shared equipment can cause SE cross-contamination between poultry houses. For certain large pieces of equipment (e.g., manure removing equipment), we recognize that it is not practical to purchase separate pieces of equipment for each house. We also recognize that certain pieces of equipment are common to all houses (e.g., egg belts). In the Layers study, approximately one-half of the positive environments were identified by egg belt or elevator sampling (Ref. 27). You must keep egg belts, manure-removing equipment, and other similar pieces of equipment clean and ensure that these pieces of equipment are not sources of SE contamination that can be spread from one house to another.

A comprehensive biosecurity program must also include provisions to limit visitors to the farm and poultry houses and to ensure proper hygiene of personnel who do move among poultry houses. Proper hygiene includes the use of protective clothing that is changed as employees move between poultry houses and foot sanitizing stations or other appropriate means to protect against contamination. In addition, you must prevent stray poultry, wild birds, or other animals from entering into poultry houses or on the grounds. You must not allow employees to keep poultry at home. You must implement the biosecurity measures stated above to prevent spreading SE from one poultry house to another on contaminated clothing or spreading SE from the environment into a poultry house by allowing stray animals entrance into a poultry house or allowing employees to keep their own poultry, which may be carrying SE, at home.

3. Rodents, Flies, and Other Pest Control

We are proposing in § 118.4(c) that you must develop and implement a pest and rodent control program to control rodents, flies and other pests. Many of the comments that we received after the egg safety public meetings in Columbus, OH (March 30, 2000), and Sacramento, CA (April 6, 2000), stated that the most important SE prevention measure that can be taken within a poultry house is rodent and pest control.

Several investigators have found strong indications that mice are carriers of invasive SE in the poultry house (Refs. 43 and 44). Kreager (Ref. 45) has stated that the SE status of rodents in a poultry house is thought to be indicative of the status of the flock. In fact, data indicate that the environments of SE-contaminated flocks are usually infected with the same phage type of SE found in mice and eggs also in that environment (Ref. 39). According to Davison et al. (Ref. 46), a single mouse can produce 100 droppings per day, and each dropping can contain up to 230,000 SE organisms. Wray and Davies (Ref. 47) have stated that mice may shed *Salmonella* intermittently for up to 18 weeks and may infect chickens consuming the fecal matter. Mice may become infected with SE from contaminated manure and then may spread it to other poultry houses that were previously SE free (Refs. 46 and 47). A few mice in one house can proliferate to 10,000 or more during the life of a flock.

Henzler and Opitz (Ref. 48) found that a poultry house with a large rodent population was approximately four times more likely to have an SE-positive environment as a poultry house with a small rodent population. In the Layers study (Ref. 26), producers reported that they had a moderate to severe problem with mice on 30 percent of farms and a moderate to severe problem with rats on 9 percent of farms. Rats have also been shown to harbor SE and are important vectors because they can travel long distances (Ref. 47). Environmental testing for the Layers study (Ref. 27) indicated that poultry houses in which 20 or more mice were captured (equals a rodent index of 2 or 3, see discussion of rodent indexing later in this section) were 9 times more likely to contain SE than poultry houses with a lower rodent index.

In addition to rodents, flies have been shown to harbor SE within the poultry house environment. Several *Salmonella* species were found in houseflies and bronze dump flies collected at caged-layer facilities that produced eggs that were implicated as the food vehicle in two recent outbreaks of SE infections. SE was isolated from 2 of 15 pools of houseflies from these facilities (Ref. 49). Both flies and rodents are attracted to feed within the poultry house and, according to the Layers study, flies and rodents have access to feed troughs on nearly all farms.

These studies indicate that rodents and pests can harbor SE that can be transmitted to layers and possibly to their eggs, potentially resulting in SE illnesses from consumption of shell eggs. We tentatively have concluded that producers must develop and implement a program to control rodents, flies and other pests.

We are proposing to require, under § 118.4(c)(1), that you must monitor rodent populations through visual inspection and use of mechanical traps or glueboards or another appropriate method. The use of traps and glueboards is appropriate if placed at regular intervals throughout each poultry house, or wherever rodents are most likely to be caught (Ref. 46). Davison et al. (Ref. 46) recommend that 12 traps be set per poultry house, left for a week, and checked twice during that week. If no mouse is caught at the first check, the trap should be moved, but no more than 15 feet. One week of trapping gives

a good indication of the level of rodent infestation in a poultry house; this is called rodent indexing (Ref. 46). If 0 to 10 mice (less than 2 mice/day) are caught, the rodent index is low or equal to 1; if 11 to 25 mice are caught, the rodent index is moderate or equal to 2; if 26 or more mice are caught, the rodent index is high or equal to 3. A low rodent index indicates acceptable rodent control.

We are proposing to require that when monitoring indicates unacceptable rodent activity (a rodent index of 2 or higher as described in Davison et al. (Ref. 46)) within a poultry house, you must take appropriate action to reduce the rodent population. We are proposing that baiting and trapping are possible methods to reduce a rodent population, but may not be effective in all situations. Producers, aware of rodent situations in their individual poultry houses, should choose a method that will be effective in their houses. If rodenticides are used, you should take care to prevent chickens or other nonrodents from consuming the bait.

We also are proposing to require under § 118.4(c)(2) that you monitor for flies and other pests through spot cards, Scudder grills, sticky traps or some other appropriate method that indicates pest activity. Spot cards are index cards used to enumerate the number of flies that land within the card area by counting fly specks (Ref. 50). Sticky traps are used to count the number of flies stuck to the trap (Ref. 51). A Scudder grill or a fly grill is a wooden grill that is placed over natural fly concentrations. The number of flies that land on the grill in 30 seconds is counted (Ref. 52). Spot cards and sticky traps should be checked weekly, while Scudder grills give an instant measure of fly activity within a poultry house.

Axtell (Ref. 50) has suggested that 50 or fewer hits on a spot card or sticky trap per week indicates satisfactory fly control. A count of less than 20 on a Scudder grill likewise indicates satisfactory fly control (Ref. 52). If monitoring indicates pest infestation (i.e., levels that do not indicate satisfactory pest control, as described above) within a poultry house, producers must use appropriate methods to reduce the pest population within a poultry house.

You would be required, under proposed § 118.4(c)(3), to remove debris within a poultry house and vegetation and debris outside of a poultry house that may harbor rodents and pests. Maintenance of a section of crushed rock around the perimeter of a poultry house helps prevent rodents from burrowing near poultry house foundations. Where possible, poultry houses should be sealed against entrance by rodents and pests.

4. Cleaning and Disinfection

We are proposing in § 118.4(d) that you must develop procedures for cleaning and disinfection of a poultry house that include removal of visible manure, dry cleaning, followed by wet cleaning using disinfectants, and finally, disinfecting. Further, we are proposing to require that you clean and disinfect a positive poultry house prior to the addition of new laying hens to the house. It is important, once a poultry house has had an SE-positive environmental or egg test, that you make every effort to rid the environment of SE before new laying hens are placed into that house to prevent the SE problem from being perpetuated in the replacement flock. Schlosser et al. (Ref. 39) reported that 50 percent of the SE-positive houses that were cleaned and disinfected according to PEQAP specifications were SE-negative when subsequently sampled. PEQAP cleaning and disinfection procedures consist of dry cleaning, wet cleaning (soaking, washing, rinsing), disinfection, and possibly fumigation with formaldehyde (Ref. 39). In addition, the Layers study found that no poultry house tested positive for SE after wet cleaning (i.e., where cages, walls, and ceilings were washed) (Ref. 27). We tentatively have concluded that, if an environmental test or an egg test is positive for SE during the life of a group in a poultry house, producers must clean and disinfect that poultry house before new laying hens are added to the house.

You must develop procedures for cleaning and disinfection in case they should ever need to be implemented. The cleaning and disinfection must include removal of all visible manure from the poultry house. Manure is a reservoir of SE that has been shed by infected laying hens. You must begin the cleaning procedure with dry cleaning of the house to remove dust, feathers, and old feed. Then, you must wet clean the poultry house, including washing with detergents. Detergents must be used according to label instructions, followed by recommended rinsing procedures. Following cleaning, you must disinfect the poultry house with spray, aerosol, fumigation or another appropriate disinfection method.

We are aware of studies that indicate that wet cleaning may have a detrimental effect on the SE status of a poultry house. In the report by Schlosser et al. (Ref. 39) mentioned in the first paragraph of this section, it is noted that, while 50 percent of the houses went from SE-positive to SE-negative after wet cleaning, 28 percent of the houses went from SE-negative to SE-positive. It is not known whether this was a testing error or a result of the wet cleaning. In addition, a Danish study found a relationship between wet cleaning procedures and SE-positive pig herds (Ref. 53). The authors were unsure whether the cleaning procedures were actually contributing to the presence of SE in the pigs or if the study was biased. Because there is some evidence, though inconclusive, suggesting that wet cleaning may result in an SE-positive poultry house environment, we specifically request comment and data on this subject. Although we are requiring cleaning and disinfection only for houses that have had an environmental or egg test that was positive for SE, we recommend that you remove manure and dry clean poultry houses as a general management practice every time you depopulate a house, even when no SE was detected in the house or eggs.

5. Refrigeration of Shell Eggs Stored More Than 36 Hours

We are proposing in § 118.4(e) that you must store eggs at or below 45°F (7.2°C) ambient temperature if you hold them at the farm for more than 36 hours after laying. This proposed requirement is the only SE prevention measure that applies to all producers with 3,000 or more laying hens regardless of whether your eggs will receive a treatment.

As we described in the shell egg refrigeration and labeling proposed rule (64 FR 36492 at 36495, July 6, 1999), although fresh shell eggs provide an inhospitable environment for *Salmonella* and other microorganisms to multiply, the chemical and physical barriers against bacterial movement and growth in shell eggs degrade as a result of the time and temperature of holding. Consequently, as a result of degradation, SE, if present, has access to the nutrient rich yolk, which provides a favorable environment for growth of SE.

Studies have shown that SE, when inoculated into the albumen of whole shell eggs, multiplied to high numbers if the eggs were not properly refrigerated (Refs. 54, 55, and 56). One study investigated the effect of holding inoculated whole eggs at five different temperatures in the range of 4 °C (39 °F) to 27 °C (81 °F). The investigators found that the SE growth response was proportional to the temperature at which the inoculated eggs were held. The study demonstrated that SE inoculated in shell eggs can multiply to substantial levels if held at 10 °C (50 °F)

or higher for up to 30 days. The authors concluded that ''because the number of SE present at the time an infected egg is laid is probably very low, egg storage at 4 °C (39 °F) could be expected to result in a smaller risk to the public health than higher storage temperatures'' (Ref. 54). In studies by Humphrey (Ref. 55) and Bradshaw et al. (Ref. 56), no growth was observed in SE inoculated into whole shell eggs at 8 °C (46 °F) and 7 °C (45 °F), respectively. We find that the scientific evidence on the growth of SE in eggs shows that control of storage temperature of shell eggs can effectively prevent the multiplication of any SE present. We seek comment and data on the impact of refrigeration on eggs after they leave the farm, such as the possibility that the eggs may ''sweat'' when removed from refrigeration.

Although we believe that it is very important that eggs be placed into refrigerated storage as soon as possible after they are laid, we realize that this may not be practical for all producers. It may be several hours or longer after the eggs are laid before they are collected or picked up for transport. It may not be practical for producers to place eggs under refrigeration within several hours after they are laid. It would be reasonable, based on what we know about current practices and the risk of SE growth in unrefrigerated eggs, to establish a time limit for holding eggs under ambient temperature conditions. According to the Layers study (Ref. 26), almost half of the farm sites surveyed had egg pick-ups every 1 to 2 days. We believe that holding eggs under ambient temperature conditions for up to 36 hours would not result in excessive growth of any SE, if present (Ref. 54). If eggs will be held at the farm for more than 36 hours after they are laid, it is important to place them in an environment that will protect the yolk membrane from degradation and, thereby, prevent any SE that may be present from multiplying. We have tentatively concluded that if eggs will be stored for more than 36 hours after they are laid, producers, with 3,000 or more laying hens, must store them at an ambient temperature of 45 °F (7.2 °C) or lower.

We are soliciting comment and data on the 36-hour threshold that eggs may be held unrefrigerated at a farm. Is this time frame practical for producers with daily egg pickup? Is it practical to refrigerate eggs held at farms for less than 36 hours?

F. Indication of the Effectiveness of the SE Prevention Measures: Testing

In addition to implementing SE prevention measures in the poultry house environment, we have tentatively concluded it is also important that you do environmental testing as an indicator of whether your measures are working effectively.

1. Environmental Testing for SE

Under proposed § 118.1(a), § 118.5 would apply to you if you are a shell egg producer with 3,000 or more laying hens, you produce shell eggs for the table market but do not sell all of your eggs directly to consumers, and any of your eggs that are produced at a particular farm do not receive a treatment as defined in § 118.3. We are proposing in § 118.5 that you must conduct environmental testing for SE as an indicator of whether your SE prevention measures are working effectively. According to Schlosser et al. (Ref. 39), the Northeast Conference on Avian Diseases recommended that the poultry house environment (e.g., manure pits and egg machinery) be sampled by swabbing. This recommendation was made with the assumption that, if SE was found in the environment, there was a high probability that the laying hens in the house were infected. Sampling of manure in a poultry house is a simple screening method for determining if laying hens are shedding SE. Some studies have shown that manure sampling gives more consistent results than sampling of egg machinery (Ref. 39), although we recognize that sampling egg machinery may be preferable in certain poultry houses, and the Layers study identified almost one-half of environmental positives through sampling of egg machinery (Ref. 27). We tentatively have determined that environmental testing of the manure or egg machinery in a poultry house is an appropriate method for screening the environment for SE and should be used as one indicator of the effectiveness of your SE prevention measures.

Testing provides an opportunity for you to evaluate the SE status of your poultry houses and to take appropriate action if your measures are not preventing SE. Many of the comments we received in response to the public meetings in Columbus, OH, and Sacramento, CA, stated that environmental testing was an appropriate indicator of whether SE prevention measures are working effectively. In addition, most of the voluntary egg QA programs contain some level of environmental testing for SE to evaluate the effectiveness of the programs.

Information from an egg QA program with a testing protocol indicates that the highest numbers of positive environmental samples are found when laying hens are 40 to 45 weeks of age (Ref. 57). The Layers study (Ref. 27) found that flocks less than 60 weeks of age (younger flocks) were 5 times more likely to test positive for SE than older flocks. Accordingly, we are proposing in § 118.5(a) that environmental testing for SE be conducted for the flock in each poultry house when each group of laying hens making up that flock is 40 to 45 weeks of age. We are proposing in § 118.5(b) that environmental testing for SE also be conducted approximately 20 weeks after the end of any induced molting process. We propose to do this because the egg industry considers the time period approximately 20 weeks after the end of a molting process to be equivalent to the time period when layers are 40 to 45 weeks of age in an initial laying cycle.

An SE-positive environmental test at the 40 to 45 week time period notifies a producer that there is a problem with SE contamination. At this point, action can be taken to determine if there are SE-contaminated eggs and to keep SE-contaminated eggs produced by an SE-positive flock out of the table egg market. Additionally, a positive environmental test during the 40 to 45 week period (just after peak lay) gives a producer sufficient notice to make arrangements for cleaning and disinfection of the contaminated poultry house at depopulation. Therefore, we have tentatively concluded that you must perform environmental testing for SE on a poultry house when each group of laying hens in the flock in that house are 40 to 45 weeks of age and, if molted, approximately 20 weeks after the end of any molting process.

We tentatively have concluded in proposed § 118.5(a)(1) that, if an environmental test at 40 to 45 weeks for SE is negative, and your laying hens do not undergo induced molting, then you do not need to perform additional environmental testing on the poultry house, unless the flock in that poultry house contains multi-aged laying hens. If the flock contains multi-aged laying hens, you must test the environment of the poultry house when each group of hens in the flock is 40 to 45 weeks of age. We are establishing minimum testing requirements to serve as one indication of whether your SE prevention measures are working effectively, and we believe that one test per laying cycle is sufficient for that purpose. In addition, a representative

from the PEQAP program stated at a recent FDA/FSIS public meeting on egg safety (Washington, DC, July 31, 2000) that 75 percent of environmental positives will be caught with one environmental test (Ref. 58).

If an environmental test for SE is positive, we have tentatively concluded, under proposed § 118.5(a)(2), that you must review implementation of your SE prevention measures and begin egg testing within 24 hours of receiving notification of the positive environmental test, unless you divert eggs to treatment for the life of the flock in that poultry house. Review of the SE prevention measures is critical to ensure that they are being implemented properly and to eliminate improper implementation as a contributor to the SE-positive environment. We are proposing that you begin egg testing within 24 hours of receiving notification of an SE-positive environmental test in order to determine as quickly as possible whether SE-contaminated eggs are being marketed to consumers.

Further, we tentatively have concluded, in proposed § 118.5(b), that you must perform an environmental test for SE at approximately 20 weeks after the end of the molting process. Under proposed § 118.5(b)(1), if an environmental test is negative approximately 20 weeks after the end of a molting process, and your laying hens are not molted again, you do not need to perform additional environmental testing, for the reasons previously stated, on that poultry house, unless the flock in the poultry house contains multi-aged laying hens. If the flock contains multi-aged laying hens, the environment of the poultry house must be tested approximately 20 weeks after the end of the molting process of each group of hens in the flock in each poultry house.

Under proposed § 118.5(b)(2), if the environmental test for SE is positive at approximately 20 weeks after the end of a molting process, you must proceed in the same manner as described when the environmental test performed when laying hens are 40 to 45 weeks of age is positive for SE.

2. Egg Testing for SE

Under proposed § 118.1(a), § 118.6 would apply to you if you are a shell egg producer with 3,000 or more laying hens, you produce shell eggs for the table market but do not sell all of your eggs directly to consumers, and any of your eggs that are produced at a particular farm do not receive a treatment as defined in § 118.3. We are proposing in § 118.6 that if you have an environmental test that is positive for SE at any point during the life of a flock, you must perform egg testing for SE, unless you divert eggs to treatment as defined in § 118.3 for the life of the flock in the positive poultry house. If an environmental test is SE-positive, the flock in that environment may be producing SE-positive eggs. Studies have shown that infected laying hens that are shedding SE into the environment are not necessarily producing SE-contaminated eggs (Ref. 14). However, data from the SE Pilot Project (Ref. 39) showed that 50 percent of flocks with an SE-positive environment produced at least one positive egg in the time period studied. The prevalence of SE-positive eggs from flocks in SE-positive environments was estimated to be approximately 1 in 3,600 from data from the SE Pilot Project (Ref. 39). The SE Risk Assessment (Ref. 15) estimated the prevalence of contaminated eggs to be as high as 1 in 1,400 from ''high risk'' flocks with SE-positive environments. We have tentatively concluded that, in order to protect public health, you must begin testing eggs within 24 hours of receiving notification that you have an environmental test that is positive for SE, unless you choose to divert eggs to treatment as defined in § 118.3 for the life of the flock in the positive poultry house.

We are proposing in § 118.6(c) that you must conduct 4 egg tests on the positive poultry house; you must collect and test eggs as required by §§ 118.7 and 118.8, respectively, at 2-week intervals for a total of 4 tests. We are also proposing in § 118.6(c) that if all four tests are negative for SE, then you may continue to supply eggs to the table egg market. However, if any one of the four egg tests is positive for SE, we are proposing in § 118.6(d) that, upon receiving notification of an SE-positive egg test, you must divert all eggs from the positive flock for treatment as defined in § 118.3 until the provisions of § 118.6(c) are met. You may divert eggs from the positive flock to egg products processing or to a treatment that will achieve at least a 5-log destruction of SE for shell eggs. You may return to providing eggs to the table egg market if they have met the provisions of proposed § 118.6(c) (see discussion in section III.G.2 of this document) and continue to meet the provisions of proposed § 118.6(e), described in the following paragraph.

We are proposing in § 118.6(e) that, if you have had a positive egg test in a flock and later meet the number of negative egg tests required in § 118.6(c) and return to table egg production, you must conduct one egg test per month on that flock (see discussion in section III.G.2 of this document) for the life of that previously positive flock. Humphrey (Ref. 14) has suggested that laying hens that are infected with SE will produce SE-contaminated eggs sporadically. Therefore, we believe that it is important that a flock that previously has produced positive eggs be monitored throughout its life for production of SE-contaminated eggs. Under proposed § 118.6(e)(1), if the monthly egg test in paragraph (e) is negative for SE, you may continue to supply eggs to the table market. If any of the monthly egg tests in paragraph (e) are positive for SE, under proposed § 118.6(e)(2), you must divert eggs from the positive flock to treatment for the life of the flock or until the conditions in paragraph (c) of proposed § 118.6 are met.

The testing schemes described in the previous paragraphs could be the basis for a performance based regulatory scheme. We are soliciting comment and data on alternative regulatory schemes that would achieve the same public health protection as the set of measures we are currently proposing. One possibility is a requirement for a specified frequency of environmental testing for all producers, followed, if necessary, by egg testing and diversion. As long as producers were maintaining poultry houses that tested negative for SE, the SE prevention measures would be recommended but not required. However, some or all of the measures may be required of producers whose houses were contaminated with SE. We solicit comment on a testing-based regulatory scheme and combinations of the prevention measures that might achieve the same public health goals as the current proposal.

G. Sampling and Testing Methodology for SE

We are proposing in § 118.7 to require that you follow a scientifically valid sampling procedure when sampling for SE in the poultry house environment and in eggs. Your ability to accurately assess the SE status of a flock and its eggs is a factor of the sampling methodology used to detect SE in the environment and in eggs. To protect public health, it is important that when you perform environmental testing for SE, you take representative samples of the manure or other appropriate material in poultry houses and, when you perform egg testing, you randomly collect 1,000 eggs from a day's production.

1. Sampling of the Poultry House Environment

We are proposing in § 118.7(a) that you use a scientifically valid sampling procedure for conducting environmental sampling within each poultry house. Currently, drag swabbing methods are being used to sample manure in poultry houses in the voluntary State QA programs (Refs. 28, 29, 30, 31, and 32). Drag swabbing has been reported to be an effective and convenient method for determining the SE status of a flock in a poultry house (Ref. 59). Drag swabbing involves pulling a square gauze pad (approximately 4 x 4 inches) that has been moistened with canned, evaporated milk across the surface of manure. Information on drag swabbing generated for the CA Egg QA Program (CEQAP) indicates that a swab becomes saturated with manure after being dragged approximately 30 linear feet (Ref. 60) and, therefore, in that program an individual swab is only dragged for 30 feet. Most other State programs drag a single swab the entire length of a row of cages within a poultry house regardless of the length of that row (Refs. 28, 30, 31, and 32). As only the one CEQAP study has been done on saturation of a drag swab, there is very little information on this subject.

Currently, two different sampling plans are being used to drag swab manure in poultry houses among the voluntary State egg QA programs. CEQAP has developed a statistical sampling plan for drag swabbing a poultry house based on an assumed level of contamination within that house. Based on this assumed level of contamination, the number of swabs necessary to give a particular probability of detecting SE can be determined. For example, if 10 percent of the area of a poultry house is contaminated with SE, taking 32 swabs would give a 96 percent probability of detecting SE in that house. For the CEQAP program, the total area of a poultry house is divided into 30-foot sections (the distance that they have determined it is valid to drag a single swab) and, in our example, 32 of those 30-foot sections would be randomly selected to be drag swabbed for SE. In this sampling plan, the assumed area of contamination can be altered to fit the conditions in a particular poultry house with consequent changes in the number of swabs that must be taken to retain a 95 percent or better probability of detecting any SE that may be present.

Alternatively, many of the other voluntary egg QA programs drag swab the entire length of every row of cages within a poultry house. Rows or banks of cages typically have a right and left side. Each side of a row is dragged with a fresh swab until all the rows have been sampled. One swab is used per side regardless of the length of that row. The number of drag swabs taken per house equals twice the number of rows in that house. In addition, there are houses with cages that are stair-stepped and can be eight cages high with a large manure pit beneath them. In houses such as these, the manure belts are usually sampled. In houses where the floors are constantly flushed with water, the floor in general is swabbed.

We are aware of the differences in the types of poultry houses within the United States and the challenges involved in sampling all houses representatively and consistently. We are specifically soliciting comment on the appropriateness of different methods of drag swabbing, including manure belt and floor swabbing, and egg machinery swabbing. We would like comments on the distance an individual swab should be dragged and whether or not it is necessary to drag every row of every house. We would also like comments on alternative methods of sampling (e.g., sampling of the air in a poultry house to detect SE) that could be utilized more uniformly in different styles of poultry houses. Based on comments received, we will consider what poultry house environmental sampling methods should be required in any final rule.

2. Egg Sampling

In § 118.5(a)(2)(B) and (b)(2)(B), we are proposing to require that you begin egg testing within 24 hours of receiving notification of a single SE-positive environmental test unless you divert eggs to treatment for the life of the flock in the poultry house. In § 118.7(b)(1), we are proposing that, when you conduct an egg test required under § 118.6, you randomly collect and test 1,000 eggs from a day's production. The 1,000-egg sample must be tested according to proposed § 118.8. You must randomly collect and test 4 1,000-egg samples at 2-week intervals for a total test of 4,000 eggs over an 8-week period. With this sampling scheme, there is approximately a 95 percent probability that a positive egg will be detected from a flock that is producing SE-contaminated eggs with a prevalence of 1 in 1,400 (Ref. 61). As mentioned previously, data have indicated that an SE-contaminated flock may be producing SE-contaminated eggs with a prevalence of 1 in 1,400 (Ref. 15). We are proposing that eggs be tested in 2-week intervals because infected flocks shed SE intermittently (Ref. 14). However, the false negative rate of the sampling scheme is sensitive to the assumption regarding the prevalence of SE-contaminated eggs (Ref. 61). We are soliciting comment on this assumption, as well as other scientifically valid egg sampling procedures.

In proposed § 118.7(b)(2) we have tentatively concluded that 1,000 eggs from a day's production should be tested per month for the life of a flock that has had an SE-positive egg test and then met the provisions of § 118.6(c) and returned to table egg production. We are requiring this monthly egg test for the life of the flock because infected layers shed SE intermittently (Ref. 14).

H. Laboratory Methods for Testing for SE

We are proposing in § 118.8(a) that you must test for SE in environmental samples according to the method ''Detection of *Salmonella* in Environmental Samples from Poultry Houses'' and in § 118.8(b) that you must test for SE in egg samples according to the preenrichment method described by Valentin et al. (Ref. 62). These methods, which are incorporated by reference, are required unless you test for SE in environmental and egg samples using other methods that are at least equivalent in accuracy, precision, and sensitivity in detecting SE. In the future, we intend to place the specified methods in FDA's Bacteriological Analytical Manual. After publication of this proposed rule, the environmental sampling method will be available on FDA's Internet Web site at *www.cfsan.fda.gov*.

The method for detecting SE in the environment that we are specifically proposing to allow, ''Detection of *Salmonella* in Environmental Samples from Poultry Houses,'' is a pre-enrichment method followed by primary enrichment method. The basic procedure for culturing samples involves incubating pre-enriched samples in enrichment broth and then streaking samples of broth onto selective media. Following incubation of the samples on the selective media, any suspect colonies that have grown on the media are identified biologically and serologically. In general, this procedure should give results in 5 days following receipt of samples by the laboratory.

The method for detecting SE in egg samples that we are specifically proposing to allow is a pre-enrichment method. The basic procedure for culturing involves incubation of pools of 20 eggs, followed by enrichment in modified tryptic soy broth. Following incubation and enrichment, samples are subcultured and streaked onto media and any suspect colonies that have

grown on the media are identified biochemically and serologically. We specifically request comment on appropriate options for conducting and funding testing of SE detection methods through State and Federal programs.

I. Administration of the SE Prevention Measures

We are proposing in § 118.9 that one individual at each farm must be responsible for administration of the SE prevention measures. Oversight by one qualified individual is essential to the effective implementation of SE prevention measures for egg production. Because egg production operations tend to be small and may have frequent turnover in staff, it is particularly important that one individual have training equivalent to a standardized curriculum recognized by FDA (discussed in the following paragraphs) or be otherwise qualified through job experience to administer the SE prevention measures.

Proposed § 118.9 requires an individual to have the requisite training or experience to administer SE prevention measures. Training on SE prevention measures for egg production must be at least equivalent to that received under a standardized curriculum recognized by FDA. We anticipate that 2- or 3-day training sessions will be provided by an egg safety training alliance, modeled after the Seafood HACCP Alliance. The Seafood HACCP Alliance is a consortium consisting of representatives from Federal and State agencies, industry, and academia who have worked to create a uniform training program that will meet the requirements of the seafood HACCP regulations with minimal cost. It is our intention to develop an Egg Safety Alliance to create a core curriculum and training materials on SE prevention measures for egg production. It also is our intention to use the Egg Safety Alliance curriculum and materials as the standard against which other course curricula and materials may be judged.

We also are proposing in § 118.9 that job experience will qualify an individual to administer the SE prevention measures if such experience has provided knowledge at least equivalent to that provided through the standardized curriculum. We acknowledge that a course on SE prevention measures for egg production might not be necessary for an individual who has experience working on an egg farm and is well-versed in SE prevention during egg production. Where job experience has imparted a level of knowledge at least equivalent to what an individual would receive through the standardized curriculum, that individual would be considered qualified to administer the prevention measures under proposed § 118.9.

We are proposing in §§ 118.9(a) through (c) that the qualified individual designated under § 118.9 must develop and implement SE prevention measures for each farm, reassess and modify the prevention measures as necessary to ensure that the requirements of § 118.4 are met, and review all records created under § 118.10. We also are proposing that the individual does not need to have performed the monitoring or created the records being reviewed. We have tentatively concluded that the prevention measures need to be implemented and, if necessary, modified and reassessed by an individual who not only is knowledgeable about egg production but who also has been trained or is experienced specifically in SE prevention measures for egg production so that the individual will be able to recognize potential problems.

J. Recordkeeping Requirements for the SE Prevention Measures

We are proposing recordkeeping requirements related to environmental testing and egg testing for SE, diversion, and eggs going to treatment.

1. Records that Egg Producers Are Required to Maintain

Under proposed § 118.1(a), § 118.10 would apply to you if you are a shell egg producer with 3000 or more laying hens, you produce shell eggs for the table market but do not sell all of your eggs directly to consumers, and any of your eggs that are produced at a particular farm do not receive a treatment as defined in § 118.3. We are proposing in § 118.10(a)(1) that you must keep records indicating compliance with environmental and egg sampling performed under proposed § 118.7 and results of environmental and egg testing performed under proposed § 118.8 as required in proposed §§ 118.5 and 118.6. If applicable, you must also keep records indicating compliance with the egg diversion requirements of proposed § 118.6. These records may be handwritten logs, invoices, documents reporting laboratory results, or other appropriate records.

Maintenance of appropriate records is fundamental to evaluating the effectiveness of your SE prevention measures. As stated in section III.A of this document, the combined SE prevention measures, when implemented properly, have been shown to result in a decrease in the number of poultry houses with SE-positive environments (Ref. 39). We have tentatively concluded that in order for you and FDA to evaluate whether these measures are being effective, it is necessary for you to keep records documenting the results of environmental testing and, if applicable, egg testing. We are proposing in § 118.10(a)(2) that if egg testing reveals SE-positive eggs you must maintain records indicating compliance with the diversion requirements in § 118.6. Records of diversion will provide assurance to both you and FDA that eggs required to be diverted are not being marketed to consumers and, thereby, putting consumers at risk of illness from SE.

We are proposing in § 118.10(a)(3) that you must keep records indicating that all of the eggs at a particular farm will be given a treatment as defined in § 118.3, if you have 3,000 or more laying hens and you are not complying with the SE prevention measures other than refrigeration (i.e., you are a producer described in § 118.1(b)). These records may include a contract with an in-shell pasteurization facility or an egg-breaking facility. It is necessary that these records be maintained so that both you and FDA will have an assurance that the potential for SE contamination in eggs is being addressed through a treatment or through the SE prevention measures.

2. General Requirements for Records Maintained by Egg Producers

In proposed § 118.10(b), we describe general requirements for records that must be maintained. Proposed § 118.10(b)(1) and (b)(2) require that records contain your name, the location of your farm, and the date and time of the activity that the record reflects. Proposed § 118.10(b)(3) requires that the record include the signature or initials of the person performing the operation or creating the record. The record signing requirement will assure responsibility and accountability by the individual who performed the activity. Also, a signature or initials ensure that the source of the record will be known if any questions regarding the record arise.

Proposed § 118.10(b)(4) requires that data reflecting compliance activities be entered on a record by the person performing or observing the activity at the time it is performed or observed in order to increase accuracy. The record must contain the actual values observed, if applicable.

3. Length of Time Records Must Be Retained

Proposed § 118.10(c) requires you to maintain all records in accordance with proposed part 118 at your place of business, unless stored offsite under § 118.10(d), for 1 year after the flock to which the records pertain has been taken permanently out of production. You must maintain records for 1 year after a flock is no longer producing eggs for consumption to allow for annual inspection and to facilitate investigation if the eggs from that flock are implicated in an outbreak of a foodborne illness.

4. Offsite Storage of Records

Proposed § 118.10(d) allows for offsite storage of records 6 months after the date the records were created. This applies to all records required under proposed part 118. We recognize that, under the recordkeeping requirements of this part, there may be more records than available storage space in an egg production facility. Therefore, we are proposing that records may be stored offsite. You must be able to retrieve any records you store offsite and provide them at your place of business within 24 hours of a request for official review. We would consider electronic records to be onsite if they are available from an onsite computer, including records transmitted to that computer via a network connection.

5. Official Review of Records

Proposed § 118.10(e) requires you to have all records required by part 118 available for official review and copying at reasonable times. The agency's access to records required by proposed part 118 is essential to understand whether your SE prevention measures are working and whether you are complying with the regulations. Our authority to require these records, and to provide for agency access to them, is discussed elsewhere in this document.

6. Public Disclosure of Records

Proposed § 118.10(f) states that records required by proposed part 118 are subject to the disclosure requirements under 21 CFR part 20. In another FDA rulemaking that discussed public disclosure of required records (60 FR 65096 at 65139, December 15, 1995), we concluded:

> [R]ecords and plans should be protected to the extent possible in order to promote the implementation of HACCP across the seafood industry. FDA has concluded that the public will benefit from the protection of records because it will actually strengthen the HACCP system. So long as the legitimate public need to be able to evaluate the system can be met through other means, the confidentiality of HACCP records and plans generally will foster the industry's acceptance of HACCP. Even though HACCP may be mandatory under these regulations, in order for it to succeed, processors must be committed to it because they see value in it for themselves. Fear of public disclosure of matters that have long been regarded as confidential business matters could significantly undermine that commitment. FDA concludes, therefore, that it is in the public interest to foster tailored HACCP plans that demonstrate understanding and thought, rather than promote the use of rote plans and minimally acceptable standards due to fear of public disclosure.
>
> FDA understands that we cannot make promises of confidentiality that exceed the permissible boundaries established under FOIA, nor does the agency wish to do so in this case. The agency still does not expect that we will be in possession of a large volume of plans and records at any given moment. However, given the significant interest in this subject as conveyed by the comments, we have concluded that the final regulations should reflect the fact that the HACCP plans and records that do come into FDA's possession will generally meet the definition of either trade secret or commercial confidential materials* * *.

We are not aware of any circumstances that would warrant different consideration on issues related to disclosure of records for SE environmental and egg sampling and testing and for diversion of eggs than those required for seafood HACCP. Therefore, we intend to consider records that come into our possession under this rule as generally meeting the definition of either a trade secret or commercial confidential materials.

7. Comment Solicitation on Recordkeeping Measures

We are soliciting comment on whether we should require two additional recordkeeping measures beyond the proposed recordkeeping requirements for environmental and egg sampling and testing, and for diversion. This solicitation is being made to assess the importance of these additional recordkeeping measures for a comprehensive SE prevention plan, given their added costs. First, we are soliciting comment on whether we should require that you establish and maintain a written SE prevention plan. If required, this SE prevention plan would set forth a producer's plan to implement the regulation's prevention and testing measures, and the requirement for diversion if eggs test positive for SE. A written plan may aid in the planning and establishing of efficient, effective, and consistently implemented SE prevention measures by facility personnel.

A written SE prevention plan also would be helpful to FDA representatives who inspect an egg facility. A written copy of a plan specific to each farm would assist FDA in establishing a link between what agency representatives see during an inspection and the overall SE prevention measures used on that farm over a longer time period. SE prevention measures may be quite different among farms, given different facility design and size, and yet be equally effective in meeting FDA's requirements. Knowledge of the specific prevention measures taken on a farm, as discussed in an SE prevention plan, would assist FDA representatives in assessing compliance with the prevention measures.

The second recordkeeping measure about which we are soliciting comment relates to a requirement that you maintain records indicating performance and compliance in implementing your facility's specific SE prevention measures. In this document, we are specifically proposing to require records only for environmental and egg sampling and testing, and for diversion of eggs found to be SE positive. We are requesting comment on whether we should require other documents demonstrating your implementation of the SE prevention measures that could be considered by FDA in assessing your compliance efforts, particularly in light of an SE-positive environmental test. Such documents, for example, might include monitoring records and activity logs. In the absence of other records to demonstrate compliance with SE prevention measures, FDA representatives who inspect a facility will base their evaluation of compliance with the regulation on observations, your sampling, testing, and any diversion records, FDA testing, and any other relevant information.

FDA did not propose to require a written plan and monitoring and compliance records because of their added costs, which FDA estimates to be $14.7 million, an 18 percent increase in the rule's total costs. Considering the information in the previous paragraphs, we are soliciting comment on the cost-effectiveness of the inclusion of a recordkeeping provision for a written SE prevention plan and a provision requiring records demonstrating compliance with all SE prevention measures in any final rule based on this proposal.

We also are soliciting comment about whether we should consider requiring, in a final rule, that you register with FDA if you are a producer who must comply with all of the SE prevention measures, as described in proposed § 118.1(a). We would use the producer registration information to create a

database that we would use to efficiently conduct inspections and allocate inspection resources. When the provisions of this rule are finalized, FDA intends to conduct annual inspections of egg farms. Oversight through annual inspection is necessary to ensure that shell eggs are being produced under controls that will prevent SE contamination and reduce the likelihood that SE-contaminated eggs will cause foodborne illness. Therefore, we solicit comment on the efficacy of requiring that producers register the location and size of their business with FDA.

K. Enforcement of On-Farm SE Prevention Measures for Shell Eggs

As discussed in section III.L of this document, FDA is proposing these regulations under both the FFDCA and the PHS Act. Failure to comply with the on-farm requirements proposed in §§ 118.1 through 118.10 would subject a producer to the administrative remedies (i.e., diversion or destruction) in § 118.12 of the proposed rule. Further, we would consider a failure to comply with the SE prevention requirements in proposed §§ 118.1 through 118.9 to result in the shell eggs being adulterated under section 402(a)(4) of the FFDCA (21 U.S.C. 342(a)(4)). Causing the eggs to become adulterated would be a violation of section 301(b) of the FFDCA (21 U.S.C. 331(b)), which prohibits adulteration or causing adulteration of food in commerce. Also, the introduction or delivery for introduction of adulterated shell eggs into interstate commerce would be a prohibited act under section 301(a) of the FFDCA (21 U.S.C 331(a)). Enforcement of adulteration regulations under the FFDCA is conducted under sections 301, 302, 303, and 304 (21 U.S.C. 332, 333, and 334).

Section 361 of the PHS Act (42 U.S.C. 264) authorizes the Secretary of Health and Human Services (the Secretary), and by delegation FDA, to issue regulations that provide for the destruction of articles and for other measures that the Secretary determines are necessary to prevent the introduction, transmission, or spread of communicable diseases. FDA tentatively concludes that the SE on-farm prevention requirements can be efficiently and effectively enforced through administrative procedures under the PHS Act. Accordingly, FDA is proposing procedures in § 118.12 under which FDA or a State or locality may order the diversion or destruction of shell eggs that have been produced or held in violation of any of the regulations in §§ 118.1 through 118.10. Under proposed § 118.12, FDA or a State or locality may issue a written order to the person holding the shell eggs requiring that the eggs be diverted or destroyed.

The proposed regulations would provide for the diversion to a treatment that achieves at least a 5-log destruction of SE for shell eggs or for processing of the egg products in accordance with the EPIA. Because EPIA requires pasteurization of egg products, any *Salmonella* present would likely be eliminated, as it would if the eggs received a treatment that achieves at least a 5-log destruction of SE. The written order would identify the shell eggs that are affected, and the grounds for issuing the order. The written order would provide that, unless the order is appealed by either filing a written appeal or by requesting a hearing, the shell eggs must be diverted or destroyed within 10-working days of the receipt of the order.

The authority for the enforcement of section 361 of the PHS Act is provided, in part, by section 368 of the PHS Act (42 U.S.C. 271). Under section 368(a), any person who violates a regulation prescribed under section 361 of the PHS Act may be punished by imprisonment for up to 1 year and may be fined. Individuals violating a regulation issued under section 361 may be fined an amount up to $100,000 if death has not resulted from the violation or up to $250,000 if death has resulted (18 U.S.C. 3559 and 3571(c)). In addition, Federal district courts have authority to enjoin individuals and organizations from violating regulations implemented under section 361 of the PHS Act (*Califano* v. *Yamasaki*, 442 U.S. 682, 704–05 (1979); *United States* v. *Beatrice Foods Co.*, 493 F.2d 1259, 1271–72 (8th Cir. 1974), *cert. denied*, 420 U.S. 961 (1975)).

We are proposing to amend § 16.5 (21 CFR 16.5) by adding paragraph (a)(5) to clarify that the regulatory hearing procedures in 21 CFR part 16 do not apply to a hearing proposed under § 118.12 on an order for diversion or destruction of shell eggs under section 361 of the PHS Act. We intend for the administrative remedies in proposed § 118.12 to be the applicable informal hearing process for any order issued under such section.

Proposed § 118.12(b) requires that shell egg producers allow FDA representatives to inspect egg production establishments. FDA does not need to provide advance notice before an inspection, and an inspection may include, but is not limited to, egg and environmental sampling, review of records, and inspection of eggs and equipment.

Proposed § 118.12(c) provides that States and localities that are authorized to inspect or regulate egg production establishments may enforce proposed §§ 118.4 through 118.10 of the rule through inspections under § 118.12(b) and through the administrative remedies in § 118.12(a). Proposed § 118.12(c) also provides that those States or localities may follow the rule's hearing procedures, substituting, where necessary, the appropriate State or local officials for designated FDA officials. The State or local officials also may use comparable State or local hearing procedures as long as such procedures satisfy due process.

L. Legal Authority

FDA is proposing these regulations under the PHS Act and the FFDCA. FDA's legal authority under the PHS Act for the proposed regulations is derived from the provisions of sections 311, 361, and 368 (42 U.S.C. 243, 264, and 271) that relate to communicable disease. The PHS Act authorizes the Secretary to make and enforce such regulations as ''are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States * * * or from one State * * * into any other State'' (section 361(a) of the PHS Act). (See sec. 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for transfer of authority from the Surgeon General to the Secretary; see 21 CFR 5.10(a)(4) for delegation from the Secretary to FDA.) This proposed rule would not be the first regulation issued by FDA that relied upon the authority of the PHS Act to prevent the transmission of communicable disease. For more than 60 years, FDA has used the PHS Act as its legal authority (in whole or in part) to issue the following regulations:

- Regulations to control the interstate shipment of Psittacine birds (21 CFR 1240.65);
- Regulations on the source and use of potable water (21 CFR 1240.80 to 1240.95);
- Regulations to control the interstate and intrastate commerce of turtles (21 CFR 1240.62);
- Regulations to control the interstate shipment of molluscan shellfish (21 CFR 1240.60);
- Regulations to require pasteurization of milk and milk products (21 CFR 1240.61);
- Regulations to require a safe handling statement on cartons of shell eggs that have not been treated to destroy *Salmonella* microorganisms and to require refrigeration of shell eggs held

for retail distribution (parts 16, 101, and 115 (21 CFR parts 16, 101, and 115));

• Regulations governing blood and tissue products in intrastate and interstate commerce (parts 606, 640, 1270, and 1271 (21 CFR parts 606, 640, 1270, and 1271));

• Regulations to require HACCP systems for juice in interstate and intrastate commerce (part 120 (21 CFR part 120); and

• Regulations to prevent the monkeypox virus from being established and spreading in the United States (21 CFR 1240.63).

Furthermore, at least one court has supported FDA's use of its PHS Act authority to issue regulations to control communicable disease. *State of Louisiana* v. *Mathews*, 427 F. Supp. 174 (E.D.La. 1977), involved an FDA regulation issued under the PHS Act banning the sale and distribution of small turtles. Plaintiffs argued that the PHS Act only provided FDA with authority to ban individual lots of infected turtles that were shown to be health hazards and did not provide authority for FDA's broad ban on all small turtles. *Id.* at 175. The court rejected this argument, observing that ''Congress has granted broad, flexible powers to federal health authorities who must use their judgment in attempting to protect the public health against the spread of communicable disease.'' *Id.* at 176. The court found that FDA's total ban was ''permissible as necessary to prevent the spread of communicable disease.'' *Id.*

Plaintiffs in the case also challenged FDA's authority under the PHS Act to promulgate a rule applicable to intrastate commerce. *Id.* FDA had concluded that controlling the spread of disease from contaminated turtles required extending the ban to intrastate sales. *Id.* Specifically, FDA reasoned that contaminated turtles may be purchased in one State for use as a pet in another and that, without prohibiting intrastate sales, unlawful interstate sales would be difficult or impossible to stop. *Id.* The court found that the intrastate ban ''is not only authorized by law, but under modern conditions of transportation and commerce is clearly reasonable to prevent the interstate spread of disease.'' *Id.*

In *Public Citizen* v. *Heckler*, 602 F. Supp. 611 (D.D.C. 1985), the court considered a request to compel the Department to act on a petition to ban all domestic sales of raw milk and raw milk products because of the risk of transmission of disease from such products. In ordering FDA to respond to the petition, the court found that the Department had authority to ban raw milk and milk products under the PHS Act: ''Under both the [PHS] Act's authorization for regulations to control communicable diseases, and the [act's] provisions for the control of adulterated foods, the Secretary has both the authority and the heavy responsibility to act to protect the nation's health in situations such as this one.'' *Id.* at 613. (internal citations omitted). See *Public Citizen* v. *Heckler*, 653 F. Supp. 1229, 1242 (D.D.C. 1987) (ordering FDA to publish a proposed rule banning the interstate sale of all raw milk and raw milk products).

In addition to the PHS Act, FDA's legal authority to require on-farm prevention measures under proposed §§ 118.1 through 118.9 derives from sections 402(a)(4) and 701(a) of the FFDCA (21 U.S.C. 371(a)). Under section 402(a)(4) of the FFDCA, a food is adulterated ''if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.'' Under section 701(a) of the FFDCA, FDA is authorized to issue regulations for the FFDCA's efficient enforcement. A regulation that requires measures to prevent food from being held under insanitary conditions whereby either of the proscribed results may occur allows for efficient enforcement of the FFDCA. See, e.g., regulations to require HACCP systems for fish and fishery products (21 CFR part 123) and juice (part 120) and regulations to require a safe handling statement on cartons of shell eggs that have not been treated to destroy *Salmonella* microorganisms and to require refrigeration of shell eggs held for retail distribution (parts 101 and 115).

Salmonellosis is a communicable disease that results from intestinal infection with *Salmonella* and is characterized by diarrhea, fever, abdominal cramps, headache, nausea, and vomiting. Contaminated shell eggs are the predominant identified food source of SE-related cases of salmonellosis in the United States. Lack of adequate on-farm prevention measures for the production of shell eggs can lead to the presence of SE in shell eggs and increase the likelihood of human illness if the eggs are not treated or thoroughly cooked. Infection may also be transmitted from person to person and animal-to-person. The provisions in the proposed rule are necessary to prevent SE from entering the farm and to prevent SE, if present, from cross contaminating the layers or eggs on the farm. We tentatively conclude that a regulation to require on-farm measures is necessary to prevent the spread of communicable disease and to prevent shell eggs from being prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health.

Although the egg market is largely regional, it involves significant shipment of shell eggs from State to State. Moreover, shipment of SE contaminated eggs from one State to another has contributed to the geographical spread of disease outbreaks in the U.S. human population. For example, eggs from Pennsylvania were implicated in an outbreak of SE infection reported in Asbury Park, NJ, involving at least 47 persons (Ref. 63). Eggs from Maryland were implicated in an outbreak in Livonia, NY, where 12 patrons of a restaurant reported gastrointestinal illness linked to consumption of omelets made from pooled grade A eggs (*Id.*). Further, consumption of raw eggs was associated with an SE outbreak at a catered wedding reception in New York, where Caesar salad dressing was implicated as the cause of SE illnesses. The Caesar salad dressing, made with 18 raw shell eggs traced to a Pennsylvania producer, was left unrefrigerated for 2 hours at the catering establishment, held in an unrefrigerated truck until delivered, and served at the reception 4.5 hours later (Ref. 64).

If eggs are not produced using SE prevention measures, SE is more likely to be present in the shell eggs, thereby increasing the likelihood of human illness if the eggs are not treated or thoroughly cooked. We tentatively conclude that it is necessary for producers with 3,000 or more layers on a farm that do not sell all of their eggs directly to consumers and that produce for the table market shell eggs that do not all receive a treatment, to produce shell eggs using all of the proposed rule's measures to prevent the spread of communicable disease. We also tentatively conclude that only the refrigeration requirements of proposed § 118.4 would apply to producers that provide shell eggs to the table market but do not sell all of their eggs directly to consumers and have 3,000 or more layers at a farm, and whose eggs receive a treatment. We have previously explained, in section III.B of this document, why we are proposing to exempt producers who sell all of their eggs directly to consumers and who have fewer than 3,000 laying hens at a farm from the SE prevention measure requirements.

Activities that are intrastate in character, such as the production and final sale of shell eggs to a retail establishment or institution for ultimate consumption by the consumer within one State, are subject to regulation under section 361 of the PHS Act when intrastate regulation is necessary to prevent the interstate spread of disease (*State of Louisiana* v. *Mathews*, 427 F. Supp. 174, 176 (E.D.La. 1977)). We tentatively conclude that the on-farm SE prevention measures in proposed §§ 118.1 through 118.10 must also apply to producers of shell eggs who sell their eggs intrastate, other than directly to consumers. The record in this rulemaking demonstrates that shell eggs can function as a vehicle for transmitting foodborne illness caused by *Salmonella* (Refs. 7, 8, and 9). Similarly, the record (Ref. 65) demonstrates that consumers, including tourists and other travelers, are likely to purchase intrastate raw shell eggs or products made with them. These consumers subsequently take the eggs or products back to their home state where the eggs or products are consumed, or the consumers carry a communicable disease back to their home state as a result of such consumption, thereby creating the risk that foodborne illness may be spread from one State to another as a result of such consumption. Although producers do not ship such eggs across State lines, there have been interstate SE outbreaks associated with such eggs (Ref. 66).

We believe that a regulation to require on-farm SE prevention measures or shell eggs produced and sold within a State would reduce the risk of SE illness. We are concerned that if we do not require on-farm prevention measures for shell eggs that are produced and sold in one state, the regulations will not prevent the introduction of SE contaminated eggs into other states and, thus, will not prevent the introduction of salmonellosis from one State to another. We tentatively conclude that the spread of salmonellosis among states from SE-contaminated eggs cannot be adequately controlled without extending the on-farm requirements to producers of eggs whose eggs are shipped within one state.

We are proposing to use our authority under section 361 of the PHS Act to institute recordkeeping requirements. We have previously imposed recordkeeping requirements under section 361 of the PHS Act in regulations governing blood and tissue products (parts 606, 640, and 1270) and juice (part 120).

Regulations governing blood and blood components require that records be kept covering each step in the their collection, processing, compatibility testing, storage and distribution and documentation covering shipping temperature and donor information (examination results, tests, laboratory data, interviews, written consent, and health certification) (§§ 606.160 and 640.72).

Recordkeeping requirements are also included in FDA's Human Tissue Intended for Transplantation regulations in part 1270, which also include requirements that records be maintained relating to infectious disease tests, donors, and the receipt, distribution, and disposition of human tissue (§ 1270.35).

HACCP systems regulations for juice also require significant recordkeeping. The regulations generally require each juice processor with a food hazard that is reasonably likely to occur to maintain a written hazard analysis and HACCP plan (21 CFR 120.12). The regulations further require that such processors maintain records documenting the implementation of the sanitation standard operating procedures, the ongoing application of the HACCP plan, verification of the HACCP system, and validation of the HACCP plan or hazard analysis. *Id.*

Section 361 of the PHS act provides FDA with authority to issue regulations necessary to prevent the introduction, transmission, or spread of communicable disease. Recordkeeping requirements are necessary for FDA to ensure that producers follow the sampling, testing, and, if necessary, diversion requirements under proposed part 118 for the production of shell eggs. We are proposing environmental testing as an indicator of whether a producer's SE prevention measures are effective. Testing would provide information on the SE status of a poultry house and indicate the need to take appropriate action if the measures were not preventing SE. Under the proposed rule, a positive environmental test would necessitate review of the implementation of SE prevention measures and testing of eggs (unless all eggs in the poultry house are subsequently diverted for the life of the flock). Testing would reduce the number of SE-positive eggs that reach consumers by: (1) Improving the effectiveness of SE prevention measures by indicating when prevention measures are ineffective and need to be modified and (2) triggering diversion to treatment of SE-positive eggs.

Records of SE testing are needed to allow FDA to determine whether SE prevention measures are being implemented in an effective manner over time. Furthermore, FDA personnel may not be present when producers perform environmental sampling and collect eggs for testing. Records would allow FDA to verify that sampling is done in a scientifically valid manner and that the required testing is conducted. Records would also allow FDA to confirm test results and that producers are taking appropriate actions based on the results (e.g., reassessment, additional testing, diversion). The records would provide assurance, to both the producer and FDA, that the risk of SE-contaminated eggs being provided to consumers is being minimized, either through an SE-negative poultry house or diversion of SE-contaminated eggs.

In addition to having the authority under the PHS Act to require recordkeeping, we believe we also have the authority to require access to the records. Because the on-farm sampling, testing, and diversion requirements are necessary to minimize the risk of communication of salmonellosis, access to records that demonstrate a farm has followed such requirements in part 118 is essential to confirm compliance and achieve the full benefits of the rule. We also have the authority, under section 361 of the PHS Act, to copy the records when necessary. We may consider it necessary to copy records when, for example, our investigator may need assistance in reviewing a certain record from relevant experts in headquarters. If we are unable to copy the records, we would have to rely solely on our investigators' notes and reports when drawing conclusions. In addition, copying records will facilitate followup regulatory actions. Therefore, we have tentatively concluded that the ability to access and copy records is necessary to enforce the rule and prevent the spread of communicable disease. A failure to comply with the rule's records provisions would subject the producer to the administrative procedures under proposed § 118.12. In other relevant sections of this document, we explain in more detail the recordkeeping provisions that we believe are necessary and, because they are limited to what is necessary, that we believe do not create an unreasonable recordkeeping burden.

Under the PHS Act, the Federal, State, and local governments have a long tradition of cooperation. The PHS Act specifically recognizes cooperation between the Federal, State, and local governments as an important tool for public health officials. Previously, in the area of food safety, FDA has used portions of the PHS Act (e.g., sections 310 and 311 (42 U.S.C. 242 and 243)) that focus on Federal assistance to the States. The Conference for Food

Protection (CFP) and the Food Code are a result of Federal, State, and local cooperation and Federal assistance to States and localities under the PHS Act. Section 311 of the PHS Act not only recognizes Federal assistance to the States, but it also recognizes that States and localities may be able to assist the Federal Government. This section provides in part: ''The Secretary is authorized to accept from State and local authorities any assistance in the enforcement of quarantine regulations made pursuant to this Act which such authorities may be able and willing to provide.''

We believe that, under sections 311 and 361 of the PHS Act, there are several ways we could accept assistance from the States in the enforcement of the on-farm regulation. For example, FDA could accept State and local assistance in the inspection of shell egg farms and then use those inspections as the basis for detention and diversion or destruction under proposed § 118.12 (as discussed in section III.K of this document) or as the basis for an enforcement action under the FFDCA. Another option would be to authorize the States and localities to conduct inspections and enforce the on-farm requirements through the administrative enforcement remedies set out in proposed § 118.12, while FDA could hear appeals with judicial review available after FDA's decision. FDA also believes that sections 311 and 361 of the PHS Act authorize the agency to issue a regulation that would allow States and localities to enforce the SE prevention on-farm requirements themselves.

After examining these options, FDA has tentatively concluded that all except the last option (allowing States and localities to enforce the requirements themselves) would prove too cumbersome. FDA believes that a cooperative approach would be the most effective means to enforce the on-farm requirements. We are proposing a similar approach to the one chosen for the egg labeling and refrigeration regulations (parts 101 and 115). Specifically, FDA has tentatively decided to allow agencies of those States and localities that are able and willing to inspect or regulate shell egg producers, as authorized under sections 311 and 361 of the PHS Act, to enforce the SE prevention measures along with FDA. FDA recognizes that States and localities currently do this type of enforcement and has tentatively concluded that this option will be the most effective and efficient use of Federal, State, and local food safety resources. Accordingly, proposed § 118.12(c) provides that those States and localities that are able and willing are authorized under sections 311 and 361 of the PHS Act to enforce proposed §§ 118.1 through 118.10 using the administrative procedures in § 118.12, as set out in section III.K of this document. With respect to the hearing procedures, we recognize that many States and localities already have administrative procedures in place for hearings. The proposed regulation would allow them to use a similar hearing process as long as that process satisfies basic due process requirements.

FDA recognizes that some of these are new approaches to enforcement of food safety regulations, and is soliciting comments on this aspect of this proposed regulation. FDA is particularly interested in comments on how State, local, and Federal food safety authorities can best work together to ensure effective and efficient implementation and enforcement of food safety standards.

M. Response to Comments Related to On-Farm Prevention Measures

In this section, we are responding to comments that the agency received in response to the 1998 joint FDA/USDA ANPRM on *Salmonella* Enteritidis in eggs and in response to the public meetings on egg safety that the agency sponsored with USDA in Columbus, OH (March 30, 2000), Sacramento, CA (April 6, 2000) and Washington, DC (July 31, 2000). FDA/USDA received approximately 73 letters to the 1998 ANPRM (Docket No. 97N–0322), each containing one or more comments. We received approximately 370 letters to Docket No. 00N–0504 for the public meetings on egg safety, each containing one or more comments. Comments on both the ANPRM and the public meetings were received from egg farmers, egg packers, trade associations, consumers, consumer interest groups, animal interest groups, academia, State government agencies, and foreign government agencies. We are responding to comments received to these dockets to the extent that they are relevant to this proposal.

(Comment 1) A few comments stated that it is not necessary to establish regulations for egg safety because the risk of illness from an SE-contaminated egg is low. Comments referenced the SE Risk Assessment in stating that the risk of an egg being contaminated with SE is 0.005 percent. In addition, 30 percent of the 3.3 million eggs that are contaminated annually are used for the production of egg products that are pasteurized and, therefore, do not result in illness. Comments maintained that the risk of illness from the remaining 2.3 million SE-contaminated eggs is less than the risk from consuming other high-protein foods and, therefore, is acceptable and does not warrant Federal regulatory action.

(Response) We do not agree with these comments. We believe that the current risk of illness from consuming SE-contaminated eggs is still too high, especially when there are cost-effective measures that can be taken that will reduce the risk. In 2001, the isolation rate of SE was 2.0 per 100,000 population and the contribution of SE (corrected for underreporting) to total salmonellosis was estimated to have been 213,046 illnesses, including 2,478 hospitalizations, and 87 deaths (Refs. 4 and 5). We estimate that the cost to society of egg-associated SE illnesses in a year is $1.8 to 3.1 billion. (See discussion in the Preliminary Regulatory Impact Analysis in section V. of this document.)

As to the argument that eggs do not carry the same risk as other high protein foods (presumably meat and poultry), this is not a reason to ignore the risk from eggs. USDA has instituted HACCP programs to reduce the risk of foodborne illness from meat and poultry. Likewise, we are proposing measures in this proposed rule to reduce the risk of foodborne illness from eggs because there are practical steps that can be taken to reduce that risk. Consumers also are more aware of the risks associated with consuming undercooked meat and poultry than they are of the risks of consuming raw or undercooked eggs (Ref. 23). Thus, we disagree with this comment and believe that the risk of foodborne illness from consumption of SE-contaminated eggs is too high and warrants Federal regulatory action.

(Comment 2) Several comments stated that not enough is known about the ecology of SE to develop credible on-farm prevention measures. The comments further stated that the relationship between an environment that is contaminated with SE and an egg that is contaminated with SE has not been established and, therefore, it is not possible to develop appropriate SE prevention measures.

(Response) We do not agree with these comments. As stated in section III.E of this document, data from the SE Pilot Project have shown that certain measures (e.g., rodent and pest control, biosecurity, use of SE-monitored chicks, and cleaning and disinfection) have been effective in reducing the number of poultry houses with SE-positive environments (Ref. 39). When these measures were implemented, the number of positive houses decreased

from 38 to 13 percent over a 3-year period. Although we agree that more information is needed on the ecology of SE, we believe that prior experience from voluntary egg QA programs has indicated that there are preventive controls that can be implemented on a farm that will prevent SE contamination of eggs.

We agree that the exact relationship between an environment that is contaminated with SE and an egg that is contaminated with SE is not known. However, data from existing QA programs have indicated that, when a poultry house environment is contaminated with SE, the prevalence of SE-contaminated eggs is approximately 1 in 3,600 or, as estimated in the SE risk assessment, 1 in 1,400. A prevalence of SE-contaminated eggs of 1 in 1,400, or even 1 in 3,600, is unacceptable from a public health standpoint. Preventive measures have been developed to prevent the SE-contamination of poultry houses on a farm, which would reduce the production of SE-contaminated eggs that may cause foodborne illness. Therefore, it is appropriate that we take steps to ensure that producers are employing these preventive measures to reduce the prevalence of SE-contaminated eggs by proposing to require use of the SE prevention measures.

(Comment 3) One comment stated that on-farm prevention measures are not necessary because most of the outbreaks of SE illness can be attributed to improper food handling.

(Response) We do not agree with this comment. Although we are aware that many outbreaks of foodborne illness occur as a result of cross contamination during food handling, many egg-associated SE outbreaks have been traced back to eggs contaminated during production. In section II.A of this document, we discuss several outbreaks that were traced back to eggs from farms that had SE-positive environments at the time of traceback. In addition, the increase in egg-associated SE outbreaks in the mid-1980s occurred at the same time that transovarian contamination of SE in eggs was first being detected. Although proper handling by retailers and consumers can reduce egg-associated illnesses, it is important to take practical measures to prevent eggs from becoming contaminated with SE in the first place.

(Comment 4) Many comments maintained that induced molting of laying hens is cruel to the birds and contributes to SE contamination of eggs and, therefore, should be banned. In support of this position, these comments cited the information outlined in the petition from United Poultry Concerns, Inc., and the Association of Veterinarians for Animal Rights (described in section II.J of this document) and data on induced molting collected during the SEPP.

(Response) The issue of whether induced molting should be stopped because it is cruel to laying birds is outside the scope of this proposed rule. With regard to the assertion that induced molting should be banned because it contributes to SE contamination of eggs, we do not agree with that comment at this time. However, we seek comment, discussed below, on whether certain practices related to molting are appropriate to reduce SE contamination of eggs within a poultry house.

Several studies (described in section II.J of this document and (Ref. 67)) have been cited in comments as evidence for the claim that induced molting increases SE contamination of eggs and, thereby, SE illness in consumers. Comments have cited studies by Holt and coworkers that indicate that induced molting impairs the laying hens' immune systems and invites SE infection. While we agree that the previously mentioned studies have implications with regard to the health of laying hens, the studies do not address infection of eggs from these birds and, therefore, cannot be interpreted to conclude that induced molting increases SE contamination of eggs (Ref. 67).

The comments also cited studies by Holt and coworkers on the relationship between indigenous intestinal microflora and induced molting. These studies noted a difference in the kinetics of intestinal infection between molted and unmolted birds but did not link intestinal microflora to intestinal infection and did not discuss transmission of SE to eggs. Studies by Henzler and Opitz (Ref. 48) linking induced molting and rodents in the poultry house environment were cited in comments. Although research has indicated that rodents are an important factor in the epidemiology of SE in the poultry house, no evidence exists that correlates infected rodents to molting (Ref. 67).

Comments requesting that we ban induced molting cited a study by Holt (Ref. 68) linking stress in molted hens to transmission of SE within a poultry house. Possible stress during molting has been suggested as a cause for increased intestinal shedding of SE, which then increases transmission of SE within a poultry house, observed in the Holt study. However, the author of the study did not provide evidence to support the hypothesis that stress increases intestinal shedding of SE, which then increases transmission of SE within a poultry house. The author also suggested several other factors aside from induced molting that could result in increased transmission of SE to uninfected hens (Ref. 67).

The comments also cited a study by Bailey and coworkers (Ref. 69), as well as the Holt study (Ref. 68), that linked consumption of SE-contaminated feathers during molting with increased infection. Although feather consumption has been observed in molted hens, and some researchers have noted that this behavior could contribute to the spread of *Salmonella* in a poultry house, there is no evidence to suggest that the behavior is related to stress-induced colonization of SE in molted hens (Ref. 67).

According to the comments, the environment, such as crowded conditions, in which induced molting is conducted also encourages SE infection and multiplication. Although induced molting in crowded conditions may exacerbate transmission of SE, there is little or no evidence to suggest that molting in crowded conditions affects SE transmission any more than would molting or crowding independently.

The comments also cited studies by Holt (Ref. 68), by Nakamura, and by Seo and coworkers (Ref. 70) indicating that induced molting increases fecal shed of SE and that induced molting promotes horizontal transmission of SE within a poultry house. We agree that molting induced by withholding feed increases fecal shedding of SE in birds infected with SE in laboratory environments and increases horizontal transmission of SE among birds. Therefore, we question whether certain practices related to molting on a farm may be appropriate to reduce SE contamination of the environment and, thus, to decrease production of SE-contaminated eggs.

In addition to concerns we have already expressed, we note that most of the research conducted on induced molting was done in conditions that limit its applicability. Most studies have been done with single lines of specific pathogen-free chickens that have been exposed to a narrower range of microflora than commercial laying hens. Therefore, the pathogen-free chickens may be immunologically naïve and, consequently, may be more susceptible to serious infection than commercial laying hens. Studies also have been performed in controlled laboratory settings that do not accurately represent the conditions in a poultry house. Finally, molting experiments have typically relied on very high populations of a single, laboratory

modified, and propagated strain of SE. Behavior of single strains may not indicate behavior of populations of wild strains of SE.

The comments opposed to molting also have stated that field data, which was used in the SE risk assessment, from the SEPP indicated that molted birds lay more SE-contaminated eggs and, therefore, molting should be prohibited for public health reasons (Ref. 71). In addition, the comments maintained that statements made by Dr. John Mason indicated that forced molting caused increased SE-contamination of eggs.

We agree that the field data collected in the SEPP suggest a link between molting and production of SE-contaminated eggs. However, we have several concerns about the conclusiveness of these data. First, there may have been bias in sampling because flocks participating in the SEPP were chosen by producers who may have had a tendency to choose flocks that were known to be SE-positive in order to implement procedures that might change the SE status of those flocks. Therefore, these flocks may not be representative of all flocks. Second, the SEPP report indicates that the authors realized that differences in egg contamination that were being attributed to molting may also be a result of the age of the layers since only older flocks are molted. With regard to the statements made by Dr. John Mason, he has indicated that, when he made statements about forced molting causing increased SE-contamination of eggs, he was referring to information from the SEPP study and research discussed in the previous paragraphs (Ref. 72).

At this time we do not believe that we have adequate data upon which to rely for a final decision on the issue of the relationship between induced molting and SE contamination of the environment and of eggs. We know that research currently is being conducted that will address several of these data gaps. To discuss some of the research and address the data gaps, FDA sponsored an SE research meeting in Atlanta, GA, on September 8, 2000 (65 FR 51324, August 23, 2000). Ongoing research that was generated or discussed at the meeting includes projects on alternative diets for laying hens undergoing molting and an on-farm study to evaluate the effect of molting on SE in eggs.

We specifically request comment and data related to our discussion of induced molting. In view of the scientific data that suggest that molting by feed withdrawal may increase shedding of SE into the environment or eggs (Refs. 68, 70, and 71), we seek comment on the following potential prevention measures that we may consider for inclusion in any final rule: (1) The use of alternative diets to replace feed and water withdrawal to induce molting, (2) the use of competitive exclusion (defined in footnote 3 of this document) to reduce fecal shedding of SE during molting, (3) more frequent removal of manure during and immediately following molting, (4) alternative timing for environmental testing or additional environmental testing during or immediately following molting, and (5) a prohibition of molting in SE-positive houses. Depending upon the comments received, we will consider including provisions regarding molting in any final rule. These provisions may include, but are not limited to, the need for additional testing of molted flocks or restrictions on the manner in which a molt may be induced.

(Comment 5) Many comments addressed the use of vaccines for laying hens as an intervention against SE contamination of eggs. Several comments stated that vaccines against SE have been proven effective in field trials undertaken through PEQAP; flocks in the PEQAP program that were vaccinated against SE had significantly fewer environmental samples positive for SE than nonvaccinated flocks. In addition, no SE-positive eggs from a vaccinated flock were found during the 3-year study period. A few comments stated that vaccinating flocks against SE would have the most significant impact on SE prevention of any possible intervention. In addition, a few comments recommended vaccination for a flock placed in a poultry house if the previous flock in that house had a positive SE environmental test. Conversely, other comments stated that the data from the PEQAP study were inconclusive because too few flocks were included in the study.

(Response) We agree that vaccines show promise in reducing the prevalence of SE in laying hens. The PEQAP data indicate that the SE bacterin vaccines used in that program were 70 percent effective in reducing SE-positive environmental samples in flocks (Ref. 73). We find these data to be encouraging. In addition, field trials in ME showed that vaccination significantly reduced the mean fecal counts of vaccinated birds compared to nonvaccinated birds (Ref. 74). We are also aware that some existing egg QA programs require their participants to vaccinate replacement flocks that are being placed into a house that had an environmental SE-positive while the previous flock occupied that house.

However, we also agree that more information on the effectiveness of vaccines needs to be generated before we would mandate vaccination as an SE prevention measure. Although approximately 900 flocks participated in the vaccination field trials in the PEQAP study, less than 100 of those flocks were vaccinated (Ref. 73). Only seven poultry houses participated in the ME field trials, three of which contained vaccinated birds (Ref. 74).

Vaccines are also expensive and labor intensive; we estimate that vaccines cost 13.5 cents per layer, including labor (see discussion in the Preliminary Regulatory Impact Analysis in section V. of this document). Members of our national egg safety standards working group indicated that vaccines are only economically justified for heavily contaminated flocks. Since we know that cleaning and disinfection can decontaminate an SE-positive poultry house (Ref. 39), we do not believe that it is currently appropriate for the agency to propose to require that producers incur the additional cost of mandatory vaccines when cleaning and disinfection, biosecurity, and rodent and pest control may resolve the problem. We encourage producers to use vaccines in the case of persistent SE contamination within a poultry house or as prescribed by a veterinarian, but do not believe that we currently can justify mandating their use.

(Comment 6) A few comments maintained that there is no indication that feed or water has ever been associated with transfer of SE to laying hens and should not be included in the required SE prevention measures. However, one comment stated that potable water should be one of the SE prevention requirements, and several comments stated that SE-negative feed should be included in mandatory SE prevention measures.

(Response) Although we acknowledge that feed and water cannot be ruled out as potential sources of SE contamination in poultry houses, we believe provisions for feed and water are not necessary in the required SE prevention measures. We are proposing to establish minimum national SE prevention measures, and evidence of feed and water being the source of SE contamination of laying hens or shell eggs is rare.

Although SE contamination of feed has been documented by researchers, SE contaminated feed has not been implicated in the occurrence of SE in laying hens or in eggs in the United States. However, as the Layers study indicated, many producers perform

some testing of feed or feed ingredients for SE (Ref. 25). We encourage this as a general good management practice.

Water has not been directly implicated in the transfer of SE to laying hens and, therefore, we have not included it in the proposed provisions in proposed § 188.4. However, we encourage producers to ensure that their water meets the microbiological standards established by the Environmental Protection Agency for potable water.

(Comment 7) Several comments stated that routine, complete cleaning of poultry houses is not practical, particularly if the house is SE-negative. A few comments also maintained that wet cleaning and disinfection of poultry houses, while it may reduce SE, is not practical in colder months.

(Response) We agree that cleaning and disinfection of poultry houses is not warranted to reduce SE if the house is SE-negative. Although cleaning and disinfection of an SE-negative poultry house at depopulation may be prudent for the control of avian diseases, and dry cleaning and manure removal at depopulation are prudent practices in general, we do not have data and information that suggest that cleaning and disinfecting an SE-negative poultry house would reduce the incidence of SE-contaminated environments or SE-contaminated eggs. In § 118.4, we are proposing to require that, if an environmental test or an egg test is positive for SE, then you must clean and disinfect the poultry house before new laying hens are added to the house. If the environmental test is negative, then cleaning and disinfection is not needed to decontaminate the house of SE. However, we recommend manure removal and dry cleaning of poultry houses between occupation by laying flocks as a general good management practice.

We recognize that there are situations in which it may be difficult for producers to wet clean a poultry house (i.e., winter months, dirt floors). Data from a voluntary QA program (Ref. 39) and the NAHMS SE study (Ref. 27) indicate that wet cleaning is effective in decontaminating SE-positive poultry houses. However, as we discussed in section III.E.4 of this document, there are some studies in which wet cleaning may have resulted in some previously SE-negative poultry houses becoming positive. Even so, based on the totality of the information we presently have, we believe that wet cleaning results in an overall reduction in the number of SE-positive poultry houses sufficient to justify its inclusion in the required SE-prevention measures. We plan to consider comments we receive on the issue and any other new evidence before deciding whether to require wet cleaning in a final rule.

(Comment 8) One comment stated that FDA should address on-farm washing of eggs because certain producers wash eggs before they are sent to a packer/processor.

(Response) We do not agree with this comment. We are not aware that on-farm washing of eggs in an offline operation (i.e., an operation that sends its eggs elsewhere for processing for retail sale) is a widespread practice. The Layers study indicated that prewashing of eggs before processing was practiced on only 5 percent of farms (Ref. 26). We would discourage the practice unless producers follow the procedures for proper egg washing outlined by USDA in 7 CFR 56.76(e).

We request comment specifically on the prevalence of on-farm washing of eggs in offline operations. If comments indicate that prewashing of eggs on the farm is more prevalent than indicated in data the agency currently have, we may consider adding a provision for washing of eggs to the required SE-prevention measures.

(Comment 9) Several comments stated that egg testing and diversion should not be used as SE management tools and that these activities would just divert producers' attention away from practices that will reduce SE in poultry houses.

(Response) Although we agree that egg testing itself is not an SE management tool, diversion of eggs that may be contaminated with SE from the table egg market is a method of preventing consumer illness and may be considered an SE management tool. In addition, we do not agree that egg testing and diversion will divert producers' attention away from SE prevention measures. We are proposing to require egg testing only if the environmental test is SE-positive.

As stated previously, data have indicated that flocks in an SE-contaminated environment produce SE-contaminated eggs with greater than average prevalence (see comment 2 of this section). These contaminated eggs could reach the consumer and cause foodborne illness. It is an important public health precaution for a producer to begin egg testing upon finding that the poultry house environment is contaminated with SE. If egg testing reveals that SE-contaminated eggs are being produced by a flock, the eggs from that flock must be diverted to a treatment as defined in § 118.3. Diversion prevents foodborne illness that might occur had those contaminated eggs reached a consumer. Prevention of egg-associated foodborne illness is the goal of the provisions in this proposed rule. We are proposing, in § 118.6, egg testing protocols by which a producer who must divert eggs can return, after certain testing conditions are met, to producing eggs for the table egg market.

(Comment 10) A few comments stated that any requirements that mandated diversion of shell eggs to breaking facilities would be devastating to the Hawaiian egg industry because there are no egg breaking facilities in HI.

(Response) We recognize that HI presently has no egg breaking facilities to which eggs can be diverted. We will consider the status of egg breaking facilities in HI prior to issuing any final rule and seek further comment in this proposed rule on options for handling diverted eggs in HI.

(Comment 11) Many comments stated that environmental testing is appropriate to indicate whether SE prevention measures are working effectively; however, a few comments noted that other methods (e.g., egg yolk antibody testing) may prove to be equally effective as environmental testing and could also be used to gauge the effectiveness of SE prevention measures.

(Response) We agree with these comments. We have stated in the proposal that environmental testing must be used to evaluate the effectiveness of the SE prevention measures and have discussed various methods to sample manure in a poultry house. However, we have also solicited comment on alternative methods of sampling the environment that may be more uniform in different styles of poultry house than manure testing. We encourage the development of methods that are at least as indicative of SE contamination in a poultry house as manure testing and that are more rapid and less expensive.

(Comment 12) Several comments stated that any SE prevention measures required for producers should take into account regional differences in the egg industry.

(Response) We agree with the comments. In this proposed rule, we are proposing to require specific controls for SE prevention, but are not specifying the exact manner in which individual producers must comply with the provisions. Each producer must develop SE prevention measures that are appropriate for his unique situation, including regional differences. We recognize there are regional differences in the egg industry and anticipate that they will be reflected in the specific SE

prevention measures. For example, producers with different poultry house styles (e.g., open-sided versus enclosed) may choose to perform rodent control or cleaning and disinfection in different manners, as the most effective method may be differ depending on house style.

(Comment 13) A few comments requested that, if egg testing is required, the number of eggs tested be based on flock size.

(Response) We do not agree with this comment. We believe that it is reasonable to require that producers with 3,000 or more laying hens test a total of 4,000 eggs in 4 1,000-egg samples, should their poultry house be SE-positive. It is important that enough eggs be tested to achieve a certain level of assurance that SE is not present in the eggs (see discussion in section III.G.2 of this document and (Ref. 61)).

(Comment 14) Several comments requested that multiple environmental tests be required during the life of a flock to ensure that the maximum number of contaminated eggs is being diverted from consumption as table eggs.

(Response) In this proposed rule, we are establishing minimum environmental testing requirements as an indicator of the effectiveness of SE prevention measures. We do not agree that multiple environmental tests are necessary. This minimum testing requirement does not preclude producers from testing more frequently during the life of a flock. To reach the public health goal of reducing SE illnesses, we have proposed to require that producers use their resources towards implementing measures that will prevent SE contamination of eggs. These measures include use of chicks and pullets from SE-monitored breeder flocks, biosecurity, rodent and pest control, cleaning and disinfection of an SE-positive poultry house, and refrigerated storage of eggs held at a farm more than 36 hours. Testing alone does not reduce SE contamination of eggs. We believe that environmental testing can be a useful indicator of whether the SE prevention measures are working effectively. We believe one environmental test per laying cycle per flock in a poultry house is sufficient as an indicator of the efficacy of the prevention measures. (See discussion in section III.F.1 of this document.)

N. Transportation of Shell Eggs

To reach the goal of significantly reducing SE illnesses, egg safety measures must be put in place along the entire farm-to-table continuum. FDA is coordinating efforts with FSIS to cover the refrigeration of shell eggs throughout distribution. Refrigerated transport and storage of eggs packaged for the ultimate consumer and refrigerated storage of eggs at retail are already required by regulation (discussed previously in section II.D.1 of this document). In a future proposed rulemaking, FSIS may consider applying safety standards to the transport of eggs from packer to packer and from packer to egg products processing plant. In order to close any gaps in the farm-to-table continuum, FDA is seeking comment on whether to require refrigerated transport of shell eggs not already required by regulation or within USDA's jurisdiction; for example, transport of shell eggs from a farm or a packer to a food manufacturing facility. We will consider putting into place requirements similar to those we finalized for refrigerated storage of shell eggs at retail (i.e., transport of shell eggs at or below 45 °F ambient temperature).

IV. Handling and Preparation of Eggs by Retail Establishments

A. Inappropriate Handling of Raw Shell Eggs by Food Preparers

SE outbreak investigations show that outbreaks commonly occur when foods prepared with raw shell eggs are not properly handled by food preparers. Common inappropriate practices for foods containing SE-contaminated shell eggs include temperature abuse (e.g., failing to keep eggs and foods prepared with eggs refrigerated) and inadequate cooking. When shell eggs are combined to prepare a large volume of an egg-containing food which is subsequently temperature abused or inadequately cooked, these practices can cause illness in large numbers of people if any of the shell eggs were initially contaminated with SE.

Temperature abuse gives SE the opportunity to multiply, thereby increasing the number of viable microorganisms ingested, especially when eggs are consumed raw. Temperature abuse and consumption of raw shell eggs were associated with an SE outbreak at a catered wedding reception in New York, where Caesar salad dressing was implicated as the cause of SE illnesses. The Caesar salad dressing was made with 18 raw shell eggs, left unrefrigerated for 2 hours at the catering establishment, held in an unrefrigerated truck until delivered, and served at the reception 4.5 hours later (Ref. 64).

Incomplete cooking of raw shell eggs (e.g., soft-boiled, sunny-side-up, and soft-poached) also allows ingestion of viable microorganisms if any of the eggs were initially contaminated. In 1997, incomplete cooking of raw shell eggs was associated with an SE outbreak in Nevada where the consumption of Hollandaise sauce served in a restaurant was linked to SE illnesses. Review of the food handling practices showed that the sauce had been prepared from raw shell eggs that were combined, incompletely cooked, and held at room temperature for several hours before serving (Ref. 7).

We also are aware that many consumers eat foods containing raw or undercooked shell eggs. An FDA survey indicated that 53 percent of 1,620 respondents ate foods containing raw shell eggs at some time (Ref. 75). Raw shell egg-containing foods mentioned in this survey included cookie batter, homemade ice cream, homemade eggnog, Caesar salad, frosting, homemade shakes, homemade Hollandaise sauce, and homemade mayonnaise. The Menu Census Survey (1992 through 1995) (Refs. 76 and 77) showed that frosting accounted for 53 percent and salad dressing 19 percent of occasions when raw shell egg-containing products were consumed.

The 1996 to 1997 Food Consumption and Preparation Diary Survey (Ref. 77) showed that 27 percent of all egg dishes consumed were undercooked (described as being runny or having a runny yolk or runny white). On average, each person consumed undercooked shell eggs 20 times a year. Within the at-risk groups, women over 65 and children under 6 consumed undercooked shell eggs 21 times a year and 8 times a year, respectively. Moreover, consumer focus group research showed that many participants did not realize that certain foods, such as chocolate mousse or key lime pie, may contain raw or undercooked shell eggs and, therefore, are potentially hazardous (Ref. 78).

B. SE and Highly Susceptible Populations

Certain populations, such as children, the elderly, and immunocompromised individuals, are more likely to experience severe health problems from eating SE-contaminated eggs than the general population (Ref. 16). For example, CDC reported that 54 of the 79 deaths associated with outbreaks of SE between 1985 and 1998 were of individuals in nursing homes (Ref. 79). In addition, the agency found that the likelihood of dying from a foodborne illness contracted in a nursing home was 13 times higher than outbreaks in other settings. According to a U.S. General Accounting Office (GAO) survey of State regulatory officials, 24 states reported that they did not require food service operators that serve highly

susceptible populations to use pasteurized eggs for any food item that usually contains raw eggs or (2) is prepared by cracking, combining, and holding a number of eggs prior to cooking or after cooking and prior to service (Ref. 79). A 1998 Dietary Managers Association survey of 136 private nursing homes, hospitals, and other care facilities and 23 Air Force hospitals across the nation showed that 35 percent of these institutions use raw eggs to prepare batters for foods that may not be fully cooked, such as French toast (Ref. 79).

C. The FDA Food Code

As noted in section II.D.3 of this document, the FDA Food Code provides FDA's best guidance to state and local authorities and to retail industry on how to prevent foodborne illness, including special provisions for those establishments that serve a highly susceptible population. To date, 41 of 56 States and territories, representing 76 percent of the population, have adopted codes patterned after some version (1993 or later) of the FDA Food Code. Twenty-one of those States and territories (35.3 percent of the population) have adopted codes patterned after the 1999 FDA Food Code, and 2 (2.3 percent of the population) have adopted codes patterned after the 2001 version. Moreover, agencies in 11 of the 15 remaining States and territories that have not adopted a new code since 1993 are in the process of doing so, and many efforts at adoption are targeted for completion in 2003. Therefore, in 2003 and under the current system of state adoption, most state and local authorities, as well as retail industry, will be administering some aspects of FDA's best guidance as detailed in the FDA Food Code. The egg-relevant safe handling and preparation practices can be found in sections 3–202.11(C), 3–202.13, 3–202.14(A), 3–401.11(A)(1)(a) and (2), and 3–801.11(B)(1) and (2), (D)(1) and (2), and (E)(1) and (2) of the 2001 FDA Food Code.

D. Request for Comments

As noted previously, the incidence and geographical distribution of egg-associated SE illnesses have made SE a significant public health concern. As discussed in section II.A of this document, data from SE outbreaks show that outbreaks can occur when contaminated eggs are mishandled by food preparers. Furthermore, consumption data establish that some consumers, including highly susceptible populations, eat raw or undercooked eggs.

Many comments to the May 1998 ANPRM and year 2000 public meetings maintained that proper handling of shell eggs is an important measure that could reduce the incidence of foodborne illness. Some contended that we should mandate those provisions of the FDA Food Code related to egg safety. At the public meetings and in the current thinking document distributed at the July 2000 current thinking meeting, FDA presented a farm-to-table approach that proposed regulations to codify all egg-related provisions of the FDA Food Code. Given State and local government authority to manage retail food safety within their jurisdictions, FDA is now requesting comment on whether: (1) The current FDA Food Code system with State adoption and implementation achieves the desired public health outcome among high-risk populations or (2) the public health outcome for high-risk populations can only be achieved through mandatory Federal standards and, if so, how those standards would be best implemented. We consider high-risk populations to be those persons who are more likely than other people in the general population to experience foodborne disease because of the following reasons: (1) Immunocompromised, preschool age children, or older adults and (2) obtaining food at a facility that provides services such as custodial care, health care, or assisted living, such as a child or adult day care center, kidney dialysis center, hospital, or nursing home, or that provides nutritional or socialization services, such as a senior center.

If you contend that the desired public health outcome for high-risk populations can only be achieved through mandatory Federal standards, we specifically request comment on which, if any, of the following measures should be mandated for retail establishments that serve highly susceptible populations:

- Using raw eggs that are clean, sound, and meet the restricted egg tolerances for U.S. Consumer Grade B, which minimizes the entry of surface bacteria to the inside of eggs;
- Using raw eggs that have been transported under refrigeration, because refrigeration lengthens the effectiveness of the eggs' natural defenses against SE and slows the growth rate of SE;
- Using only egg products that have been pasteurized in accordance with USDA's requirements under 9 CFR 590.570, which are designed to kill or inactivate SE and other bacteria;
- Cooking raw eggs and raw egg-containing foods thoroughly, which kills viable SE that may be present;
- Substituting eggs treated to achieve at least a 5-log destruction of SE or pasteurized egg products for raw eggs in the preparation of foods, e.g., soft-boiled, poached, or sunny-side-up eggs, meringue, Caesar salad, hollandaise or Béarnaise sauce, homemade mayonnaise, eggnog, homemade ice cream, that will be served undercooked, which minimizes the risk of egg-associated SE illnesses in consumers of those foods; and
- Substituting eggs treated to achieve at least a 5-log destruction of SE or pasteurized egg products for raw eggs in the preparation of foods where eggs are combined, since combining raw eggs to prepare a large volume of food that is subsequently temperature-abused or inadequately cooked can cause illness in large numbers of people if any of the eggs were initially contaminated with SE.

If FDA were to require any of these measures, we would rely on section 361 of the PHS Act, just as we are relying on it for the requirements we are proposing in this document. (See section III.L of this document.)

E. Response to Comments Related to Retail Standards

(Comment 1) Several comments maintained that the agency should place a greater emphasis on the retail segment of the farm-to-table continuum because that is where the majority of the SE outbreaks occur, with the implicated food containing undercooked eggs.

(Response) We disagree with this comment. We do not believe that a greater emphasis should be placed on any one segment of the farm-to-table continuum, i.e., producer, packer, processor, or retail establishment. In this document, FDA is proposing requirements for the producer to produce safe eggs. As stated in section II.G of this document, FSIS will develop standards for the packer to maintain the safety of eggs, and for the processor to further enhance the safety of eggs. At retail, the FDA Food Code provides guidance on handling and preparing raw eggs to maintain or enhance egg safety. Additionally, we are seeking comment on whether we should require facilities that specifically serve a highly susceptible population to follow certain safe handling and preparation practices for raw eggs.

Most SE outbreaks occur at retail establishments because that is where the same food is served to large numbers of people. This does not mean that retail establishments cause the majority of SE outbreaks due to eggs. Rather, the cause is a combination of factors starting at the producer level, where the eggs may

become contaminated, and extending to the retail level, where inappropriate handling or preparation practices may not eliminate or minimize the impact of the contamination.

(Comment 2) Many comments supported Federally-mandated food safety education, training, and certification for retail food service managers and employees.

(Response) We agree that food safety education and training for retail food service managers and employees is necessary, and manager certification is a useful means of demonstrating food safety knowledge; however, FDA has not decided whether food safety training and certification should be Federally mandated. FDA has actively promoted industry food safety training and certification, and encouraged joint regulatory-industry-academia training initiatives.

Presently, there are a wide variety of industry management training and certification programs being offered by regulatory agencies, academic institutions, food companies, industry groups, professional associations, and third-party organizations. Most certification programs share a common desire to have the food manager certificate they issue universally recognized and accepted by others, especially by the increasing number of regulatory authorities that require food manager certification.

Certification programs vary in focus and primary mission of sponsors, organizational structures, staff resources, revenue sources, testing mechanisms, policies toward applicants and employers of food managers, and policies pertaining to such things as public information, criteria for maintaining certification, and the need for recertification. Where courses are offered, they vary in scope, content, depth and duration, quality of instructional materials, qualifications of instructors, and instructional approach (classroom, on-the-job, PC-based, home study, etc.). Where testing is a program component, varying degrees of attention are given to test construction and test administration as they relate to nationally accepted standards (reliability, validity, job analysis, subject weighting, cut scores, test security, etc.).

We believe in the utility of a mechanism for regulatory authorities to use in determining which certificates should be considered credible based on which certificate-issuing programs meet sound organizational and certification procedures and use defensible processes in their test development and test administration. Certified food protection managers are knowledgeable about the development, implementation and enforcement of specific policies, procedures, or standards aimed at preventing food borne illness. Specifically, they understand the concepts necessary for the identification of hazards, supervising or directing food preparation activities, coordinating training, and taking corrective action as needed to protect the health of the consumer. CFP recently has provided the standards and procedures necessary for the independent evaluation and accreditation of food protection manager certification programs. (The CFP, founded in 1971, is a non-profit organization designed to create a partnership among regulators, industry, academia, professional organizations, and consumers to identify problems, formulate recommendations, and develop and implement practices that ensure food safety.)

On May 28, 2002, the CFP entered into a cooperative agreement with the American National Standards Institute (ANSI) regarding the accreditation of certification bodies responsible for ensuring the food safety knowledge of all managers it certifies. (ANSI, a private non-profit organization, administers and coordinates the U.S. voluntary standards and conformity assessment system.)

On June 28, 2002, CFP published a revised version of ''Standards for Accreditation of Food Protection Manager Certification Programs.'' These standards identify the essential components a Food Protection Manager Certification Program must meet for universal acceptance of its certificates. The standards have been developed after years of CFP research into, and discussion about, Food Protection Manager Certification Programs and are based on nationally recognized principles used by a variety of organizations providing certification programs for diverse professions and occupations.

In January 2003, ANSI assumed responsibility for accrediting certification bodies based on the CFP Standards for Accreditation of Food Protection Manager Certification Programs.

FDA has developed educational materials on safe egg handling and preparation practices for food preparers and anticipates making these materials widely available to all providers of food safety training or certification services. While these materials will address safe practices specific to eggs, we believe that all retail food service establishments should ensure that their managers and employees are properly trained in general safe food practices. We recommend that all retail food service establishments follow the management and personnel provisions in chapter 2 of the FDA Food Code, specifically sections 2–101, ''Responsibility,'' 2–102, ''Knowledge,'' and 2–103, ''Duties.'' We further recommend that food regulatory officials recognize food managers who have been certified through an ANSI-accredited program as meeting the food safety knowledge requirement.''

(Comment 3) One comment called for uniform recordkeeping requirements for retail establishments to facilitate traceback and recall activities.

(Response) In the FDA Food Code, FDA recommends the implementation of HACCP, of which recordkeeping is a vital component, in food establishments because it is a system of preventive controls that is the most effective and efficient way to ensure that food products are safe. Use of a HACCP system emphasizes the industry's role in continuous problem solving and prevention rather than relying solely on periodic facility inspections by regulatory agencies.

HACCP offers two additional benefits over conventional inspection techniques. First, it clearly identifies the food establishment as the final party responsible for ensuring the safety of the food it produces. HACCP requires the food establishment to analyze its preparation methods in a rational, scientific manner in order to identify critical control points (CCPs) where food safety hazards might occur and to establish critical limits and monitoring procedures. A vital aspect of the establishment's responsibility under HACCP is to establish and maintain records that document adherence to the critical limits that relate to the identified CCPs, thus resulting in continuous self-inspection.

Secondly, as recognized in the FDA Food Code, a HACCP system allows a regulatory agency to determine an establishment's level of compliance more comprehensively. A food establishment's use of HACCP requires development of a plan to prepare safe food. This plan and associated monitoring records must be shared with the regulatory agency so that the agency can verify that the HACCP plan is working. Using conventional inspection techniques, an agency can only determine conditions during the time of inspection, which provide a ''snapshot'' of conditions at the moment of the inspection. However, when evaluating an establishment using a HACCP approach, an agency can determine both current and past conditions. When regulatory agencies review HACCP

records, they have, in effect, the ability to look back through time. Therefore, a regulatory agency can better ensure that processes are under control. ''HACCP Guidelines'' are presented in annex 5 of the 2001 FDA Food Code.

In section III.J.8 of this document, we are seeking comment on whether we should require egg producers to maintain certain records.

(Comment 4) One comment stated that the risk of illness is not significantly increased if an egg is not fully cooked.

(Response) We do not agree with this comment. As stated in section IV.A of this document, SE outbreak investigations show that outbreaks can occur when foods prepared with SE-contaminated eggs are not appropriately handled by food preparers. Practices inappropriate for foods containing SE-contaminated eggs include temperature abuse (i.e., failing to keep the eggs and foods prepared with eggs refrigerated) and inadequate cooking. Combining raw eggs to prepare a large volume of an egg-containing food that is subsequently temperature abused or inadequately cooked can cause illness in large numbers of people if any of the raw eggs were initially contaminated with SE.

As discussed in section IV.A of this document, incomplete cooking of raw eggs (e.g., soft-boiled eggs, sunny-side-up eggs) can allow ingestion of viable microorganisms, including SE, if any of the eggs were initially contaminated. In 1997, incomplete cooking of raw eggs was associated with an SE outbreak in Nevada, where the consumption of Hollandaise sauce served in a restaurant was linked to SE illnesses. Review of the food handling practices showed that the sauce had been prepared from raw eggs that were combined, incompletely cooked, and held at room temperature for several hours before serving (Ref. 7). Another outbreak of SE illness in an Indiana nursing home was linked to the consumption of baked eggs. The baked eggs were prepared by combining 180 Grade A raw shell eggs, mixing with a whisk, and baking in a single pan at (an oven temperature of) 204 °C (400 °F) for 45 minutes to 1 hour. Investigators believed that inadequate cooking occurred because the mixture was not stirred while baked (Ref. 64).

(Comment 5) One comment asked that we cover rodent control and *Salmonella* monitoring in institutional and commercial kitchens as we would for producers as part of an on-farm SE prevention plan.

(Response) We disagree with this comment. As discussed in section IV.A of this document, SE outbreak investigations show that outbreaks occur when foods prepared with SE-contaminated eggs are not appropriately handled (i.e., temperature abuse, undercooking, combining more than one egg) by food preparers. Although the retail establishment environment may be the source for some foodborne illness outbreaks, this proposed regulation focuses on the control of SE in shell eggs, based on practices on the farm. We seek comment on whether we should extend the rule to address the contamination of eggs or other foods from food service environments serving a highly susceptible population.

Furthermore, we expect that all retail establishments will make sure that their facilities are clean and sanitary and do not contribute to the contamination of food being prepared or served. Although this proposal does not address rodents or other environmental factors of retail establishments that may cause food to become contaminated, we recommend that all retail establishments follow the physical facilities provisions in chapter 6 of the FDA Food Code, specifically in subsections 6–202.15, ''Outer Openings—Protected,'' 6–202.16, ''Exterior Walls and Roofs, Protective Barrier,'' 6–501.111, ''Controlling Pests,'' and 6–501.112, ''Removing Dead or Trapped Birds, Insects, Rodents, and Other Pests.'' Of course, the retail standards contained in the FDA Food Code are additions to basic sanitation practices already established by Federal and State regulations covering rodent control and environmental hazards.

(Comment 6) One comment recommended that food handlers be periodically tested for *Salmonella*, Listeria, and *Escherichia coli*.

(Response) We disagree with this comment. As discussed in section IV.A of this document, SE outbreak investigations show that outbreaks can occur as a result of SE-contaminated eggs being inappropriately handled by food preparers, including temperature abuse (i.e., failing to keep eggs and foods prepared with eggs refrigerated), inadequate cooking, and combining two or more eggs. While food preparers may be the source for some foodborne illness outbreaks, the scope of this proposed regulation addresses the prevention of SE in shell eggs and does not extend to contamination of eggs or other foods from other sources, such as food preparers. We expect that all retail establishments will ensure that the health, cleanliness, and hygienic practices of their employees do not contribute to the contamination of food being prepared or served. Although this proposal does not require that food service workers be tested for the presence of bacteria which may cause foodborne illness, we strongly recommend that all retail establishments follow the management and personnel provisions in chapter 2 of the 2001 FDA Food Code, specifically in section 2–201, ''Disease or Medical Condition.''

V. Preliminary Regulatory Impact Analysis (PRIA)

A. Introduction

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Reforms Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this proposed rule is an economically significant regulatory action.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: an annual effect on the economy of $100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, the Office of Management and Budget (OMB) has determined that this proposed rule, if it becomes final as proposed, would be a major rule for the purpose of congressional review.

B. Need for Regulation

Private markets operating within the framework of the legal system promote the health and safety of consumers. Limitations of both the marketplace and the legal system, however, can result in inadequate control of some health and

safety hazards, and reduce societal welfare.

In a perfectly competitive market in which consumers and producers both have full information, the optimal level of production of eggs will be provided at an optimal level of safety. In the egg market, however, consumers and producers do not have sufficient information on the SE status of particular eggs. In the case of SE-contaminated eggs, the lack of awareness and information about the risk suggests that an inefficiently high demand exists for eggs that are produced without using measures to prevent SE.[3] Since the demand for eggs is not sufficiently affected by safety considerations, the farmer's incentive to invest in safety measures is diminished. Consequently, the market does not provide the incentives necessary for optimal egg safety.

With sufficient information for consumers and producers, a legal system that awards compensation for harm done due to SE-contaminated eggs has the potential to remedy market imperfections by providing producers with incentives to provide the level of safety that is best for society. The legal system does not ensure the optimum level of shell egg safety because consumers who become ill due to SE contamination often do not know the reason for or source of their illness. Even in cases where consumers are aware that their illness was contracted from eggs, imperfect information makes it difficult to determine who is ultimately responsible for their illness.

In sum, the imperfect information about the risk associated with SE from particular shell eggs means that neither the legal system nor the marketplace is able to provide adequate economic incentives for the production of SE free eggs. The government may therefore be able to improve social welfare through targeted regulation. In what follows, we will look at the costs and benefits of the provisions in the proposed rule. We will also look at the costs and benefits of other measures to control SE that we considered, but did not include in the proposed rule.

C. Economic Analysis of Potential Mitigations: Overview

We considered many possible SE prevention measures. Because of the large number of provisions considered (and the large number in the proposed rule) we begin our analysis in this section with an overview of our methods of estimating the benefits and costs of the various measures to control SE in shell eggs. In section V.D of this document, we summarize the benefits and costs of the proposed rule and some leading regulatory options. In section V.E of this document, we present the detailed analysis of all of the SE prevention measures we considered (including those in and those not in the proposed rule).

1. Measuring Benefits

a. *Modeling benefits.* The primary benefit of the provisions in this proposed rule (and the other possible measures) would be an expected decrease in the incidence of SE-related illnesses. The benefits will be calculated using the following model:

Benefits = base line risk x prevention (C_1, C_2, C_3, * * *) x value of prevention

where,

Benefits = annual health benefits realized due to this proposed rule;

base line risk = the base line level of risk facing consumers today, expressed as the number of SE cases attributable to shell eggs;

prevention (C_1, C_2, C_3, * * *) = the prevention due to the implementation of a rule with components C_1, C_2, C_3, and so on; and

value of prevention = the social cost of one representative case of salmonellosis. This cost includes medical costs, the value of lost production, and the loss of welfare the individual experiences due to pain and suffering and lost leisure time.

We write the prevention component of the benefits equation in a general functional form rather than an additive form because combinations of the proposed rule's components (C_1, C_2, C_3, * * *) will usually not result in linear, proportional reductions of risk. Instead, we assume that some components are partial substitutes for one another while others complement each other.[4] The total risk reduction will not be the sum of the individual components; the effectiveness of the rule could be less than or greater than the sum of its parts.

b. *Base line risk from SE in eggs.* We estimated the reduction in SE illnesses by applying the percentage prevention to the base line number of illnesses. We estimated the base line levels of egg contamination and the number of human illnesses that result from such contamination.

The CDC passive surveillance system recorded 5,614 illnesses due to SE in 2001. Using the CDC multiplier (used to estimate total cases based on ratio of total to reported cases) of 38, we estimated the number of illnesses due to SE to have been 213,330 in 2001.[5] Because SE is not unique to eggs, not all of the 213,330 illnesses due to SE in 2001 can be attributed to domestic shell eggs. CDC estimates that 16 percent of the cases reported were acquired outside of the United States. Consequently, the base line level of domestic SE cases is 179,200. A total of 53 percent of all SE illnesses identified through outbreak surveillance are attributable to eggs. Where a vehicle of transmission was identified, 81 percent of outbreaks and 79 percent of illnesses identified through outbreaks were attributed to eggs. The midpoint of the lower bound (53 percent) and upper bound (79 percent) estimates is 66 percent, which we assume to be the mean percent of domestic SE illnesses attributable to eggs. Using these figures we calculate a lower bound estimate of 94,980 (53 percent x 179,200), and an upper bound estimate of 141,570 (79 percent x 179,200) cases due to SE in eggs. The CDC method generates a mean point estimate, based on 2001 data, of 118,270 (66 percent x 179,200) cases for 2001.

To estimate a base line level of risk for this proposed rule, we adjust the estimated number of cases downward to account for the projected effects of the refrigeration and labeling rule, which will reduce the number of cases in the coming years. We previously estimated that the refrigeration and labeling rule will reduce illnesses from shell eggs by 15 to 20 percent. We use the higher figure to ensure against double counting, so the net result is a new expected base line of 94,620 SE illnesses attributable to eggs and likely to be affected by this proposed rule.

Table 1 of this document illustrates how we arrived at our base line.

TABLE 1.—BASE LINE EGG-RELATED *Salmonella* ENTERITIDIS (SE) CASES

2001 Passive Surveillance Cases	5,614
Multiplier	38
Estimated SE Cases in 2001	213,330

[3] Many consumers may not know that many common methods of preparing eggs for consumption will not eliminate SE in a contaminated egg.

[4] An example of substitute components would be rodent poisons and traps. By themselves rodent poisons and traps may reduce the problem of SE contamination by X percent and Y percent respectively. However, when used together the effect on SE contamination will be somewhat less than X percent + Y percent (though still higher than each component alone).

When prevention measures are complements, the total prevention from using the two measures that reduce risk by A percent and B percent separately is greater than A percent + B percent.

[5] All data for the calculations in this paragraph and the following paragraph are from Meade (Ref. 4) and CDC (Refs. 5, 6, 7, and 9).

TABLE 1.—BASE LINE EGG-RELATED *Salmonella* ENTERITIDIS (SE) CASES—Continued

Cases From Outside the United States	-16%
Estimated Domestic SE Cases	179,200
Percent of SE Cases From Eggs	
Minimum	53%
Mean	66%
Maximum	79%
Egg related SE cases in 2001	
Minimum	94,980
Mean	118,270
Maximum	141,570
Adjustment for Refrigeration and Labeling rule	-20%
Future Egg Related SE Cases	
Minimum	75,980
Mean	94,620
Maximum	113,250

c. *Measuring the health benefits from preventing Salmonellosis*. i. *The economic impact of illness from SE in eggs*. Measuring the economic impact of illness due to the consumption of SE-contaminated eggs is a critical part of our analysis. It is therefore important that we include all of the effects of SE on human health. These effects include both monetary and non-monetary losses and are both acute and chronic in nature.

Epidemiological evidence suggests that SE leads to both acute and chronic illnesses. The acute illness that accompanies SE generally causes gastrointestinal symptoms. SE illness may also result in chronic arthritis (Ref. 81). Finally, SE can result in death, especially for the immunocompromised, children, and the elderly (Ref. 80).

ii. *The consequences of SE illness*. We outline the consequences of SE illnesses in table 2 of this document. Table 2 of this document includes the medical outcomes of SE illness, the duration of conditions acquired due to SE illness, and the probability of occurrence for each condition with a given level of severity.[6]

We classify the gastrointestinal illness caused by SE illness as either mild, moderate, or severe. A mild case of SE is defined as a case that causes gastrointestinal symptoms, but is not severe enough to warrant visiting the doctor. An individual with a mild case of SE illness will be ill for 1 to 3 days. A moderate case of SE illness lasts for 2 to 12 days and is characterized as a case severe enough to necessitate a trip to the doctor or other health care professional. A severe case of SE illness results in hospitalization and typically lasts from 11 to 21 days.

TABLE 2.—CONSEQUENCES OF *Salmonella* ENTERITIDIS INFECTION

Condition and Severity	Outcome	Duration (Days per Year)	Percent of Cases
Gastrointestinal Illness			
Mild	No Physician Visit	1 to 3	90.7
Moderate	Physician Visit	2 to 12	8.1
Severe	Hospitalized	11 to 21	1.2
Arthritis			
Short-term	Waxing and Waning, Eventually Resolved	1 to 121	1.26
Long-term	Chronic Arthritis	365	2.40
Death	Death		0.04

We do not have direct estimates of the distribution of outcomes of SE illnesses separate from the outcomes of illnesses for all nontyphoidal *Salmonella*. In the absence of better information we assume that all *Salmonella* serovars will result in similar distributions of illness severity. We therefore use information that applies either to all 1,400,000 estimated annual cases of salmonellosis or to the 1,340,000 estimated annual foodborne cases of salmonellosis. Using general results for all diarrheal illnesses, CDC has estimated that 113,000 of the 1,400,000 *Salmonella* illnesses in 1997 could have resulted in physician office visits, a rate of 8.1 percent (113,000 ÷ 1,400,000) (Ref. 82). CDC also has estimated that foodborne *Salmonella* cases lead to about 15,600 hospitalizations per year, which is about 1.2 percent (15,600 ÷ 1,340,000) of annual foodborne cases (Ref. 4). We assume that the remaining 90.7 percent of gastrointestinal illness cases are mild.

SE may also result in reactive arthritis. This illness can manifest itself either as a relatively short-term bout of joint pain or as a chronic condition. Studies of outbreaks imply that short-term arthritis may last from 1 day to a total of 121 days. Chronic arthritis lasts from the time of onset until death. Overall, we estimate that 1 to 10 percent of SE infections lead to some form of arthritis. We expect two-thirds of these to be long-term and one-third to be short-term (Ref. 81).

The most severe potential result of SE infection is death. CDC estimates that 553 deaths occur due to foodborne *Salmonella* (Ref. 4). The estimate implies that about 0.04 percent (553 ÷ 1,340,000) of foodborne cases result in death.

iii. *Quality adjusted life years (QALYs)*. The benefits from this regulation will be presented in both monetary and non-monetary terms. In section V.E of this document, the benefits will be expressed in illnesses and deaths averted by each regulatory provision under consideration. In the summary of benefits due to the regulation, we present both a cost effectiveness framework (cost per illness averted and cost per QALY saved) and a monetary benefits estimation.

One approach to estimating health benefits involves the use of QALYs. QALYs can be used to measure the loss of well being that an individual suffers due to a disease or condition. QALYs do not include the value of health expenditures caused by the condition in question; we estimate health expenditures separately.[7] QALYs range from 0 to 1 where 0 is equivalent to death and 1 is equivalent to perfect health.

A number of methods have been constructed to measure QALYs. One class of methods uses surveys to ask laypersons and doctors to use a QALY scale to estimate how much someone else who is afflicted with a given symptom or condition will suffer. This direct survey approach has been used widely, partly because surveys of QALY values for a large variety of symptoms and functional limitations have been

[6] We use recent data from CDC to estimate the relative prevalence of illnesses of different severities (Ref. 82). The expected duration of illness for each category of severity is taken from Zorn and Klontz (Ref. 81).

[7] Although some QALY estimates include the value of medical expenditures, particularly QALY estimates derived from survey data, the QALY estimates used in this study do not.

published (Ref. 81). An alternative method used by Cutler and Richardson uses regression analysis to estimate the effect of particular conditions on overall health status (Ref. 83). In our analysis, we use both methods where appropriate.[8]

In table 3 of this document, we present estimates of the number of quality adjusted life days (QALDs) lost due to SE. Total QALDs lost are derived by multiplying the estimated number of QALYs lost by 365. Then, to calculate the disutility per day, or one QALD, we divide by the average duration of the illness. Like QALYs, QALDs range from 0 to 1 where 0 is equivalent to death and 1 is equivalent to perfect health. We report the loss in QALDs since most of the illnesses associated with *Salmonella* Enteritidis last days rather than years. The QALD values listed for mild, moderate, and severe cases of SE infection were estimated by Zorn and Klontz using data from Kaplan, Anderson, and Ganiats (Ref. 81). This approach calculated that the acute effects of food poisoning (vomiting, diarrhea, and general gastrointestinal illness) lead to a loss of QALDs greater than 0.5 for each day of illness. Furthermore, these lost QALDs persist for 2 to 16 days. Thus, the total loss of QALDs from gastrointestinal illness is calculated to be 1.05 to 9.99.

TABLE 3.—LOST QUALITY ADJUSTED LIFE DAYS DUE TO *Salmonella* ENTERITIDIS

Severity	Disutility per Day (QALDs Lost)				Total QALDs Lost per Illness
	Functional	Symptom	Total	Average Days Ill	
Illness					
Mild	0.44	0.08	0.53	2	1.05
Moderate	0.44	0.08	0.53	7	3.68
Severe	0.53	0.09	0.62	16	9.99
Arthritis					
Short-term	--	--	0.22	25	5.41
Long-term	--	--	0.14	18,250	2,613.12

For arthritis, we used the regression of Cutler and Richardson (Ref. 83) The regression approach yields estimates of losses per day of 0.22 for short-term arthritis and 0.14 for long-term arthritis. We estimate that short-term arthritis results in a loss of 5.4 to 10.8 QALDs while long-term arthritis results in a loss of 2,613 to 5,223 QALDs.

We do not present the estimated QALYs saved for each provision considered in this analysis. Instead, we present benefits by provision in an ''illnesses averted'' metric for each option and provision. This practice allows us to calculate cost per illness averted by each provision. In the summary we present the result of alternate valuation methods that do and do not rely on QALY estimates. Since a large portion of the loss due to chronic reactive arthritis is due to pain and suffering not associated with direct medical expenditures, it is difficult to capture the full economic loss due to SE related arthritis without using QALYs or some other measure of morbidity effects. Benefits estimates not relying on QALY estimates will necessarily be significantly lower than estimates with QALYs. The results of all methods of valuation are presented in section V.E of this document.

iv. *Valuation of SE illnesses*. Table 4 of this document illustrates how we calculate the dollar value of a typical case of SE under different assumptions. The first column of table 4 of this document lists the type of ailment. The second and third columns of table 4 of this document are taken from tables 2 and 3 of this document. The health loss per case is calculated by multiplying the value of a QALY, scaled to the value of a single day, by the actual number of QALDs lost, and then discounting where appropriate (only values of chronic cases of reactive arthritis are affected by the discount rate). The values in this column will vary depending upon the particular assumptions about the value of a statistical life (VSL), QALY, and the discount rate. The assumptions about the different values for these parameters will be discussed in a following paragraph. The fifth column of table 4 of this document shows the annual medical costs of each condition that is caused by SE infection (long term reactive arthritis is the only condition where the afflicted will incur medical costs for more than a single year). The sixth column of table 4 of this document shows the weighted dollar loss per outcome caused by SE. The probability that a case of SE infection results in a given outcome (column 2) is multiplied by the sum of the average health and medical costs per case. These results will vary depending on the economic assumptions. The weighted dollar values in column 6 are summed to calculate the total expected loss associated with a typical case of SE. We present the range of estimates of dollar losses per case in table 5 of this document.

[8] The Cutler and Richardson approach has several advantages over the Kaplan, Anderson, and Ganiats approach. However, it is not clear that this approach is appropriate for valuing acute illnesses. Therefore the Kaplan, Anderson, and Ganiats approach is used for acute illnesses and the Cutler and Richardson approach is used for chronic conditions. See Scharff and Jessup for a discussion of the pros and cons of each approach (Ref. 84).

TABLE 4.—VALUING OF A TYPICAL CASE OF *Salmonella* ENTERITIDIS[1]

Type and Severity	Case Breakdown	Total QALDs Lost per Illness	Health Loss per Case	Medical Costs per Case	Weighted Dollar Loss per Case
Illness					
Mild	90.7%	1.05	$864	$0	$784
Moderate	8.1%	3.68	$3,025	$74	$250
Severe	1.2%	9.99	$8,208	$8,500	$203
Arthritis					
Short-Term	1.26%	5.41	$4,442	$100	$57
Long-Term	2.40%	2,613.12	$592,411	$531	$14,244
Death	0.04%	18,250.00	$5,000,000		$2,143
Total Expected Loss per Case					$17,682

[1] The value of a typical case will actually vary widely depending on assumptions about the VSL, QALY, and the discount rate. These figures are based on an assumption of VSL=$5 million, QALY=$300 thousand, and a discount rate of 7%.

[2] ''Health Loss per Case'' and ''Weighted Dollar Loss per Case'' for ''Death'' are calculated using a VSL=$5 million. If we use the QALD calculation, assuming the average victim of death due to SE loses 50 years of life, the Health Loss per Case is $4.14 million and the Weighted Dollar Loss per Case is $1,773.

Cost of illness estimates usually include the medical costs associated with SE. For example, Buzby et al. produced a summary of medical and other costs for U.S. salmonellosis cases (Ref. 80).[9] The figures they estimated include the lost productivity of workers due to salmonellosis. Because we estimate lost productivity separately, we must net out these costs.

For mild SE illnesses, we assume that most persons will not obtain medical services. The cost estimated for this category chiefly reflects lost productivity (Ref. 80).

For medical costs for those who contract moderate illnesses, we use figures from Williams (Ref. 85) updated with medical cost indices (Ref. 86). In 1996, the average total cost of treatment for a nonurgent medical problem, including physician's fees and medication, was $62. We adjust these numbers to account for the increased cost of medical care since 1996. The consumer price index (CPI) for medical services rose from 227.8 in 1996 to 272.5 in June 2001.

The data for the medical cost of a severe case of SE was obtained from the Health Cost and Utilization Project's (HCUP) Nationwide Inpatient Sample (NIS) (Ref. 87). Medical costs due to arthritis are based on Zorn and Klontz (Ref. 81). Zorn and Klontz estimated that short-term arthritis medical costs were approximately $100 per case. We estimate that long-term reactive arthritis costs had a present value of $5,370 in 1992.[10] We use the CPI for medical care in general to update this cost to current dollars. Between 1992 and June 2001, the CPI for medical care rose from 190.1 to 272.5 (Ref. 86).

FDA uses a range to estimate the value of an additional year of life to reflect the uncertainty in the literature. As a lower bound, FDA uses $100,000 per (quality-adjusted) statistical life year. Cutler and Richardson (Ref. 83) use a similar estimate, and Garber and Phelps (Ref. 88) conclude that estimates of the value of a life year are about twice the level of income, though they present a broad range to reflect uncertainty associated with risk aversion and discount rates. Updating Garber and Phelps' estimates suggests that $100,000 per life year is a reasonable estimate, given that median family income in 2002 was about $51,000 (Ref. 89). Moreover, this estimate is close to the estimate used in FDA's economic analysis of the regulations implementing the Nutrition Labeling and Education Act of 1990. To reflect other underlying literature, and following suggestions from other federal agencies, we begin with an estimate of the VSL of $6.5 million. This estimate is consistent with the survey by Aldy and Viscusi (Ref. 90) on the premium for risk observed in labor markets. Annualizing this value over 35 years at 3 percent and at 7 percent discount rates implies estimates of a value of an additional year of life of about $300,000 and $500,000. Therefore, calculations for estimated benefits will reflect three estimates of the value of a statistical life year (VSLY): $100,000, $300,000 and $500,000, for both of the methods of estimating gains in life years. Total benefits differ from mortality-related benefits by including the value of reduced morbidity and health care costs. Furthermore, FDA assumes values of a statistical life of $5 million and $6.5 million. This range of VSL estimates is consistent with one reasonable interpretation of studies of willingness to pay to reduce mortality risks. (Refs. 90 and 91) FDA uses the lower value to reflect the fact that many of the estimates of willingness to pay to reduce mortality risk from papers not surveyed by Aldy and Viscusi are relatively low.

In table 5 of this document, value of a typical case of SE under different assumptions is shown.

[9] As with the CDC data above, we assume that the characteristics of SE-related illnesses are similar to those of *Salmonella* in general.

[10] This is based on the fact that in 1992 there were $64.8 billion in costs due to arthritis, 24 percent of these costs were medical costs, and there were 40 million arthritis sufferers. This yields $389 per arthritis sufferer in direct medical costs. Discounted at 7 percent, the present value of medical expenditures for 50 years with reactive arthritis is $5,370.

TABLE 5.—VALUE OF A TYPICAL CASE OF *Salmonella* ENTERITIDIS UNDER DIFFERENT ECONOMIC ASSUMPTIONS

	Discount Rate=$3%		Discount Rate=7%	
	VSL[1]=$5 million	VSL=$6.5 million	VSL=$5 million	VSL=$6.5 million
VSLY[2]=$0	$2,646	$3,289	$2,464	$3,107
VSLY=$100 thousand	$11,885	—	$7,602	—
VSLY=$300 thousand	$30,363	$31,006	$17,879	$18,522
VSLY=$500 thousand	—	$49,484	—	$28,799

[1] VSL means value of a statistical life.
[2] VSLY value of a statistical life year.

The expected value of a typical case of SE varies greatly depending on the assumptions. The values when the QALY is taken out of the calculation are, as expected, the lowest, ranging from $2,464 per case to $3,289 per case. These values do not account for pain and suffering, which are a large part of the economic loss associated with chronic arthritis. The highest expected value for a case of SE, $49,484, occurs when we assume a VSL of $6.5 million, a QALY of $500 thousand, and a discount rate of 3 percent. The average of all of the values is $17,254 per case. This most closely corresponds to the assumption set where VSL = $5.0 million, QALY = $300 thousand, and the discount rate = 7 percent, which produces a value of $17,879 per case.

d. *Other benefits.* Pathogens other than SE have been associated with eggs. In particular, *Campylobacter* (Ref. 92) and non-SE *Salmonella* (Ref. 14) have been found on the shells of eggs. The presence of pathogens on the eggshell may be harmful to humans if one of two scenarios occurs. First, under certain conditions, pathogens may migrate through the shell of the egg to infect the egg's contents (Ref. 93). Second, eggshell contamination could result in the contamination of egg contents if eggs are broken in such a way that the shell of the egg comes into contact with the contents of the egg (Ref. 93).[11] Current USDA washing and sanitizing standards are designed to reduce pathogens on the exterior of the egg. Also, pathogen migration is unlikely given current USDA standards and industry practices.[12] Consequently, we do not expect benefits from the reduction of illnesses due to pathogens other than SE to be large.

2. Measuring Costs

The measurement of costs is relatively straightforward. We measure costs based on the best available information from government, industry, and academic sources. Furthermore, we assume that total costs are typically the sum of the costs of individual provisions. What this assumption means is that, unlike benefits, the cost of one provision is generally independent of the cost of other provisions. Where economies of scope with respect to SE mitigation exist, we adjust the costs downward to account for the economies.[13]

3. Coverage of the Analysis

We estimate costs and benefits of potential prevention measures for all farms that produce eggs for distribution in retail markets. Because the proposed rule exempts very small farms (<3,000 layers) from all provisions, wherever the data permit we calculate costs and benefits separately for both very small farms and for larger farms (>3,000 layers). The separation of costs and benefits by size of farm allows us to estimate the total costs and benefits of the proposed rule, as well as the total costs and benefits of regulatory alternatives that do not necessarily exempt very small farms. In addition, calculating what the proposed rule would cost very small farms allows us to measure the regulatory relief provided by the exemption for very small farms. Farmers who sell all of their eggs directly to consumers are exempt from all provisions. Sales of eggs directly to consumers include sales of a farmer's own eggs to neighbors, at farmers markets, and at roadside stands. Farms that sell their eggs to another person for distribution or resale are not assumed to be exempt from the listed provisions. We do not anticipate any control measures for farms that sell all of their eggs directly to consumers, so we exclude them from the analysis.

We estimate that approximately 4,100 farm sites with roughly 8,600 poultry houses may be covered by some or all parts of the proposed rule. These figures are calculated as follows:

- We used the NASS 1997 Census of Agriculture to determine the number of farm sites with layers on hand. NASS estimated that there are 69,761 farms with layers over 20 weeks old in their inventory (Ref. 22).
- Next, we adjusted for the fact that a large portion of farms with fewer than 3,000 layers either sell their eggs directly to the consumer or do not sell their eggs at all. We estimated that, of the approximately 64,800 farms with fewer than 3,000 layers,[14] over 33,800 of these farms sell their eggs, but not directly to the consumer.[15]
- NASS data suggested that 82 percent of layers are table egg layers (Ref. 98). For those farms with more than 3,000 layers, we adjusted the estimated number of farms affected by the NASS estimate. The resulting estimated number of farm sites is illustrated in the first column of table 6 of this document.
- The estimated number of houses per farm site is broken down by size

[11] The use of centrifuges would cause this to occur.

[12] Most modern egg washing machines are spray-washers (63 FR 27502 at 27505, May 19, 1998). Migration of SE through the eggshell is more commonly associated with immersion washing (Ref. 94).

[13] Where economies of scope with regards to SE mitigation occur, we observe that the incremental cost of one provision decreases with the implementation of another provision. For example, if rodent control decreases the chance of SE detection through environmental testing, we would expect the amount (and the cost) of follow up egg testing to decline.

[14] The NASS Census of Agriculture uses farms with 3,200 birds as its cutoff point for categorization. FDA uses 3,000 birds as its cutoff point for small versus large farms, because this is the measure that is used in other egg and poultry regulations. To adjust the NASS data, FDA assumes that all flocks are uniformly distributed across the 400 to 3,200 bird category. Using this assumption, 7.1 percent (200 ÷ 2,800) of these farms fall in the over 3,000 bird category while the remaining 92.9 percent fall in the small farm category.

[15] Based on assumptions that the expert members of the egg safety action group did not disagree with, we have calculated that approximately 2,860 farms sell eggs via retail channels other than farmers markets, roadside stands, and neighborhood sales (Refs. 95, 96, and 97). Many of the remaining 61,940 very small farms sell their eggs to consumers indirectly at roadside stands or farmers markets (Ref. 97). In the absence of better information, we assume that half of those remaining 61,940 very small farms sell eggs indirectly to consumers.

category in table 6 of this document. We used data from the 1999 Table Egg Layer Management in the U.S. Survey (Refs. 25 and 26) to estimate the number of houses per farm site for those farms with more than 3,000 layers.[16] For those farms with fewer than 3,000 layers, we assumed that there is only one house per farm site.

• We calculate the total number of poultry houses that will be affected by this rule by multiplying the adjusted number of farm sites by the expected number of houses per farm site. As table 6 of this document demonstrates, the majority of the houses are on farm sites with fewer than 3,000 layers.

TABLE 6.—FARMS POTENTIALLY COVERED BY THE PROPOSED RULE

Farm Size (No. of layers)	Adjusted No. of Farm Sites	No. of Houses Per Site	Total No. of Houses
Less than 3,000	33,824	1.0	33,824
3,000 to 19,999	2,337	1.4	3,155
20,000 to 49,999	940	1.4	1,317
50,000 to 99,999	359	2.4	861
100,000 or more	443	7.4	3,279
Total Potential Coverage	37,903	1.1	42,435

D. Summary of Costs and Benefits of Regulatory Options and the Proposed Rule

In this section of this document, we summarize the costs and benefits of the proposed rule and the regulatory options. In section V.E of this document, we provide a detailed analysis of the costs and benefits of all of the SE prevention measures we considered, both those in and those not in the proposal.

We considered a number of regulatory options that may be used to prevent the problem of SE in eggs, including no new regulatory action, classification of SE-positive eggs as restricted or SE-positive, HACCP, the proposed rule, more extensive on-farm prevention measures, less extensive on-farm prevention measures, and retail prevention measures.

1. No New Regulatory Action

One possible alternative to the proposed rule is to rely on current Federal, State, and industry efforts to control SE in shell eggs. These efforts include relying on an FDA final rule for labeling and refrigerating shell eggs, FDA educational programs, and the growth of membership in State and industry quality assurance programs. We believe these methods of control, while valuable, are unable to fully address the problem of SE contamination of shell eggs.

FDA issued a related rule designed to help prevent the growth of SE in eggs by requiring refrigeration of shell eggs at retail and requiring shell egg labeling (65 FR 76092, December 5, 2000). As part of that rule, we set refrigeration temperatures to reduce the potential growth of SE inside shell eggs at the retail level, and required safe handling instructions on all cases and cartons of shell eggs. We expect that the consumption of undercooked and raw eggs will decline as a result of that rule. Nevertheless, labeling and refrigeration standards do not prevent or limit the growth of SE while eggs are in production.

FDA also is pursuing a program designed to inform consumers about microbial hazards in egg preparation. The nationally distributed Fight BAC! program targets children in schools and television audiences with a more general food safety message that likely results in better egg handling practices. Again, this program, while useful, does not prevent the initial contamination of eggs with SE.

Several of the large egg producing States and industry groups have encouraged producers of eggs to follow on-farm practices aimed at mitigating SE in their flocks. One of the first States to implement a structured quality assurance program was Pennsylvania. Though voluntary, the Pennsylvania Egg Quality Assurance Program has been accompanied by a significant decrease in SE-related illnesses in those areas where eggs from Pennsylvania are marketed. Industry groups also have drawn up quality assurance plans as guidelines for their members to follow. The voluntary programs have achieved some success in reducing SE contamination in eggs, and the more comprehensive plans contain many preventive measures similar to those in this proposed rule (Ref. 99). These voluntary programs have now been in operation for many years and are well-known throughout the industry. Although the State and industry programs are potentially effective, many producers choose not to participate. As data from CDC show, SE illnesses continue to be associated with shell eggs even in those areas where voluntary programs are in place. Option 1, relying on current Federal, State, and industry efforts to control SE in shell eggs, will be used as a baseline for the rest of the analysis.

2. Classification of SE-Positive Eggs as Restricted or SE Positive

FDA considered the option of labeling eggs that are diverted to breaker plants (called ''breakers'') from an SE-positive flock with a label similar to the USDA ''restricted'' label or with a ''SE positive'' label. The advantage of requiring a label would be that high-risk eggs would be identified and could not be resold in the table egg market.

The economic loss associated with labeling eggs as either ''restricted'' or ''SE positive'' would be very high, as is illustrated in table 7 of this document. It has been estimated that eggs labeled SE positive will be discounted up to $0.08 per dozen at breaker plants. The price received for restricted eggs at the breaker plant is equivalent to the price received for checked eggs.[17] Restricted eggs generally command a price that is

[16] Data from the Layers study are used throughout this document. We acquired the data either directly from the NAHMS Web site or through direct correspondence with Lindsey Garber, Centers for Epidemiology and Animal Health (CEAH), Veterinary Services (VS), APHIS, USDA.

[17] Checked eggs are eggs with minute fissures in their eggshells. These eggs generally command less of a price in the breaker market because they are more likely to break in transit and are more susceptible to contamination.

$0.13 to $0.14 less per dozen than do nest run eggs.

We believe that the pasteurization process used at breaker plants is sufficient to largely eliminate any threat from SE-positive eggs. As long as eggs sent to the breaker plant are subjected to pasteurization, the benefits from requiring eggs from an SE-positive flock to be labeled are insignificant. We rejected the option of labeling eggs from an SE-positive flock because the public health benefits of labeling these eggs likely would be small and the cost of doing so would be very high.

TABLE 7.—EGG PRICES[1]

(PRICE PER DOZEN EGGS)

Region	Regional Weight (in %)	Shell Egg Price to Producer	Breaking Eggs		Cost of Diversion	
			Nest Run	Checks And Undergrades[2]	Nest Run	Checks and Undergrades
North Atlantic	17.0	$0.42	$0.31	$0.17	$0.11	$0.26
North Central	68.4	$0.39	$0.30	$0.17	$0.09	$0.22
South Atlantic	4.3	$0.43	$0.31	$0.17	$0.12	$0.26
South Central	5.1	$0.47	$0.30	$0.17	$0.17	$0.30
West	5.2	$0.55	$0.31	$0.17	$0.25	$0.39
Average Cost of Diverting Eggs[3]					$0.13	$0.24
Additional Discount for SE+ Eggs[4] $0.00 to 0.08						$0.00
Total Cost of Diverting Eggs $0.13 to 0.21						$0.24

[1] See section V.F.2 of this document for a full description of the derivation of this table.
[2] Data on the price received for checks and undergrades is from the Poultry Yearbook (Ref. 100).
[3] The average cost of diverting eggs is weighted by regional production (Ref. 98).
[4] SE-positive eggs are intrinsically less valuable than other eggs because they are limited in how they may be used.

3. HACCP

We could require that a HACCP system be implemented on layer farms. Although the general sanitation and hazard control measures in the proposed rule contain some HACCP-like features, the agency has not defined and is not ready to mandate HACCP on farms. HACCP requires the science-driven identification of critical control points throughout production. The technological knowledge needed to identify critical control points for eliminating SE from shell eggs, however, is incomplete. In addition, HACCP is most appropriate in situations where there are many chemical, physical, and microbiological hazards to control. In this proposal, we are concentrating only on the microbiological hazard of transovarian SE, a subset of the hazards that might be covered under HACCP.

4. The Proposed Rule

The proposed rule (as described in the previous paragraph) includes the following requirements for farms with more than 3000 layers that do not have all of their eggs treated or sell all of their eggs directly to consumers: Rodent and pest control, biosecurity, cleaning and disinfecting, use of SE-monitored chicks and pullets, testing and diversion, records of testing and diversion, and refrigeration.

The benefits from the SE prevention measures in the proposed rule would take time to be fully realized, but the costs would be more immediately incurred. Table 8 of this document shows the initial costs and illnesses averted and the eventual costs and illnesses averted of the proposed rule.[18] Following are the detailed calculations underlying table 8 of this document, in section V.E of this document.

TABLE 8.—ANNUAL COSTS AND ILLNESSES AVERTED OF THE PROPOSED RULE

	Costs	Illnesses Averted	Cost per Illness Averted
Initially			
Interest Rate = 7%	$84,000,000	22,132	$3,795
Interest Rate = 3%	$79,000,000	22,132	$3,569
Eventually			
Interest Rate = 7%	$82,000,000	33,452	$2,451
Interest Rate = 3%	$77,000,000	33,452	$2,302

[18] The interest rate is used here to annualize the costs of refrigeration equipment, plan designs, and training. For simplicity, subsequent summary tables will only include figures reflecting the interest rate of 7 percent. Those interested in the total cost number reflecting a 3-percent interest rate should subtract roughly $5 million from the calculations performed with a 7-percent interest rate. The exact difference is shown in section E.1.i of this document, describing the costs and benefits of the refrigeration option, and section E.2, describing the costs of administrative measures.

5. More Extensive On-Farm SE Prevention Measures

FDA could issue a proposed rule that provides the following information: (1) Does not exempt farms with fewer than 3,000 layers from any provisions and (2) includes more on-farm provisions than those in the proposed rule. Additional on-farm provisions include requiring training, the use of SE-negative feed, and vaccinating flocks against SE. We could also require record keeping for all provisions, rather than only for sampling, testing, and diversion.

The option of more extensive controls leads to total eventual costs of $243 million and eventual expected number of illnesses averted of 33,604 (the cost-effectiveness of each additional provision is calculated separately and presented in table 33 of this document and in the analysis of on-farm prevention measures in section V.E of this document). This approach increases costs by over $160 million, while only increasing the number of illnesses averted by about 150 cases, for a marginal cost-effectiveness of more than $1 million per additional illness averted. The main reason for the small increase in benefits relative to costs is that much of the increase in costs comes from adding farms with fewer than 3,000 layers. The large number of such farms (over 33,000, as shown in table 5 of this document) means that requiring them to comply with all provisions of the proposed rule would greatly increase costs. These farms, however, account for less than 1 percent of egg production, so requiring them to comply with all of the SE prevention measures would have a small effect on the volume of shell eggs that could be contaminated with SE. In addition, including these very small farms likely would result in the cessation of egg production at a large number of farms. For these reasons, FDA has decided not to pursue this option.

6. Less Extensive On-Farm SE Prevention Measures

We could also require fewer controls than the proposed rule. Several provisions could be combined to provide a less extensive set of controls than in the proposed rule. Many of the prevention measures could be put forth as stand-alone regulations. We have not presented each of these prevention measures as a separate option, but the reader can see the individual effects of the various on-farm prevention measures in table 28 (see section V.E of this document). As documented in table 28 of this document, the various individual measures would, by themselves, generate lower net benefits than the integrated program outlined in the proposed rule.

7. Retail SE Prevention Measures

FDA examined the possibility of including a retail component in the proposed rule. In particular, we have qualitatively examined the costs and benefits of applying certain SE prevention measures to establishments that specifically serve highly susceptible populations. Those measures include using only eggs that are clean, sound, contain no more restricted eggs than the proportion allowed in U.S. Consumer Grade B, and have been transported at an ambient temperature of 45 °F or below. Other measures that could apply to establishments serving highly susceptible populations, but for which we lack data, include thoroughly cooking raw eggs and raw egg-containing foods, and substituting pasteurized eggs or egg products for raw eggs in the preparation of foods where eggs are combined or served undercooked.

At present, we do not have adequate information to accurately estimate the total costs and benefits of all the retail measures. Nevertheless, we have estimated that more than 130,000 retail establishments would be affected by the retail provisions we examined. We ask for comment regarding the costs and benefits of retail prevention measures.

E. Benefits and Costs of Potential SE Prevention Measures: Detailed Analysis

In this section, we describe the SE prevention measures we considered, including provisions that were not included as proposed requirements or that were only required for certain producers in the proposed rule. For example, we calculated costs and benefits for SE prevention measures, such as rodent control and biosecurity, for producers with fewer than 3,000 layers, but these measures would not be required of such producers in the proposed rule. In addition, FDA looked at a number of administrative requirements designed to support the direct SE prevention measures. Finally, we calculated the total costs and benefits for the provisions in the proposed rule.

We examined a number of on-farm measures, which includes the following measures:

- Rodent and pest control,
- Biosecurity measures,
- Cleaning and disinfecting of layer houses between flocks,
- The use of SE monitored chicks or pullets,
- The use of SE negative feed,
- Vaccinating flocks against SE,
- Refrigeration of eggs,
- Layer house environmental testing,
- Followup egg testing, and
- The diversion of SE positive eggs.

For each of the on-farm measures previously discussed, we estimated the costs of the following administrative measures: registration, training, plan design, and recordkeeping.

Finally, FDA considered retail provisions to help prevent illness from SE positive eggs. The retail provisions would cover retail establishments that specifically serve highly susceptible populations.

1. On-Farm SE Prevention Measures

a. *Interdependence of on-farm measures.* Rodent control, pest control, biosecurity and cleaning and disinfecting all have a role in eliminating SE in the poultry house. Although the actions taken under each heading may be distinct, the effects of each action are related. For example, a biosecurity plan may include provisions to limit standing water and high grass in areas adjacent to the poultry house. Although categorized as biosecurity measures, these practices also help control both rodents and pests. Similarly, cleaning and disinfecting removes not only SE, but also rodents and pests.

This interdependence means that the efficacy of on-farm controls cannot be determined by adding the effects of each provision (as determined by studies that focus on each provision separately). The measurement difficulty arises for two reasons. First, as mentioned earlier, when two practices substitute or complement one another, the efficacy of the first practice is affected by the introduction of a second. Second, a simple comparison of farms that use a given practice with farms that do not use that practice is insufficient in measuring the effectiveness of the practice in question. The use of one good practice tends to be positively correlated with the use of other good practices and therefore a simple comparison between farms will overstate the effectiveness of the practice. For example, those houses that use the best rodent control practices are also likely to be using other SE controls as well, so a measure of rodent control effectiveness is likely to pick up the effects of good biosecurity, pest control, and cleaning and disinfecting practices. On the other hand, a simple farm to farm comparison of practices that are correlated with prevalence may understate the effectiveness of the practice. For example, a group of farms may have practices in place because

they are part of a voluntary SE plan, which in turn may have been put in place in areas with higher than average prevalence. In this case the practices would appear to be correlated with higher than average prevalence.

b. *Organization of economic analysis of potential provisions.* FDA has considered a number of on-farm SE prevention measures. The provisions that we considered are examined below. We have included some, but not all, of these provisions in the proposed rule. The costs and benefits of the provisions included in the proposed rule are summarized in table 35 in section V.F of this document.

c. *Control of rodents and other pests.*

i. *Rodent and pest control provisions.* One potential rodent and pest control provision is a requirement that each layer house be under a rodent and pest control program. Such a program could include the use of traps or poisons to reduce rodents and other pests. A provision also might require that each farm have a written rodent and pest control plan and that rodent and pest control records be kept to verify that the program is accomplishing its goals.

ii. *Current industry practices—rodent and pest control.* Most farms currently address rodent and pest control problems to some extent. However, if SE-positive eggs are required to be diverted, there will be a financial incentive to find ways to prevent SE in poultry houses. As a result, the effectiveness of rodent and pest control in eliminating SE in the poultry house will lead many farms to institute rodent and pest control programs that are more stringent than those currently in place.

Currently, 99.2 percent of all commercial farms with more than 30,000 layers use some form of rodent control, but not all methods of rodent control are compatible with the goal of eliminating SE in poultry houses. In particular, we believe that biological predators such as cats should not be used as a method of rodent control because cats can be vectors for SE contamination.

Table 9 of this document illustrates, by farm size, the number of programs of rodent control that would satisfy the provisions in the proposed rule. Farms that do not use rodent controls as specified in this provision (e.g., many farms primarily use cats as a rodent control measure) are counted as having unacceptable rodent control programs. Based on data from the Layers study (Refs. 25 and 26), we estimate that the number of farms with inadequate rodent control programs will range from 1.8 percent for farms with over 100,000 layers to 21.0 percent for farms with 20,000 to 49,999 layers.[19] Furthermore, we believe that the potential costs of diversion of SE-positive eggs will encourage farmers currently using a level of rodent control that would satisfy the proposed provision to increase their rodent control efforts.[20] Without better information about the number of farms that would increase rodent control efforts, we assume the true number will lie between 0 percent and 100 percent of those currently using an acceptable level of rodent control.

TABLE 9.—RODENT CONTROL

Farm Size (No. of layers)	Unacceptable Rodent Control (in %)	No. of Farms With Unacceptable Rodent Control	No. of Farms Increasing effort
Less than 3,000	50.0%	16,912	8,456
3,000 to 19,999	18.8%	439	949
20,000 to 49,999	21.0%	197	371
50,000 to 99,999	3.8%	14	172
100,000 or more	1.8%	8	218
All Farms		17,570	10,166

We assume that between 25 percent and 75 percent of very small farms (those with fewer than 3,000 layers) are using an acceptable level of rodent control.

Pests, other than rodents, commonly found in poultry houses include flies, mites, beetles, and ants (Ref. 101). For the purposes of this provision, however, we chiefly are interested in the presence of flies and fly control because they have been implicated in the transmission of *Salmonella* (Ref. 102).

The survey used to develop the Layers study asked questions about on-farm fly control practices (Refs. 25 and 26). Using these data, we estimate that over 90 percent of those farms with over 3,000 layers use some form of fly control. Some of these methods, however, should not be used. In particular, we do not suggest the use of biological predators, such as wild birds, for fly control since these predators may themselves be vectors for SE transmission (Ref. 102).

[19] Our primary source for on-farm practices related to SE prevention measures is the Layers study (Refs. 25 and 26). As the only major current survey of the industry, this study has provided us with data that has allowed us to characterize the industry. The study, however, does not fully represent the industry. A total of 526 farm sites responded to the first part of the survey and 252 responded to the second part of the survey. Furthermore, only operations with more than 30,000 layers were included in the survey. Consequently, we had to approximate the practices of smaller farms based on a limited amount of information. Nonetheless, the Layers study has added greatly to our understanding of the industry and its practices.

[20] This conclusion assumes that there will also be a testing and diversion component to the proposed rule. If the proposed rule does not include a testing and diversion component, it is unlikely that farms with an acceptable testing and diversion program would increase rodent control efforts beyond what is required, because the incentive to avoid diversion would not be present.

TABLE 10.—FLY CONTROL

Farm Size (No. of layers)	Unacceptable Fly Control (in %)	No. of Farms With Unacceptable Fly Control	No. of Farms Increasing effort
Less than 3,000	50.0%	16,912	8,456
3,000 to 19,999	26.9%	629	854
20,000 to 49,999	17.5%	165	388
50,000 to 99,999	11.8%	42	158
100,000 or more	21.7%	96	173
All Farms		17,844	10,030

Table 10 of this document shows the number of farms with unacceptable (not sufficient to satisfy the proposed rule) programs of fly control. We assume that farms that do not use fly control or that use biological predators, such as birds, as their primary method of fly control are not using acceptable methods. We estimate that a total of 17,844 farms are using unacceptable methods of fly control.

The actual number of farms that are using unacceptable methods of fly control is likely to be higher than the estimates in table 12 of this document would suggest. The mere fact that a particular method is used does not automatically guarantee that it is used at its optimal level. As with rodent control, even farmers in compliance with the proposed provision would be likely to increase their use of fly controls. We assume that between 0 and 100 percent of farms using acceptable fly control methods will increase their fly control efforts. Consequently, an additional 10,030 farms will increase their fly control efforts.

iii. *Costs of rodent and pest control.*[21] We estimate the cost of rodent and pest control to farms in table 11 of this document. We assume that a farm with an adequate rodent and pest control program will be using a number of control measures.

Included in the cost of rodent control are the cost of setting up and maintaining bait stations and the cost of rodent indexing. The annual cost of rodent control ranges from $30 for the average farm with less than 3,000 layers to $4,970 for the typical farm with over 100,000 layers. The costs of limiting rodents' access to feed and patching holes in the walls of poultry houses are not included in our estimates.

Pest control measures include the cost of sprays, baits, fly monitoring, and manure pit fans. We expect the annual cost of pest control to range from $110 for farms with less than 3,000 layers to $63,500 for farms with more than 100,000 layers.

TABLE 11.—COST OF RODENT AND PEST CONTROL

(IN THOUSANDS)

Farm Size (number of layers)	Rodent Control		Pest Control		Total
	Unacceptable Controls	Increased Effort	Unacceptable Controls	Increased Effort	
Less than 3,000	$501	$125	$1,905	$476	$3,008
3,000 to 19,999	$241	$260	$2,355	$1,600	$4,456
20,000 to 49,999	$133	$125	$1,125	$1,326	$2,709
50,000 to 99,999	$15	$93	$544	$1,016	$1,667,
100,000 or more	$40	$541	$6,102	$5,507	$12,187
All Farms	$929	$1,144	$12,031	$9,922	$24,027

The total cost of rodent and pest control, as expressed in table 11 of this document, is found by multiplying the cost per farm by the number of farms affected, as illustrated in tables 9 and 10 of this document. For those farms that are already using acceptable rodent and pest control methods, but that will increase their rodent and pest control efforts, we estimate that the cost of rodent and pest control will be approximately half of the cost of farms with unacceptable controls. This provision would result in costs of $3.0 million for farms with less than 3,000 layers and costs of $21.0 million for farms with over 3,000 layers.

iv. *Benefits of rodent control.* Rodent control appears to be effective in controlling SE. As a critical vector, rodents may spread SE throughout a given poultry house and between houses. Rodents spread the disease through their droppings, which often are consumed by layers. In this section of this document, we merge

[21] All cost estimates in this section are from data supplied to the FDA through a contract with Research Triangle Institute. Derivations of estimates are described more fully in a memorandum to the record (Ref. 103).

epidemiological data with estimates of the current level of rodent infestation on farms to assess the benefits from increased rodent control.

We used the Layers study (Refs. 25 and 26) to determine the magnitude of the rodent problem on farms. The first four rows of table 12 of this document show the percentages of farms in four size categories with four severities of mouse or rat infestation.[22] Table 12 shows that larger farms are generally more likely to experience moderate or severe rodent problems. The greater prevalence in the larger houses means that, while only 17 percent of houses have moderate or severe rodent problems, 33 percent of all layers are currently in houses with moderate or severe problems.[23]

TABLE 12.—SEVERITY OF RODENT PROBLEM

	Severity in %				No. of Houses in Category
	Severe	Moderate	Slight	None	
Farm Size (No. of Layers)					
<20,000	0.0	14.8	81.7	3.5	36,979
20,000 to 49,999	9.1	13.2	70.1	7.6	1,317
50,000 to 99,999	1.2	28.4	52.3	18.1	861
100,000 or more	1.5	32.1	60.1	6.3	3,279
Percent of Houses Affected	0.5	16.9	78.7	3.8	.....
Percent of Layers Affected	2.9	31.4	60.2	5.5	.....
Risk Ratio	4.2	3.1	2.1	1.0	Total
Percent of Layers in Houses with Positive Environments	19.2	14.3	9.5	4.6	11
Maximum Expected SE Reduction from Increased Rodent Control[1]	38.1	34.0	25.8	0.0	27.3

[1] These values are calculated using the following equations:
Severe: [(19.2 - 4.6) ÷ 2] ÷ 19.2 = 38.1%.
Moderate: [(14.3 - 4.6) ÷ 2] ÷ 14.3 = 34.0%.
Slight: [(9.5 - 4.6) ÷ 2] ÷ 9.5 = 25.8%.
None: [(4.6 - 4.6) ÷ 2] ÷ 4.6 = 0.0%.

Henzler examined the link between rodents and SE, and found that environmental tests of manure in houses with large rodent populations were 4.2 times more likely to be positive for SE than similar tests in houses with small rodent populations.[24] We assume that the risk ratio for SE can be linearly extrapolated between 1 for those farms with no rodent problem and 4.2 for those farms with a severe rodent control problem. This extrapolation is presented in table 11 of this document along with the estimated level of rodent infestation for farms of different sizes.

The third section of the Layers 99 study (Ref. 27)[25] supports the Henzler study. The Layers study finds that farms with a rodent index of at least 20 mice have an SE prevalence rate of 10.1 percent, while farms with a rodent index of less than 20 mice have a prevalence of SE of only 2.0 percent.[26] This difference is statistically significant.

Using data from the Henzler study, we estimated the base level of environmental SE prevalence for houses without rodent problems to be 4.6 percent when the overall prevalence of SE-positive houses is 11 percent. We calculated the base as Base = Overall ÷ [(prevention$_{SEV}$ x Birds$_{SEV}$) + (prevention$_{MOD}$ x Birds$_{MOD}$) + (prevention$_{SLT}$ x Birds$_{SLT}$) + (prevention$_{NON}$ x Birds$_{NON}$)]; where Base is the base level of prevalence for a rodent free house; ''Overall'' is the total prevalence for all houses; ''prevention'' is the risk ratio for each level of rodent infestation; and ''Birds'' is the percentage of layers in houses with a given rodent problem. The subscripts SEV, MOD, SLT, and NON refer to the cases of severe, moderate, slight, and no rodent problems. The percentage of layers in houses with environments positive for SE is found by multiplying the SE risk ratio times the base level of risk. Again, houses with severe rodent control problems are 4.2 times more likely to be positive for SE than houses with no problems (19.2 percent versus 4.6 percent).

In the last row of table 12 of this document, we estimate the expected reduction in SE due to increased rodent control. If rodent control were wholly effective, we would assume that it would result in a drop in SE from current levels to 4.6 percent, the level associated with no rodent problem. For a severe rodent infestation, rodent control would therefore result in a 76.2 percent decline in SE, but such a large decline is not likely for most farms. Those farms with a rodent control problem probably have a problem partly because of factors not experienced by those farms without a problem. House design (open walls, dirt floors, and other

[22] Severity level is self-assessed by respondents to the survey.

[23] To determine the percent of houses affected, the percent of farms with a given rodent problem was weighted using the number of houses in each size category. The number of birds affected was determined by weighting the percent of farms with a given rodent problem in each size category by the number of birds in each size category.

[24] A total of 84 flocks were examined in Pennsylvania (Ref. 48).

[25] The third part of the Layers study (Ref. 27) provides estimates for the prevalence of SE on 200 farm sites with different management practices. For many of the variables analyzed, however, the sample size was too small for statistically significant differences to be measured.

[26] The standardized rodent index is calculated as (number of rodents trapped) x (7 ÷ number of days) x (12 ÷ number of functional traps).

The index standardizes the number of rodents trapped to the equivalent of having 12 traps function for 7 days (Ref. 27).

features), unfavorable location (near other rodent-infested entities, climate, and so on), and lack of knowledge regarding proper rodent control techniques are likely to diminish the effectiveness of rodent control. Consequently, we assume that the effectiveness of rodent control for a particular farm will be uniformly distributed between no reduction and reduction to an SE risk of 4.6 percent. Overall, this leads to an estimated average 27.3 percent reduction in SE, as shown in table 12 of this document.

Based on information from the egg industry, we believe that rodent control may take up to 4 years to be fully effective. During the 4-year transition period, we assume that the effectiveness of rodent control will average 13.7 percent, half of the eventual effectiveness.

We use the base line number of SE cases due to eggs and the value of a typical case of salmonellosis to estimate the value of rodent and pest control benefits. For farms with fewer than 3,000 layers a rodent and pest control program would result in benefits of 71 illnesses averted initially and 142 cases averted eventually at a cost of $58,450 per case averted. For farms with more than 3,000 laying hens, the benefit from rodent and pest control increases from an expected 12,853 illnesses averted initially to 25,701 illnesses averted eventually at a cost of $1,390 per illness averted.

The narrow definition of rodent control is limited to direct methods of catching, killing, and blocking rodents from entering a poultry house. Measures such as pest control, biosecurity, and cleaning and disinfecting also affect rodent control. Cleaning and disinfecting a house, when done properly, removes rodents and their nests from an infested house. Similarly, biosecurity makes rodent penetration of a house more difficult. As a result, the benefits estimated for rodent control are partly due to the adoption of other measures that may be required. We therefore believe that the expected effect of rodent control by itself (assuming no other control measures) would be smaller than our estimates suggest.

v. *Benefits of pest control.* Pests other than rodents also have been shown to be vectors in the spread of SE. In particular, Davies and Wray showed that the ingestion of SE-contaminated maggots by a chicken protects *Salmonella* from the stomach acids of the chicken and aids in the establishment of SE in the chicken's gut (Ref. 102).[27] Beetles and wild birds have also been implicated in the transmission of SE (Ref. 102). Wild birds currently have access to layer feed troughs on 23.5 percent and flies on 91.3 percent of farms (Refs. 25 and 26).

Despite the high prevalence of pests other than rodents on farms, most farms do attempt to limit their presence. Approximately 82 percent of farms currently use fly control methods other than the use of biological predators (Refs. 25 and 26).[28] As with rodents, the effectiveness of fly control is limited by the characteristics of the farm. Farms that operate in damp climates and that are not able to seal their facilities against pests (many houses have dirt floors and open walls) are likely to have more difficulty reducing infestation of all pests.

The third section of the Layers study (Ref. 27) illustrates the effect of pest control. On those farms in which pests have access to feed storage sites, the prevalence of SE is estimated to be 9.6 percent. For farms on which pests do not have access to feed in storage, the prevalence of SE is only 5.8 percent.

vi. *Other benefits of rodent and pest control.* The rodent control provisions are expected to decrease the rodent population in poultry houses. Since rodents consume large amounts of feed, this reduction will benefit producers by lowering their feed costs.

The Cooperative Extension Service of Oklahoma State University estimates that each rat in a poultry house consumes $2.18 worth of feed annually (Ref. 104). Since mice eat 5 to 10 percent as much as rats (Ref. 101), the expected annual loss of feed for each mouse in a house is estimated to cost $0.11 to $0.22.

The upper bound of the savings from increased rodent control due to this provision is the cost of implementing the rodent control measures. In the absence of mandated rodent control, an informed producer will use a level of control that maximizes profits. Any increased rodent control that leads to feed savings in excess of the cost of the control program already will have been implemented before the implementation of a quality assurance program.

We estimate that an infested house may have over 1,000 mice (Ref. 48). This infestation will cost a farmer approximately $165 for that house (1,000 ' $.165). A house infested with rats may have as many as 700 rats (Ref. 105). In this case, the infestation costs the farmer $1,526 (700 ' $2.18).

TABLE 13.—FEED SAVINGS FROM RODENT CONTROL

Problem	Rodents in a House	Feed Savings Per House	% of Houses[1]	Houses in Classification[2]	Cost to Houses in Classification
Mice					
Severe	1,000	$165.00	2.4	114	$18,800
Moderate	500	$82.50	25.5	1,212	$100,000
Slight	250	$41.25	62.4	2,966	$122,300
None	0	$0	9.7	461	$0
Rats					
Severe	700	$1,526.00	1.6	76	$116,000
Moderate	350	$763.00	6.9	328	$250,200
Slight	175	$381.50	43.7	2,077	$792,300

[27] See also Olsen (2000) (Ref. 49).

[28] Use of biological predators is not seen as an effective pest control technique because the predators may themselves become a vector for SE transmission.

TABLE 13.—FEED SAVINGS FROM RODENT CONTROL—Continued

Problem	Rodents in a House	Feed Savings Per House	% of Houses[1]	Houses in Classification[2]	Cost to Houses in Classification
None	0	$0	47.8	2,272	$0
Total Cost of Rodents					$1,399,700
Expected Savings from Control (Assumes 50% reduction)					$699,850

[1] The percentages are from the Layers study (Refs. 25 and 26).
[2] Because rodent populations are estimated for large houses only (over 54,000 layers), we estimate the number of houses to be the number of large house equivalents. This implies that two 27,000-bird houses are counted as one house in this analysis.

The total feed savings from rodent control are illustrated in table 13 of this document. If rodent control leads to just half of all rodents being eliminated, the savings in lost feed from rodent control are estimated to be almost $700,000 annually.

d. *Biosecurity*. i. *Biosecurity provisions*. We have examined the effects of several potential biosecurity provisions. These include the following effects: (1) Limiting visitor access; (2) avoiding the movement of contaminated equipment between poultry houses; (3) ensuring that employees are hygienic; (4) keeping stray poultry, birds, and other animals away from the layer houses; and (5) prohibiting employees from keeping poultry at home.

The first biosecurity measure we examine is the limitation of visitors' access on poultry farms. Limiting a visitor's access may include prohibiting a visitor from entering a house on one farm if that person has already entered a house on another farm. Also, visitors may be banned from entering poultry houses altogether.

Contaminated equipment can also spread SE on a farm. One way to mitigate this problem is to ensure that equipment that is used in multiple houses (such as forklifts and manure removing equipment) is kept clean.

The hygiene of persons moving between houses affects the likelihood of cross-contamination. To protect against cross-contamination, farms may require that employees and visitors use footbaths, change their clothing, or use protective clothing when on the farm. Farms also may choose to require that their employees work on only one farm site on a given day.

Stray poultry, birds, and other animals must also be kept away from the farm's grounds and facilities. This may be done keeping grass and weeds cut, minimizing the existence of standing pools of water near the house, and fencing off the farm site.

Finally, biosecurity precludes employees of the farm from keeping poultry at home.

ii. *Current industry practices; biosecurity*. Most farms already practice some form of biosecurity.[29] According to the Layers study, 68.1 percent of farms do not allow non-business visitors and 22.1 percent do not allow business visitors into layer houses. Of those that do allow visitors to enter, 65.6 percent have biosecurity rules for non-business visitors and 69.5 percent have biosecurity rules for business visitors.

Farms use different methods to keep employee, contract crew, and visitor hygiene at an acceptable level. The Layers study estimates that 24.5 to 24.6 percent use footbaths, 3.9 to 4.8 percent require showers to be taken, and 17.6 to 32.0 percent require persons to change clothes or wear coveralls.

Many farms use biosecurity measures aimed at keeping stray poultry, birds, and other animals away from the layer houses. While data on the number of farms that trim grass and discourage standing pools of water are not available, the Layers study did estimate that fencing is currently used at 26.7 percent of farms.

Finally, 75.7 percent of farms do not allow employees to keep their own layers at home.

iii. *Costs of biosecurity*. It is difficult to quantify many of the costs of biosecurity. This is especially true because the biosecurity measures may be implemented in different ways, allowing each farm to adapt the measures to their operation, as appropriate. However, a few of the costs can be quantified.

First, the cost of limiting visitors can be estimated as the cost of monitoring and providing protective clothing to visitors who are allowed on the farm. The cost of monitoring visitors includes the cost of posting signs asking visitors to check in, the cost of having visitors sign in, and the cost of accompanying visitors around the farm. Protective clothing costs $78.75 for a box of 25 disposable coveralls and $105.38 for a box of 200 plastic shoe covers (Ref. 106). Because farms will choose to implement this part of biosecurity in different ways, it is impossible to determine what the actual cost will be.

The cost of cleaning contaminated equipment is uncertain because we do not know how individual farmers will choose to do this. In our analysis, we assume that the amount of equipment that needs to be kept clean increases linearly with the number of houses on a farm. In particular, we assume that a farm with two houses requires 1 hour of cleaning per week, a farm with three houses requires 2 hours, and so on. Using data from the Layers study, we find that the average farm with more than 3,000 layers will devote 69 labor hours annually to cleaning equipment. At a labor rate of $8.84 per hour, doubled to include overhead costs, the total expected labor cost of this provision is $1,210 per farm, or $5.0 million for all farms with more than 3,000 layers. We expect that there will be little or no cost for farms with fewer than 3,000 layers because the vast majority of these farms have only one layer house.

The cost of chlorine footbaths also can be estimated. We calculate the cost of a footbath as the sum of the cost of the plastic vessel, the cost of bleach, and the cost of the labor needed to fill footbaths. We estimate the total cost per house on farms with more than 3,000 layers to be $420 per year.[30] Houses with fewer than 3,000 layers generally are very small and will need only one footbath. As a result, the cost per house for farms with fewer than 3,000 layers would be $210. Because only 24.6 percent of houses currently use footbaths, the total annual cost of footbaths is estimated to be (100 - 24.6 percent) x 8,612 houses x $420 per house = $2.7 million. We assume

[29] All data in this section are from the Layers study (Refs. 25 and 26).

[30] This estimate is based on the following assumptions: (1) The plastic vessel costs $5 and is replaced annually; (2) bleach costs $1 a gallon, a gallon is used per footbath, and it is changed once a week; (3) there are two footbaths per house; (4) labor costs $8.84 an hour (Ref. 107) and is doubled to include costs of overhead; and (5) changing the bleach-water mixture takes 10 minutes. The estimate in the text is calculated as 2 x ($5 + $1 x 1 x 52 + $17.86 x 0.67 x 52) = $420 per year.

that an insignificant number of farms with fewer than 3,000 layers use footbaths. Therefore, the cost to these very small farms is $7.1 million (33,824 houses x $210 per house).

Employee biosecurity also includes the cost of using protective clothing when moving between houses. As noted above, the cost of plastic coveralls is $78.75 per box of 25, and the cost of plastic shoe covers is $105.38 per box of 200. Because employees will only wear these garments under certain conditions, it is impossible to precisely estimate the annual cost to a farm. We assume that the cost of protective clothing increases linearly with the number of houses on a farm. In particular, we assume that a farm with two houses will use one coverall and two shoe covers per day, a farm with three houses will use 2 coveralls and 4 shoe covers, and so on. If only one coverall and two shoe covers are used per day because of this provision, the annual cost would be $1,534 per farm (365 x ($78.75 ÷ 25 + $105.38 ÷ 100)). The average cost for a farm with more than 3,000 layers would be $2,027. We estimate that the total cost of protective clothing would be $8,268,400 for farms with more than 3,000 layers. We do not foresee that employees on very small farms will use protective clothing because cross-contamination of SE-positive flocks with SE-negative flocks is unlikely (most small farms have one flock), and the cost of protective clothing is relatively high for these producers.

Finally, the cost of keeping stray poultry, birds, and other animals away from poultry houses already is accounted for under rodent and pest control costs. The estimated cost for a complete rodent and pest control program includes all biosecurity measures that contribute to rodent and pest control.

There are potentially significant costs that we have not included here. These include the cost of creating barriers (such as fences) to keep stray poultry and wildlife from entering a layer house.

The total measured costs of biosecurity provisions are $16.0 million for farms with 3,000 or more layers and $7.1 million for farms with fewer than 3,000 layers.

iv. *Benefits of biosecurity*. The importance of biosecurity in the reduction of disease transmission is well established.[31] For example, the Layers study (Ref. 27) estimates that farms allowing non-business visitors onsite are five times more likely to test positive for SE than farms that ban such visitors. Farms allowing non-business visitors have a prevalence of SE of 17.0 percent while farms that do not only have an SE prevalence of 3.6 percent. We include the benefits from biosecurity with those of rodent control, because the effects cannot be estimated separately.

e. *Cleaning and disinfecting*. i. *Cleaning and disinfecting provisions*. Specific cleaning and disinfecting provisions include the removal of all visible manure, a dry clean followed by a wet clean of the house, and disinfecting of the house.

ii. *Current industry practices; cleaning and disinfecting*. To a large extent the layer industry already performs adequate cleaning and disinfecting procedures. For larger houses, the Layers study (Refs. 25 and 26) estimates that, at some point, manure is removed from 100 percent of houses, 80.5 percent of houses are dry cleaned, 53.6 percent of houses are wet cleaned, and 65.1 percent of houses are disinfected. The prevalence of these practices on large farms is illustrated in table 14 of this document.

TABLE 14.—CURRENT CLEANING AND DISINFECTING PRACTICES FOR LARGE FARMS

	Manure Removal (%)	Dry Clean (%)	Wet Clean (%)	Disinfect (%)
Between each flock (cleaned annually)	96.6	79.4	30.6	44.5
After two or more flocks (cleaned occasionally)	3.4	1.1	23.0	20.6
Never	0	19.5	46.4	34.9

We assume that smaller farms are likely to remove manure and dry clean at the same rate as larger farms. The likely economies of scale for wet cleaning and disinfecting houses, however, imply that the cost per square foot wet cleaned or disinfected would be higher for small farms than for larger farms. The cost of hiring someone to complete the job includes the cost of travel time, overhead, and the cost of setting up equipment. Farmers may find it economical to rent or buy equipment. When this occurs, the farmer's labor hours expended on cleaning and disinfecting are likely to be higher than that of trained professionals.

iii. *Costs of cleaning and disinfecting*. The cost of cleaning and disinfecting houses with more than 3,000 layers is illustrated in table 15 of this document. For each component of cleaning and disinfecting, we estimate the annual cost as the number of houses that this provision will affect each year times the cost per house. We calculate the number of houses affected as the product of the percent of houses not using a practice (100 minus the percent using the practice in table 15 of this document), the probability of a positive flock, and the number of houses with 3,000 or more layers (8,612, calculated from data in table 6 of this document).

TABLE 15.—COST OF CLEANING AND DISINFECTING HOUSES WITH 3,000 OR MORE LAYERS

	Houses Using Practice (%)	Probability of a Positive Env. Test (%)	No. of Houses Affected	Cost Per House	Cost to Industry
Dry Clean	79.8	8.4	146	$1,054	$154,090

[31] A number of State extension services have written extensively about the importance of biosecurity (Refs. 108, 109, and 110).

TABLE 15.—COST OF CLEANING AND DISINFECTING HOUSES WITH 3,000 OR MORE LAYERS—Continued

	Houses Using Practice (%)	Probability of a Positive Env. Test (%)	No. of Houses Affected	Cost Per House	Cost to Industry
Wet Clean	38.3	8.4	446	$5,750	$2,564,834
Disinfect	51.4	8.4	351	$513	$180,094
Total Cost					$2,899,018

The percentages of houses engaged in the different cleaning and disinfecting practices (the first column of numbers in table 15 of this document) is based on the first two rows of table 14 of this document. In table 15 we calculate the percent as CA + (CO x PC), where CA is the percent of farms that are cleaned and disinfected annually, CO is the percent of farms that are cleaned and disinfected occasionally, and PC is the probability that a farm that is cleaned occasionally would have been cleaned in a year that it had a positive environmental test. We assume that PC is distributed uniformly between 0 and 0.667, with a mean value of 0.333. CA and CO are taken directly from table 14 of this document.

The per-house cost for each component is taken from Morales and McDowell (Ref. 111). We assume that the true cost of each component is distributed uniformly between the low and the high estimates given.

We show the cost of cleaning and disinfecting separately for farms with fewer than 3,000 layers in table 16 of this document. For the reasons stated above, we assume that it will be more economical for small farmers to do their own cleaning and disinfecting, as opposed to hiring professionals.

TABLE 16.—CLEANING AND DISINFECTING COSTS FOR FARMS WITH FEWER THAN 3,000 LAYERS

	Dry Clean	Wet Clean	Disinfect
Equipment Cost	$10	$90	$0
Chemical Costs	$0	$30	$100
Labor	$141	$283	$71
Cost per House	$151	$403	$171
Percent of Houses Affected	1.7%	6.8%	6.2%
No. of Houses Affected	574	2295	2109
Total Cost	$86,674	$924,885	$360,639

For each category of cleaning and disinfecting we have estimated the equipment, chemical, and labor costs of performing the task. We value labor at the average hourly wage for livestock and poultry workers, $8.84, doubled to include overhead costs (Ref. 107).

Dry cleaning is a necessary precursor to wet cleaning. In this stage of the process, loose dirt, cobwebs, rodent nests, organic matter, litter, and feed are removed from the house. Equipment needs include brooms, shovels, wheelbarrows, and other implements. We assume that farms already will have these types of equipment but may need to pay for protective clothing and masks. We estimate that it will take a day of labor to dry clean a small house.

Wet cleaning is more complicated than dry cleaning. The first step of wet cleaning is to cover all sensitive equipment in the house (such as lighting and any other electrical appliances) with plastic. Next, a pressure washer (in conjunction with an acceptable detergent) is used to thoroughly clean the cages and walls of the house. We assume the pressure washer will be rented for 3 days. Finally, standing pools of water are expelled from the house and the house is left to dry. We assume that 2 days worth of labor will be required to complete a wet clean on a small house.

In the final stage, a disinfectant is sprayed throughout the dried house (or the house may be professionally fumigated). We assume that this will take only a half of a day worth of labor for a small farm.

We assume that the probability of a positive flock is the same for all size farms (8.4 percent). We also assume that the percent of houses that would be affected by the drying cleaning provisions would be the same for farms with fewer than 3,000 layers as for farms with 3,000 or more layers: The percent not dry cleaning multiplied by the probability of a positive flock ((1 - 0.798) x 0.084). Small farms are less likely to wet clean and disinfect; we assume that the percentage of farms with fewer than 3,000 layers not using those practices is uniformly distributed between the percentage of farms with 3,000 or more layers not using those practices and 100 percent. We therefore estimate that 81 percent of farms with fewer than 3,000 layers do not wet clean and 74 percent do not disinfect houses. We multiply these estimates by the probability of a positive flock to estimate the percentage of small farms affected by the wet cleaning and disinfecting provisions.

To estimate the number of farms with fewer than 3,000 layers that would be affected by dry cleaning, wet cleaning, and disinfecting provisions, we multiply the percentage affected by each provision by the number of such farms (33,824). For each practice, dry cleaning, wet cleaning, disinfecting, we multiply the costs per house by the number of houses affected. We then sum the results to estimate the total costs of

cleaning and disinfecting houses on farms with fewer than 3,000 layers. The total increased cost of cleaning and disinfecting on these very small farms would be about $1.4 million.

iv. *Benefits of Cleaning and Disinfecting.* Cleaning and disinfecting is another tool that may decrease or eliminate SE in an infected house. Schlosser et al. estimate that cleaning and disinfecting a house reduces, by 50 percent, the probability that a previously infected house will test positive (Ref. 39). Because cross-contamination is not addressed in this study, the 50 percent reduction is likely to be an overestimate of the actual efficacy of cleaning and disinfecting. Furthermore, the same study estimates that 28 percent of negative houses tested positive after cleaning and disinfecting.

The Layers Report (Ref. 27) finds that farms that are cleaned and disinfected are less likely to be contaminated with SE. No surveyed farms that performed wet washes of houses between flocks were found to be positive. By contrast, houses that neither wash nor fumigate between flocks had SE prevalence rates of 12.2 percent. These results suggest that cleaning and disinfecting a layer house is negatively correlated with SE prevalence.

f. *SE-Monitored chicks and pullets.* i. *Chick and pullet provisions.* We also considered the provision that farmers obtain their chicks or pullets from an SE monitored breeder flock.[32]

ii. *Current industry practices—SE-monitored chicks and pullets.* According to the Layers study (Refs. 25 and 26), 94.6 percent of farm sites representing 94.5 percent of layers received their chicks from flocks that were bred under the NPIP program. Furthermore, NPIP has successfully integrated all of these layers into the NPIP U.S. *Salmonella* Enteritidis monitored program (Ref. 112).

NASS estimates that a total of 138,292,380 pullets and chicks were sold in 1997 (Ref. 22). If 94.5 percent of these birds were purchased from breeder facilities that are NPIP SE monitored, then 5.5 percent (7,606,080) of chicks and pullets are not currently monitored for SE.

iii. *Costs of SE-monitored chicks and pullets.* We do not have data for the cost of monitoring chicks for SE. However, Morales and McDowell (Ref. 111) estimated that pullets monitored for SE cost approximately $0.003 to $0.02 more per pullet. If we assume the cost difference is the same for chicks, the total increased annual cost of requiring SE-monitored chicks is estimated to be $22,820 to $152,120 with a mean expected value of $87,470.[33] If we assume that all farms would be proportionally affected by this provision, the approximate annual cost to farms with fewer than 3,000 layers would be $500, and the annual cost to farms with 3,000 or more layers would be $87,000.

iv. *Benefits of SE-monitored chicks and pullets.* The prevalence of SE in breeder flocks is relatively low.[34] Between 1994 and 1996 only 9 out of 847 breeder flocks (1.1 percent) had environments that tested positive for SE. Furthermore, over the same period only two breeder flocks (0.2 percent) had layers that tested positive for SE.[35] For our estimate of benefits, we used the 0.2 percent figure because breeders under the NPIP program must destroy their flocks when layers test positive, not when the environment tests positive.

The 0.2 percent estimate understates the probability that a farm not currently using NPIP SE-monitored layers will test positive. To the extent that farmers obtain their chicks from multiple sources,[36] we would expect the probability that a farm obtains SE-positive chicks to be greater than the underlying prevalence of SE in hatchery flocks.[37]

We calculated the expected benefit of this provision using the percentage of farms affected by the provision multiplied by the probability of a positive test. Because only 5.5 percent of farms receive birds from breeder flocks that are not SE monitored, the expected effect of this provision on SE contamination on the farm and, hence, human illness, is projected to be slightly greater than 0.01 percent (5.5 percent x 0.2 percent). This percent translates into an expected benefit of less than one case of SE per year averted at farms with fewer than 3,000 layers, and 10 illnesses averted for farms with 3,000 or more layers. The cost per illness averted is $8,960 for farms with fewer than 3,000 layers and $8,410 for farms with more than 3,000 layers.

This provision attempts to bar the introduction of SE onto the farm. SE can be difficult to control once it has been introduced onto a farm, but if SE is never introduced, it is impossible for it to spread. For this reason, effective SE control in chick populations has been cited as critical.

g. *SE-Negative feed.* i. *Feed provisions.* We considered proposing to require the use of feed that meets the standards for SE-negative feed, as defined by FDA's Center for Veterinary Medicine (CVM). CVM defines SE-negative as 10 subsamples that are negative for SE (measured using the Bacteriological Analytical Manual method) collected for a lot of feed (60 FR 50098, September 28, 1995). Composite samples may be used to reduce testing costs. We received comments that SE-negative feed is not currently available commercially.

ii. *Current industry practices—SE monitoring of feed.* The layer industry obtains feed from both independent feed mills and from egg farmers that produce feed in their own mills. The Economic Research Service (ERS) report on the feed manufacturing industry estimates that egg producers operated a total of 144 feed mills in 1984 (Ref. 114). In the absence of more recent data, we assume that they operated the same number in 2002. To isolate the number of independent feed mills operating in the United States, we used the July 2000 version of Dun's Market Identifiers (Ref. 115). Using this database, we were able to isolate 210 mills that primarily produce poultry and chicken feeds. We consider this figure to be the lower bound of the number of independent feed mills producing layer feed. For the upper bound, we assume that all 2,459 establishments that Dun's Market Identifiers reports as producers of animal feeds produce layer feed.[38] This estimate is similar to the 1984 Economic Research Service estimate of 2,432 primary feed manufacturers. Assuming that the true number of feed mills producing layer feed is uniformly distributed between the upper and lower bounds, we estimate that approximately 1,300 feed mills produce layer feed.

iii. *Costs of monitoring feed for SE.* The cost of this provision to a feed mill would be the sum of the labor, laboratory, and shipping costs for testing, multiplied by the number of lots

[32] NPIP certified or the equivalent.

[33] If monitoring costs $0.003 per layer, the total cost is 7,606,080 layers x $0.003 = $22,820. If monitoring costs $0.02 per layer, the total cost is 7,606,080 layers x $0.02 = $152,120. The average of these two figures is $87,470.

[34] The data for this paragraph is drawn from Rhorer (Ref. 113).

[35] Under the NPIP program a flock only loses its certification as a NPIP SE-monitored flock if birds test positive.

[36] The Layers study estimates that 38.2 percent of farms obtain pullets from multiple sites (Refs. 25 and 26).

[37] The following example illustrates this point. If a farmer obtains pullets from two different flocks, each of which has a 0.2 percent chance of having SE positive birds, the probability that the farm will obtain SE positive birds is 0.2 percent + 0.2 percent - 0.04 percent = 0.36 percent.

[38] The lower bound estimate is likely to underreport the number of mills producing layer feed because most firms did not report to Dun's Market Identifiers what kinds of feeds they produced.

tested. In addition, SE-positive feed would have to be treated or destroyed.

The laboratory cost per test has been estimated to be approximately $49.75 per sample.[39] In addition, we estimate that the collection and preparation of each subsample will take approximately 10 minutes. Given an hourly wage of $14.65 for production inspectors at grain and feed mills (Ref. 117), doubled to include overhead costs, we estimate the cost of labor to be $48.84 ($29.30 x 1.667 hours) for each full sample. The cost of shipping each sample to a lab is estimated to be $22.[40] The total cost per composite sample is $121.47 ($49.75 + $48.84 + $22.88).

Samples must be taken for each lot of feed. We expect that, because of limited storage space for finished feed, a lot of feed will not exceed 3 days worth of production for most large mills. For some small mills, however, a lot may be a week's worth of production; for some large mills a lot may be a day's worth of production. Given these parameters, we assume that the frequency of feed testing will be distributed uniformly between once a week and five times a week with a mean frequency of 3 times a week. Consequently, the expected annual cost of testing for a typical feed mill is calculated to be approximately $18,950 ($121.47 per sample x 52 weeks x 3 times a week). The cost of testing all of the approximately 1,450 entities that produce feed is estimated to be $27.5 million. If these costs are passed on to farmers at a rate proportional to the number of layers on the farm, the total cost to farms with fewer than 3,000 layers would be $137,500 and the cost to farms with more than 3,000 layers would be $27,362,500.

In the event of a positive feed test, feed mills would have to treat or destroy the suspect feed. It is also likely that the mill would take action to address the problem at its source. Furthermore, any feed that the mill has shipped would be considered adulterated. The mill would have to recall this feed and treat or dispose of it, which could be very costly. If, however, an SE positive lot were identified through testing, this provision would result in increased benefits.

iv. *Benefits of monitoring feed for SE.* Feed contaminated with SE is theoretically also a vehicle for the introduction of SE on the farm. In 1997, SE was found in 0.3 percent of finished feed samples that were serotyped in the United Kingdom (Ref. 119). In the United States, however, testing for SE in finished layer feed at the mill has almost never yielded positive results.[41] Nonetheless, the fact that SE has been isolated from finished feed at mills in the United Kingdom and from feed ingredients suggests that SE contamination is a potential problem (Ref. 102).

If feed is contaminated with SE, the consequences for human health are potentially large. A feed mill that does not test feed for SE and becomes contaminated with SE could deliver a large number of shipments of contaminated feed before the problem is uncovered. The potential financial consequences to the farms using the feed include costs due to increased cleaning and disinfecting, egg testing, and diversion of eggs. Also, there likely would be adverse health effects from the consumption of SE-positive eggs.

h. *Vaccination of flocks.* i. *Vaccination provision.* Inoculating layers with vaccines is another potential way of preventing the growth of SE in layers. FDA could mandate that all layers be inoculated against SE.

ii. *Current industry practices; vaccination of flocks.* The Layers study (Refs. 25 and 26) estimates that at least 14.6 percent of all layers on farms with 3,000 or more layers are vaccinated against SE. We assume that an insignificant number of layers on farms with fewer than 3,000 layers are vaccinated against SE.

iii. *Cost of vaccinating flocks.* Vaccination costs approximately $0.135 per layer for an inoculation[42] (Ref. 121). Given 255.5 million layers on larger farms and 1.4 million layers on smaller farms, we expect that this provision would result in 218.0 million new vaccinations on larger farms and 1.4 million new vaccinations on smaller farms. Consequently, the cost of vaccination on farms with at least 3,000 layers would be $29.3 million. The total cost for farms with fewer than 3,000 layers would be $0.2 million.

iv. *Benefits of vaccinating flocks.* The evidence regarding the efficacy of vaccines in reducing SE in laying hens is mixed. Gast et al. showed in an experimental setting that vaccines do partially reduce the shed of SE from laying hens (Ref. 122). By contrast, Davison et al. used a field experiment to show that vaccines are relatively ineffective in stopping the spread of SE on farms (Ref. 123).

v. *Refrigeration.* i. *Refrigeration provisions.* We considered a refrigeration provision that all eggs held for more than 36 hours after lay be refrigerated at a maximum ambient temperature of 45 °F.

ii. *Current industry practices; refrigeration.* Because eggs packed on the farm do not have to be transported to a packing plant, we assume that eggs on these farms are packed for sale within 36 hours of lay. Accordingly, we assume that this provision would impose additional costs only on those farms that do not pack their eggs for the ultimate consumer, are currently storing their eggs for longer than 36 hours, and currently do not refrigerate their eggs at an ambient temperature at or below 45 °F. We use data from the Layers study (Refs. 25 and 26), shown in table 17, to determine the percentage of farms affected by the on-farm storage temperature requirements.

TABLE 17.—FARMS AFFECTED BY ON-FARM EGG STORAGE TEMPERATURE REQUIREMENTS

Farm Size (No. of Layers)	Packed Off-Farm (%)	Stored Longer Than 36 Hours (%)	Temp >45 Degrees F (%)	Percent of Farms Affected	No. of Farms Affected
Less than 3,000	100.0	100.0	81.2	81.2	27,465
3,000 to 19,999	98.3	98.2	78.1	75.4	1,762

[39] This is the cost of an Association of Official Analytical Chemists test for *Salmonella* genus and a serotype test at Silliker Laboratories (Ref. 116). One option that mills have is to initially test for the genus of *Salmonella* ($19.75) and then, if the test is positive, follow through with a test for the serotype enteritidis ($30). We assume that mills will not choose this option because *Salmonella* positive feed is considered adulterated and firms will not want to test to see if their feed is adulterated unless mandated to do so by FDA.

[40] The cost of shipping a 2-pound package overnight in the United States ranges from $18.00 to $27.75. These figures include a $3 pick-up charge. The average charge is estimated to be $22.88 (Ref. 118).

[41] SE has been isolated in ingredients at feed mills in the United States (Ref. 120).

[42] This is based on a per layer cost of $0.035 for vaccine plus $0.10 for labor (Ref. 121).

TABLE 17.—FARMS AFFECTED BY ON-FARM EGG STORAGE TEMPERATURE REQUIREMENTS—Continued

Farm Size (No. of Layers)	Packed Off-Farm (%)	Stored Longer Than 36 Hours (%)	Temp >45 Degrees F (%)	Percent of Farms Affected	No. of Farms Affected
20,000 to 49,999	96.3	100.0	75.8	73.0	686
50,000 to 99,999	83.1	83.4	92.1	63.8	229
100,000 or more	65.6	75.0	72.6	35.7	158
Total	81.2	87.3	81.2	57.6	30,300

The first three columns of table 17 of this document are taken directly from data collected for the Layers study. The percentage of farms affected (fourth column) is the product of multiplying the first three columns. The number of farms affected (final column) is estimated by multiplying the percent of farms affected by this provision by the total number of farms covered by the provision.

It is clear from the percentages of farms affected (fourth column) that temperature requirements are more likely to affect smaller farms than larger farms. For those farms with fewer than 3,000 layers, we assume that all eggs are packed off the farm,[43] all are stored for more than 36 hours, and 81.2 percent (the average for all other categories) are stored at a temperature higher than what is required for the provision.[44]

iii. *Cost of refrigeration.*[45] The refrigeration provision will cause producers to choose to perform the following tasks: (1) Turn down the thermostats in their coolers, (2) install new refrigeration, or (3) renegotiate their shipping contracts to require more frequent pickup of unpacked eggs.

In table 17 of this document, we estimate that a total of 30,300 farms do not meet the standards set by the refrigeration provision. Of these farms, some are currently using refrigeration, albeit at higher temperatures than the proposed provision would permit. Others do not have any refrigeration installed on their farms. We assume that those farms that report storing their eggs between 45 and 60 °F already have refrigeration installed. For these farms, the cost of complying with the refrigeration provision is simply the cost of increasing electricity usage to further cool their eggs. For farms that store their eggs at a temperature greater than or equal to 60 °F, we assume that no refrigeration is currently installed. The cost to these farms includes the cost of installing an insulated egg room with refrigeration units.

In table 18, we use data from the Layers study to determine how many covered farms will have to install refrigeration and how many will only have to reduce the temperatures in their egg rooms. The majority of smaller farms lack refrigeration facilities, while larger farms are more likely to use refrigeration at an inadequate level.

The cost of this provision to farms that are using refrigeration at an inadequate level is assumed to be the cost of increased energy usage.[46] If temperatures in egg rooms on these farms are uniformly distributed between 45 and 60 °F, the average needed temperature reduction is 7.5 °F. If the electricity rate is $0.09 per kilowatt-hour, farms will spend between $23 for farms with fewer than 100 layers to over $2,200 for farms with more than 100,000 layers. These estimates are based on the assumption that refrigeration must be run 18 hours a day to achieve the 45 °F mark, while it must be run 15 hours a day to achieve the 60 °F mark. We estimate that the average farm with 20,000 to 50,000 layers would need to run one 5-horsepower refrigeration unit and one 1-horsepower unit to sufficiently cool its egg room. A 5-horsepower unit uses 4.83-kilowatt hours per hour of operation, while a 1-horsepower unit only uses 1.73-kilowatt hours. Therefore, the cost of cooling to 60 °F is (4.83 + 1.73) kilowatt hours used per hour x 15 hours of operation x $0.09 per kilowatt hour used x 30 days ≈ $265 per month, or about $3,190 per year. The cost of cooling to 45 °F is (4.83 + 1.73) kilowatt hours used per hour x 18 hours of operation per day x $0.09 per kilowatt hour x 30 days ≈ $319 per month, or about $3,830 per year. The resulting cost of decreasing the ambient temperature in the egg cooler by 15 °F is approximately $640. Assuming a linear relationship between refrigeration and cost gives us an estimate of approximately $320 for a 7.5 °F reduction.

[43] Although there are some small farms that pack their eggs on the farm, we assume that most small farms that pack their own eggs sell all of their eggs directly to consumers, and therefore are not covered by the proposed rule. We have no information regarding how many farms that are covered by this rule pack their eggs. We request comment on the prevalence of this practice.

[44] The assumptions that all eggs from farms with fewer than 3,000 layers are packed off of the farm and are stored for longer than 1 day are based on an extrapolation of the trends by farm size that are apparent in table 17 of this document. Because there is no obvious trend for compliance with temperature requirements, we use the mean value for all farms as our assumption for farms with fewer than 3,000 layers.

[45] All cost estimates in this section are from data supplied to FDA through a contract with the Research Triangle Institute. Derivation of estimates is more fully described in a memorandum to the record (Ref. 124).

[46] We recognize that some of these farms may require additional refrigeration units to achieve the 45 °F threshold. However, because we do not currently have information that allows us to estimate how many farms fall into this category, we assume that the only cost facing farms that use an inadequate level of refrigeration will be the cost of increased energy usage.

TABLE 18.—ANNUAL COST OF REFRIGERATING AFFECTED FARMS

Farm Size (no. of Layers)	No Refrigeration			Inadequate Refrigeration		Total Cost (in thousands)	
	Number	Cost per Farm (7% discount rate)	Cost per Farm (3% discount rate)	Number	Cost per Farm	7% interest rate	3% interest rate
Fewer than 100	13,950	$325	$312	11,565	$23	$4,800	$4,618
100 to 3,000	1,066	$833	$733	884	$42	$925	$819
3,000 to 19,999	963	$7,763	$5,882	799	$201	$7,636	$5,825
20,000 to 49,999	205	$15,026	$11,052	482	$319	$3,234	$2,419
50,000 to 99,999	94	$28,510	$20,716	135	$553	$2,755	$2,022
100,000 or more	35	$121,329	$87,497	123	$2,219	$4,519	$3,335

The fixed cost of new refrigeration for larger farms includes the cost of constructing an egg room, insulating that room, and installing refrigeration units. Storage rooms and their insulation are assumed to last 30 years. Refrigeration units last from 10 to 20 years. Using these values, along with a 7-percent interest rate, we estimate that the annualized cost of installing new refrigeration would be from $330 for a farm with 300 layers to $94,700 for a farm with 400,000 layers. With an interest rate of 3 percent, we estimate that the annualized cost of installing new refrigeration would be from $230 for a farm with 300 layers to $60,870 for a farm with 400,000 layers.

The cost of constructing an egg room equals the number of square feet required times the construction cost per square foot. The number of square feet required is estimated as the number of square feet required per 1,000 dozen eggs times the number of eggs produced in a 24-hour period (1,000 dozens) times the number of days the eggs are expected to be stored. The cost of construction per square foot has been estimated to be between $50 and $75. Therefore, for the average farm with 20,000 to 50,000 layers the cost of construction is 294 square feet per thousand dozen eggs x 1.7 thousand dozen eggs x $62.50 per square foot x 3.9 days worth of storage = $125,000. The amortized cost over 30 years at 7 percent is approximately $10,050.

The cost of insulating an egg room equals the number of square feet to be covered times the insulation cost per square foot. Insulation costs $11.80 for a 32 square foot sheet. For a farm with 20,000 to 50,000 layers the expected cost of insulation is therefore 3,670 square feet x $0.37 per square foot = $1,350. The annualized cost of insulation (amortized over 30 years at 7 percent) is $110.

The fixed cost of refrigeration for an egg room is the cost of buying and installing refrigeration units. We assume that installation costs are approximately 5 percent of the purchase price of the unit. For a farm with 20,000 to 50,000 layers, the cost of refrigeration is the purchase price for needed refrigeration units ($9,100) plus the cost of installation ($9,100 x 5 percent) = $9,100 + $455 = $9,555. Amortizing this cost over 15 years at 7 percent yields an annual cost of $1,050.

The total annualized cost of installing a refrigerated egg room on a farm with 20,000 to 50,000 layers is estimated to be approximately $11,200. This figure does not include the cost of energy. Including the cost of energy increases the total cost to $15,026.

The smallest farms (those with fewer than 100 layers) will not have to install egg rooms. We believe that farms with fewer than 100 layers will be able to store their eggs in a household refrigerator without a freezer. We estimate the cost of a 16.7 cubic foot frost-free stand-alone refrigerator (without a built-in freezer) to be $500. Amortized at 7 percent over 15 years brings the annualized cost of this purchase to $55. Amortized at 3 percent over 15 years brings the annualized cost of this purchase to $42.

For all types of refrigeration, there also will be a cost associated with the use of electricity to run the cooling units. Given that electricity costs $0.09 per kilowatt-hour, we estimate that farms will spend an additional $270 to $26,600 annually for power.[47]

The cost of this provision to a farm without any refrigeration in place is estimated to range from about $325 for farms with fewer than 100 layers to over $121,300 for farms with more than 100,000 layers. The total cost of the refrigeration provision is approximately $23.9 million ($5.7 million of which is incurred by farms with fewer than 3,000 layers) using a 7-percent interest rate and approximately $19 million ($5.4 million of which is incurred by farms with fewer than 3,000 layers) using a 3-percent interest rate. However, some farms will choose to increase the frequency of egg pickups instead of installing additional refrigeration to remain in compliance with the provision. If more frequent egg pick-ups are a lower cost alternative to refrigeration installation, the previously mentioned figures may overstate the actual cost of increased refrigeration.

iv. *Impact of refrigeration on egg processors.* Eggs washed at a temperature more than 40 degrees over their internal temperature are more likely to suffer thermal checks. These minute cracks increase the chance of egg breakage and egg contamination with pathogens from outside of the egg. Because of this problem, egg processors will not want to wash eggs that have an internal temperature of less than 50 degrees.

We are considering a refrigeration provision requiring that eggs be kept at an ambient temperature of 45 degrees, if they are held by the producer for more than 36 hours.

Whether high wash water temperatures will damage refrigerated eggs depends on whether the internal temperature of the eggs is less than 50 degrees. As a result, the cooling rate of refrigerated eggs becomes an important question. We ask for comment on this question and on the costs to processors.

v. *Benefits of refrigeration.* The probability that an individual will become ill from an SE-contaminated egg

[47] As noted previously, for a farm with 20,000 to 50,000 layers the annualized cost of cooling an egg room to 45 °F is (4.83 + 1.73) kilowatt hours used per hour x 18 hours of operation per day x $0.09 per kilowatt hour x 30 days ≈ $319 per month, or about $3,830 per year.

depends, among other things, on the number of bacteria within the infected egg. Refrigeration of eggs at 45 °F significantly slows the reproduction of the SE bacteria (Ref. 15). This provision would require that eggs that are stored for more than 36 hours after laying be refrigerated at 45 °F while on the farm. In this section, we calculate the effectiveness of potential storage and refrigeration requirements using the USDA SE risk assessment model (Ref. 15). This model is designed to estimate the effects of preventive measures on SE illness.

In the following cost model, we estimate that 35.7 percent (farms with fewer than 3,000 layers) to 81.2 percent (farms with more than 100,000 layers) of farms currently meet the refrigeration standards of the proposed provision. Taking a weighted average, we estimate that 46.6 percent of eggs are produced on farms that do not currently meet the standards set forth in the provision.[48] We programmed the SE risk assessment to estimate the effects on SE if all farms meet the refrigeration requirement. A storage and refrigeration provision is expected to incrementally reduce illnesses by 2.3 percent. In the absence of other provisions this percentage reduction translates into a benefit of 10 illness averted annually for farms with less than 3,000 layers and more than 2,160 illnesses averted for farms with more than 3,000 layers. The cost per illness averted on farms with less than 3,000 layers is $563,206 when we use a 7 percent interest rate ($534,829 when we use a 3 percent interest rate). The cost per illness averted on farms with more than 3,000 layers is $8,380 when we use a 7 percent interest rate ($6,282 when we use a 3 percent interest rate).

j. *Routine environmental testing.* Environmental testing does not serve directly as an SE prevention measure. Testing serves primarily as an indicator of the effectiveness of the SE prevention measures.

i. *Environmental testing provision.* This potential provision would require every farm to routinely test the environment of their layers for SE. For flocks that do not undergo a molt, this requirement would be limited to a test for SE in the environment when each group of layers in the flock is 40 to 45 weeks of age. For those flocks that do undergo a molt, testing would be required when each group of layers is 40 to 45 weeks of age and 20 weeks after molting for each group is completed.

Testing would be accomplished by a method such as swabbing manure piles in the poultry house and then culturing those swabs using a primary enrichment testing method. We are considering variants of sampling protocols that are currently in use. California currently uses a sampling plan that relies on randomly swabbing 30-foot sections of the poultry house (Ref. 125). To obtain a 95 percent probability of catching a house that is 10 percent infected, we estimate that 32 samples would have to be taken. Many other States, including Pennsylvania, require the span of each row of the layer house to be swabbed with one swab, regardless of row length (Ref. 39).

ii. *Current industry molting practices.* Molted flocks face additional testing under this provision, so current industry molting practices are an important element in determining the cost of this provision. Overall, 62.1 percent of all large flocks are molted once and 12.1 percent are molted twice before depopulation (Refs. 25 and 26). Industry molting practices, however, vary by region and by farm size.

Farms in the Central and Great Lakes regions are least likely to molt their flocks while farms in the Southeast and West are most likely to use molting as a practice. (See table 19 of this document.)

TABLE 19.—REGIONAL MOLTING PRACTICES[1]

Region	Times Molted (percent)		
	0	1	2
Great Lakes	30.0	65.2	4.8
Southeast	7.3	80.2	12.5
Central	48.8	51.2	0.0
West	17.9	50.0	32.1

[1] Layers study data provided by Animal and Plant Health Inspection Service.

The implication of the regional disparities in molting practices is that any rule that treats molted and non-molted flocks differently will also affect regions differently.

Molting practices also vary by farm size. As table 20 of this document illustrates, smaller farms are less likely to molt their layers than are larger farms. While almost 85 percent of all farms with 50,000 or more layers molt their layers, only 27.8 percent of farms with fewer than 20,000 layers molt their flocks. This disparity plays a significant role in the determination of the expected cost of testing and diversion.

TABLE 20.—MOLTING PRACTICES BY FARM SIZE[1]

Farm Size (No. of layers)	Times Molted (in %)		
	0	1	2
Fewer than 20,000	72.2	27.8	0.0

[48] The weighted average number of eggs affected by this proposed rule is calculated using the following formula. Percent of eggs affected = the sum of (farms affected$_i$ x percent of birds in size category$_i$), where i is an index for farm size. This formula yields: Percent of eggs affected = (78.8 percent x 0.23 percent) + (71.8 percent x 10.55 percent) + (63.7 percent x 10.51 percent) + (56.1 percent x 9.67 percent) + (27.5 percent x 69.04 percent) = 38.9 percent.

TABLE 20.—MOLTING PRACTICES BY FARM SIZE[1]—Continued

Farm Size (No. of layers)	Times Molted (in %)		
	0	1	2
20,000–49,999	35.3	54.0	10.7
50,000–99,999	13.6	68.4	18.0
100,000 or more	15.7	72.3	12.0

[1] Layers study data provided by Animal and Plant Health Inspection Services.

iii. *Current environmental testing practices.* According to the Layers study, approximately 52 percent of all farms with more than 30,000 layers currently conduct some routine environmental tests for SE (Refs. 25 and 26). The vast majority of these producers are also members of formal quality assurance programs. Because very few small farmers are members of these programs, we assume that no farmers with fewer than 3,000 layers currently engage in routine testing of the environment for *Salmonella*. This assumption is likely to lead to an overestimation of testing costs. However, we also assume that all houses contain only one group of layers. Because there are some multi-age houses that are considered to have multiple groups for the purposes of testing, assuming that each house has only one group is likely to lead to an underestimation of costs.

iv. *Environmental testing costs.* The cost of routine environmental testing depends on how many samples are tested, the labor cost of collecting the samples, the cost of shipping the samples to a laboratory, and the laboratory cost per sample tested.

We assume that it will take approximately 15 minutes to collect and pack each sample. Since the wage for a typical livestock and poultry worker is approximately $8.84 per hour (Ref. 107), doubled to reflect overhead costs, the cost of labor is assumed to be (15 ÷ 60) x $17.68 = $4.42 per sample collected.

The cost of shipping samples will vary by the weight of the shipment. We assume that a swab, with its packing material, weighs approximately one pound. To calculate the cost of shipping, we estimate the average number of swabs sent per shipment and use rate tables (Ref. 118) to determine the cost of shipment.

We estimate the laboratory cost of testing for SE that has been collected from the environment to be approximately $37.50 per sample.[49]

The average cost of routine testing for SE in a given house is determined by multiplying the number of tests required for that house by the expected cost per test. For any plan that is used, the per house cost of testing is estimated to be Cost = SWABS x (LABOR + MAIL + LAB), where SWABS is the number of required swabs, LABOR is the cost of labor per test, MAIL is the cost of shipping samples to a lab, and LAB is the laboratory costs of testing for SE.

To determine the testing cost of the row-based plan, we multiply the cost per test by the estimated number of rows that will have to be swabbed. We assume that all farms that are currently conducting routine testing (52 percent) (Refs. 25 and 26) are in compliance with the row-based plan.

The number of rows that will have to be swabbed in larger houses is estimated in table 21 of this document. Information for the first three columns is drawn from the Layers study (Refs. 25 and 26). We estimate the number of houses affected by the provision (the fourth column) by multiplying the number of large houses (8,560) by the percent of houses affected by the provision (48 percent), and then multiplying the product by the percent of houses in the given category. We estimate the number of rows that will have to be swabbed because of the provision as the number of rows per house times the number of houses affected by the provision. A total of 24,960 rows would have to be swabbed due to this provision.

TABLE 21.—NO. OF ROWS TO BE SWABBED

(HOUSES WITH 3,000 OR MORE LAYERS)

No. of Rows or Batteries of Cages	Average No. of Rows[1]	Percent of Houses	No. of Houses Affected	No. of Rows Affected
1	1.0	1.9	80	80
2 to 3	2.5	12.5	520	1,290
4 to 5	4.5	50.8	2,100	9,450
6 or more	10.0	34.2	1,410	14,140
Total	6.1	.....	4,110	24,960

[1] The average number of rows per house is estimated as the midpoint of the range estimated by Layers study. For the "6 or more" category we assume that these houses have an average of 10 rows each. We ask for comment on the validity of this assumption.

Because each row has two sides, each of which will have to be swabbed, the total number of swabs required is estimated to be approximately 49,910. On average, 12.1 swabs will be used for each house with more than 3000 layers.

[49] This is the average of in-State and out-of-State pricing in the California Animal Health & Food Safety Laboratory System (Ref. 126).

The total cost of testing the average large house is $541 (12.1 swabs x ($4.42 labor + $2.77 shipping[50] + $37.50 lab culture)) when two swabs are used per row.

We assume that no houses with fewer than 3,000 layers currently conduct these tests. Furthermore, we assume that these smaller houses have from one to two rows of cages. Thus, the estimated average number of swabs used per small farm is three. The total cost of one round of testing for each very small farm is $148 (3 swabs x [$4.42 labor + $7.42 shipping[51] + $37.50 lab culture]) when two swabs are used per row.

The random swabbing plan requires that 32 samples be taken per house. Although 52 percent of houses are in compliance with the row-based plan, far fewer are likely to be in compliance with the random swabbing plan. In the absence of better information, we assume that between 0 and 52 percent (uniformly distributed) of large houses that are currently testing use random swabbing plans.[52] The cost per swab under the random swabbing sampling plan is $43.65 ($4.42 labor + $1.73 shipping[53] + $37.50 lab culture). The total cost of one round of testing under the random swabbing plan is calculated to be $47.2 million for farms with fewer than 3,000 layers (33,820 houses not in compliance x 32 swabs per house x $43.65 cost per swab) and $12.0 million for farms with more than 3,000 layers (8,610 houses not in compliance x 32 swabs per house x $43.65 cost per swab).

k. *Followup egg testing*. i. *Egg testing provisions*. Followup egg testing would occur if an environmental test is positive for SE. If egg testing is triggered, the following protocol must be followed. First, the farmer must submit 1,000 eggs to a recognized lab initially, and subsequently every 2 weeks, for a total of 4,000 eggs. Consistent with the method described by Valentin-Bon et al (Ref. 62), the eggs that are submitted for testing may be pooled in samples of 10 to 20 eggs each. If pooled into samples of 20 eggs each, a total of 200 egg tests are conducted. If any of these egg tests are positive, the farm will be required to divert its eggs until four consecutive rounds of egg tests are found to be negative. Furthermore, a farm that has had a positive egg test must continue to test 1,000 eggs each month for the life of the flock.

If the cost of egg testing is high enough, however, the farmer may simply choose to forego egg testing and divert all eggs for the life of the flock.

ii. *Current industry practices; Followup egg testing*. We assume that those farms currently under a recognized quality assurance plan that mandates egg testing following a positive environmental test are currently in partial compliance with this provision. Of the major plans, only the Pennsylvania and Maryland plans have followup testing provisions that are largely the same as this provision (Ref. 99). According to ''Chicken and Eggs'' (Ref. 98), egg production in Maryland and Pennsylvania accounted for 9.7 percent of the U.S. total. Only 85 percent of the eggs in these States fall under the State quality assurance programs. We therefore estimate that 8.2 percent (9.7 percent x 85 percent) of all eggs are currently in partial compliance. Because farms with fewer than 3,000 layers are not currently in these quality assurance programs, we assume that no farms with fewer than 3,000 layers conduct followup egg tests.

Even farms in compliance with the Pennsylvania and Maryland plans are not currently in full compliance with the provision described in this section. This provision would require that batches of 1,000 eggs be tested, while the Pennsylvania and Maryland plans only require 480 eggs to be tested in each batch. Farms on either the Pennsylvania or the Maryland plans are only 48 percent (480 ÷ 1000) in compliance with the provision.

These numbers suggest that the current net level of compliance with the provision is 0 percent for farms with fewer than 3,000 layers and 3.9 percent (8.2 percent x 48 percent) for farms with more than 3,000 layers.

iii. *Egg testing costs*. The cost of followup egg testing is composed of the following: (1) The labor cost of collecting the eggs, (2) the value of the eggs being tested, (3) the cost of shipping the eggs to a qualified laboratory, and (4) the lab costs of testing the eggs.

The cost of collecting the eggs is the hourly cost of labor times the number of hours spent collecting the eggs. We assume that it will take the typical farmhand approximately one-half minute per egg to randomly select eggs for testing, so the labor cost of egg testing is $146.74 per 1,000 eggs tested (50 samples x 20 eggs per sample x 0.0083 hours per egg x $17.68 dollars per hour) (Ref. 107).

The lost value of the eggs used for testing is the number of eggs tested times the value of an unpacked egg. To avoid the double counting of the cost of diversion (for those eggs being tested), we modify this value to account for the fact that as many as 26 percent of eggs being tested may be under required diversion at the time of testing. The price that the typical producer receives for table eggs is about $0.43 per dozen, while the price a producer receives for diverted eggs is about $0.26 per dozen eggs (See table 23). The expected value of a diverted egg is the weighted average of the value of a table egg and a diverted egg, or about $0.03 per egg.[54] The value of the eggs tested is the value per egg times the number of eggs tested. The value of every 1,000 eggs tested is $32.47.

Eggs that are collected will have to be shipped to a laboratory for analysis. The cost of shipping these eggs depends on the weight of the eggs being shipped. We estimate that 1,000 large eggs weigh approximately 111 pounds. The cost of shipping these eggs in two 60-pound packages (including packing) to the laboratory is approximately $179.50.[55]

The largest cost of egg testing is the laboratory; we estimate the lab cost for 1 batch of 20 eggs to be $30 (Ref. 111). Hence, for 50 tests the laboratory cost of eggs testing is $1,500 per 1,000 eggs tested (50 batches x $30 per test).

The total cost of egg testing is the sum of each of the previously stated costs. Therefore, the cost of egg testing is $1,859 per 1,000 eggs tested ($146.74 collection costs + $32.47 lost income from egg sales + $179.50 shipping costs + $1,500 lab costs).

l. *Diversion*. i. *Diversion provisions*. Under this provision, farms that test positive for SE in their eggs would be required to divert their eggs to breaker plants until they are able to show via testing that SE is not present in the eggs produced in the infected house. Both the expected level of diversion and the expected cost of diversion will vary by each operation's location and size.

ii. *Regional differences in the cost of diversion*. Regional differences in the

[50] The cost of shipping 12 swabs (12 pounds) overnight is estimated to be between $26.25 and $40.25, including pickup charges (Ref. 118). We divide the average cost of shipping by 12 to obtain the cost per swab ($2.77).

[51] The cost of shipping 3 swabs (3 pounds) overnight is estimated to be between $19.25 and $25.25, including pickup charges (Ref. 118). We divide the average cost of shipping by 3 to obtain the cost per swab ($7.42).

[52] We assume that no small houses are testing using random swabbing plans.

[53] The cost of shipping 32 swabs (32 pounds) overnight is estimated to be between $40.50 and $70.50, including pickup charges (Ref. 118). We divide the average cost of shipping ($55.50) by 32 to obtain the cost per swab ($1.73).

[54] The following calculation is used to reach this figure. [(74 percent of farms not under diversion x $0.46 per dozen table eggs) + (26 percent of eggs under diversion x $0.26 per dozen diverted eggs)] ÷ 12 eggs in a dozen = $0.03 per egg.

[55] The cost of shipping a 60-pound package overnight is between $64.50 and $115.00, including pickup charges (Ref. 118). We multiply the average cost of shipping ($89.75) by 2 to obtain the total cost of $179.50.

cost of production have led to the centralization of the breaker industry in the North Atlantic and North Central regions of the United States. As table 22 of this document shows, these regions are responsible for only 52 percent of overall egg production, but over 86 percent of breaker eggs.[56] The centralization of the breaker industry is even more cogently illustrated in the fourth column of table 22 of this document. While 36 to 44 percent of eggs make it to breaker plants in the northern regions, the corresponding figures for the west and south are only 10 percent and 6 to 7 percent. The primary purpose of breaker plants outside of the North appears to be as an outlet for eggs not suitable for retail sale as table eggs.

TABLE 22.—PRODUCTION AND BREAKING OF EGGS

Region	Eggs Produced		Eggs Broken		Percent of Eggs Produced That Are Broken
	Millions of Eggs[1]	Percent	Thousands of Dozens[2]	Percent	
North Atlantic	10,106	12.31	300,406	17.12	35.67
North Central	32,869	40.03	1,212,758	69.12	44.28
South Atlantic	13,979	17.03	69,774	3.98	5.99
South Central	14,512	17.68	84,071	4.79	6.95
West	10,636	12.95	87,662	5.00	9.89
Total	82,102	100	1,754,671	100.00	25.65

[1] National Agricultural Statistical Services (NASS) (Ref. 98).
[2] NASS (Ref. 127).

To predict how the industry will respond to a provision mandating diversion, it is important to know the following reasons: (1) Why the breaker egg industry is regionally concentrated while the shell egg industry is distributed more evenly throughout the United States and (2) why the concentration has occurred in the northern regions of the United States.

There are a couple of reasons why the breaker industry is centralized and the shell egg industry is not. First, it is much more expensive to transport shell eggs than it is to transport egg products. Shell eggs are relatively bulky and are susceptible to breakage in transit. Second, shell eggs are ultimately delivered directly to consumers in their natural state, while egg products are often used as ingredients in large-scale food manufacturing operations. Since processed foods are less costly to transport than are their ingredients, it makes sense to locate processed foods facilities in areas where ingredients are locally available. To the extent that these ingredients are available in the northern regions, processed food plants will locate there. Consequently, it makes sense to locate breaker plants in this region as well.

If centralization of breaker plants is going to occur, it will likely occur in the northern regions, for several reasons. The cost of egg production is lowest in the north, partly because feed grains (such as corn and wheat) are locally available at low prices in this region.[57] Also, farms in the north are more likely to be characterized by large in-line houses (up to 250,000 layers). These houses take advantage of economies of scale to produce more eggs more cheaply. Furthermore, since the demand for egg products is higher in the northern regions, breaker plants can avoid the high transportation costs of shipping to food processors by locating closer to their customers.

The implication of the industry structure, as laid out above, is that there are likely to be regional disparities in the cost of diversion. Egg products and, hence, breaker egg prices are not expected to vary regionally by as much as shell egg prices. Where the cost of egg production is high (such as in California), the cost of diversion is likely to be high. Similarly, where the price of egg production is low (such as in Ohio and Pennsylvania), the cost of diversion is likely to be low. Furthermore, there are some remote areas, such as Hawaii, where the absence of breaker plants makes local diversion infeasible. Because it is not economical to ship these eggs to breaker plants in the continental United States, the cost of diversion is simply the lost value of a clean table egg.

FDA met with industry representatives in each of the above regions and was given estimates of diversion costs that are consistent with the above reasoning. The diversion cost per dozen eggs in PA was estimated to be insignificant while the diversion cost in CA was estimated to be $0.21 to $0.42 per dozen.

iii. *Effect of operation size on diversion costs.* Operation size can have a significant effect on average diversion costs for a given producer. A large producer is less likely to be affected by an individual house that tests positive, because the risk is generally spread across many houses and farm sites. Furthermore, in areas where it is economically feasible to produce eggs that are dedicated to breaker plants, large operations are less likely to have contract problems because they can simply substitute SE-positive eggs for the eggs that originally were contracted to go to the breaker plant. By contrast, the economic losses from a positive house may be devastating to a small farm with one house.

iv. *Effect of SE-positive status on diversion costs.* It has been suggested that eggs from an SE-positive flock will command a lower price at the breaker than will other eggs. Indeed, some concern has been raised over whether, because of liability concerns, breakers will be willing to accept these eggs. The

[56] In table 22 of this document, the number of eggs produced includes hatching eggs as well as table eggs. Because most hatching eggs are produced in the South and hatching eggs do not go to breaker plants, the percentages of eggs going to breaker plants are biased downward for the southern regions.

[57] Shipping grains from the Midwest to the West Coast by rail can cost over $1 per bushel (Ref. 128).

pasteurization process for breaker eggs is designed to achieve at least a 5-log reduction in any SE that may be in eggs. Furthermore, eggs from an SE-positive flock are not explicitly labeled as such under this provision. However, because these eggs are limited in how they may be used, SE-positive eggs are intrinsically less valuable than SE-negative eggs.

Contracts for both table and breaker eggs are generally in place before a specific flock is tested for SE. Producers with SE-positive flocks may therefore have to break existing contracts for table eggs and make new contracts for breaker eggs. This new contracting not only will be costly in its own right, but also may send a signal to packers that the eggs that are being supplied under these new contracts are more likely to be from an SE-positive flock. To some extent, the packer will take this possibility into account and purchase these eggs at a discount.

v. *Cost of a diverted egg.* Given all of the factors stated in the previous paragraphs, we estimate that, on average, breaker eggs from an SE-positive flock will command a price below that received for shell eggs. Table 23 illustrates the prices that producers receive for shell and breaker eggs by region. As expected, the North Central region, with its proximity to inexpensive feed and a large food processing industry, has the highest level of production, the lowest prices for eggs, and the lowest cost for diversion. The West, with its higher feed costs and smaller layer houses, has the highest prices for eggs and the highest cost of diversion. We find the weighted average cost of diversion to be approximately $0.13 per dozen eggs. If there is an additional discount for those eggs with SE, the total cost could rise as high as $0.21 per dozen eggs.

TABLE 23.—TOTAL COST OF DIVERTING EGGS

Region	Regional Weight (in %)	Shell Egg Price to Producer[1]	Breaking Eggs(Nest Run)[2]	Cost of Diversion (Nest Run)
North Atlantic	12.3	$0.42	$0.31	$0.11
North Central	40.0	$0.39	$0.30	$0.09
South Atlantic	17.0	$0.43	$0.31	$0.12
South Central	17.7	$0.47	$0.30	$0.17
West	13.0	$0.53	$0.31	$0.22
Average Cost of Diverting Eggs[3]				$0.13
Additional Discount for SE+ Eggs (Ref. 111)				$0.00 - 0.08
Total Cost of Diverting Eggs				$0.13 - 0.21

[1] The shell egg price paid to producers for the North Central Region was estimated as equivalent to the prices Agricultural Marketing Service (AMS) reported as paid in Iowa, Minnesota, and Wisconsin. For regions other than the North Central Region, the shell egg price to the producer was calculated by discounting the price to retailer by a percentage equal to the percent difference between the price to the producer and the price to retailer in the North Central Region. All figures were taken from AMS data accessed through The Institute of Food and Agricultural Services at the University of Florida (Ref. 129).

[2] All figures are from AMS data accessed through the North Carolina Department of Agriculture (Ref. 130).

[3] The average cost of diverting eggs is weighted by regional production (Ref. 98).

vi. *Expected cost of diversion.* The expected cost of diversion is determined by the cost of diverting an egg, the number of eggs in commerce affected by the provision, and the probability that a given egg will be diverted.

m. *A model of testing and diversion costs.* i. *The model.* We use a dynamic model for estimating testing and diversion costs. We model these costs as depending on the probability of SE detection, farm size, molting practices, and the farmer's choice between conducting followup egg tests and diverting until depopulation.

In the first stage of the model, we estimate the probabilities associated with environmental and egg tests. For environmental tests, we estimate that 9.7 percent of all flocks currently test positive. We then adjust this estimate downwards to 8.4 percent initially and 7.1 percent eventually to account for the expected reduction of SE on the farm due to adoption of other provisions to reduce SE. In the experience of Pennsylvania, a flock with at least one environmental positive is likely to have at least one egg test positive 26 percent of the time (Ref. 131). We do not know if the experience of Pennsylvania is representative of the nation as a whole. In the absence of better information, we used the Pennsylvania figure.

In the next stage of the dynamic model, the expected cost of testing and diversion is calculated for farms in each of the five size categories used throughout this analysis. There are two reasons why this is a necessary step. First, the estimation of cost for different size categories allows for the explicit representation of the fact that both the number of tests required and the cost of diversion are directly related to the number of layers on the farm. Second, using different size categories facilitates an algebraic model design that uses logical operators to allow farmers (in the model) to make the low cost choice between egg testing and diversion.

Molting practices are accounted for in the next stage. The different testing protocols for molted and non-molted layers makes it necessary to look at the cost of testing and diversion separately for each of these types of flocks. At this stage of the model, we set out the possible scenarios for testing and diversion, derive the expected cost of each scenario, and calculate the statistical probability that each scenario will occur. The mathematical model for this stage is contained in appendices A and B of this document.

In the final stage of the testing cost model, we insert logical operators into the model in such a way that farmers are given the choice of diverting rather than testing eggs when it is cost-efficient to do so. Failure of the model to give the farmer this choice may lead to estimated costs that are up to double the actual expected costs.[58]

[58] A further refinement of the model would be to include the option of depopulating the flock and

ii. *The costs of testing and diversion.* The model described in the previous paragraph produces estimates of the annual expected cost of testing and diversion for layer houses. Estimates are obtained for each of the size categories by molting practice.

As tables 24 and 25 in this document illustrate, the expected costs of testing and diversion for a poultry house range from $150 to $3,760 depending on house size, environmental testing protocol, and molting practices.[59] The low figures in the environmental testing and total cost columns represent costs given the row-based sampling scheme, while the high estimates represent the random swab sampling method. The costs for molted houses are annualized for the purpose of comparison.

TABLE 24.—COST PER HOUSE (NON-MOLTED FLOCKS)

Farm Size (No. of layers)	Environmental Testing	Egg Testing	Diversion	Dynamic Total Cost	Static Total Cost
Fewer than 3,000	$150 to $1,400	$0	$4	$154 to $1,404	$1,010 to $2,260
3,000 to 19,999	$540 to $1,400	$0	$750	$1,290 to $2,150	$1,520 to $2,380
20,000 to 49,999	$540 to $1,400	$620	$470	$1,630 to $2,490	$1,690 to $2,550
50,000 to 99,999	$540 to $1,400	$860	$410	$1,810 to $2,670	$1,810 to $2,670
Over 100,000	$540 to $1,400	$860	$760	$2,160 to $3,020	$2,170 to $3,020

TABLE 25.—COST PER HOUSE (MOLTED FLOCKS)

Farm Size (No. of layers)	Environmental Testing	Egg Testing	Diversion	Dynamic Total Cost	Static Total Cost
3,000 to 19,999	$540 to $1,400	$610	$640	$1,800 to $2,650	$1,920 to $2,780
20,000 to 49,999	$540 to $1,400	$900	$690	$2,130 to $2,990	$2,180 to $3,040
50,000 to 99,999	$540 to $1,400	$920	$700	$2,170 to $3,030	$2,360 to $3,210
Over 100,000	$540 to $1,400	$1,050	$940	$2,530 to $3,370	$2,900 to $3,760

The inclusion of a choice to opt out of egg testing also results in egg testing costs increasing with farm size. The choice to opt out of egg testing significantly increases diversion costs for smaller farms while having a limited effect on larger farms.[60] This difference is apparent in the comparison between dynamic total costs and static total costs. If the incentive to switch from egg testing into diversion were removed, the costs incurred would be the static total costs. Nonetheless, diversion costs also generally rise with farm size.

Whether or not a farmer chooses to molt the flock also has an effect on cost. The annual cost of testing and diversion for a molted flock is greater than that for a non-molted flock, largely because a molted flock forced to divert for the life of the flock is expected to experience diversion for a longer time. In the dynamic model, where the farmer can opt out of testing, molting has a secondary effect of increasing egg-testing costs due to the high expected cost of opting out.

For comparison with dynamic costs, the static cost of testing and diversion is included in the final column of tables 24 and 25 of this document. As expected, when the producer is given the choice of opting out of egg testing the total cost of testing and diversion falls. The savings to the farmer are greatest on the smallest farms, where expected costs may fall by over 75 percent.[61] On the largest farms, it is less economical to divert, and thus the cost savings can be insignificant.

To obtain the total cost of testing and diversion for all houses on all farms we multiplied the cost per house in each category by the number of houses in each category and the percentage of houses that would be affected by the provision. These costs are summarized in tables 26 and 27 of this document.

TABLE 26.—TOTAL COST OF TESTING AND DIVERSION: ROW-BASED SAMPLING (THOUSANDS OF DOLLARS)

Farm Size (No. of layers)	No. of Houses	Percent Molted	Environmental Testing	Egg Testing	Diversion	Total Cost
Fewer than 3,000	33,824	0	$5,006	$0	$122	$5,129
3,000 to 19,999	3,155	28	$1,268	$513	$2,088	$3,869
20,000 to 49,999	1,317	65	$529	$1,017	$736	$2,282
50,000 to 99,999	861	86	$346	$756	$523	$1,625

starting over with a new flock. There is a large degree of uncertainty over whether this is feasible given that the growing cycle of chicks and pullets must be coordinated with the laying cycle of flocks. Therefore, we did not include this option in our analysis. For the final rule we invite comment on the feasibility of this option.

[59] Tables 24 and 25 of this document present the cost estimates for houses based on the current estimated prevalence of SE. In the total cost tables (26 and 27 of this document), we also present an estimate that reflects the expected prevalence following the full implementation of this rule.

[60] It is never in the interest of the smallest farms to test eggs because the expected cost of testing exceeds the revenue loss from simply diverting all eggs for the life of the flock.

[61] This conclusion assumes that the farmer will be paying all of the costs of testing and diversion.

TABLE 26.—TOTAL COST OF TESTING AND DIVERSION: ROW-BASED SAMPLING (THOUSANDS OF DOLLARS)—Continued

Farm Size (No. of layers)	No. of Houses	Percent Molted	Environmental Testing	Egg Testing	Diversion	Total Cost
Over 100,000	3,279	84	$1,317	$3,200	$2,747	$7,264
All Farms, Initially			$8,466	$5,487	$6,216	$20,169
All Farms Eventually			$8,466	$4,608	$5,236	$18,310

TABLE 27.—TOTAL COST OF TESTING AND DIVERSION: RANDOM SWAB SAMPLING (THOUSANDS OF DOLLARS)

Farm Size (No. of layers)	No. of Houses	Percent Molted	Environmental Testing	Egg Testing	Diversion	Total Cost
Fewer than 3,000	33,824	0	$47,353	$0	$122	$47,475
3,000 to 19,999	3,155	28	$3,269	$513	$2,088	$5,870
20,000 to 49,999	1,317	65	$1,364	$1,017	$736	$3,117
50,000 to 99,999	861	86	$892	$756	$523	$2,171
Over 100,000	3,279	84	$3,397	$3,200	$2,747	$9,344
All Farms, Initially			$56,275	$5,487	$6,216	$68,978
All Farms, Eventually			$56,275	$4,608	$5,236	$66,119

As shown in table 26 of this document, the estimated total cost of testing and diversion is approximately $20.2 million when row-based sampling is used. When we assume that a random swab method of environmental sampling is used, as in table 27, the estimated costs increase to $69.0 million. There also will be a cost associated with reviewing and updating the SE prevention measures when a poultry house tests positive.[62] We assume that the review and updating would take approximately 20 hours of supervisory labor for the typical house. We assume that, as with plan design and implementation (see following), farms with fewer than 3,000 layers that are subject to SE prevention measures would not be equally burdened. We therefore assume that the review and updating of the measures for these smaller houses would take 10 hours of supervisory labor. We estimate the total initial cost of review and updating to be $524,900 for farms with at least 3,000 layers (20 hours x $36.28 an hour x 8,612 larger houses x 8.4 percent of houses testing positive) and $1,030,800 for smaller farms (10 hours x $36.28 an hour x 33,824 smaller houses x 8.4 percent of houses testing positive). The decline of positive houses from 8.4 percent to 7.1 percent over 4 years will be met with a corresponding decline in the cost of prevention measure review. In particular, the total cost to larger farms will fall to $443,700, while the total cost to very small farms will fall to $871,300.

n. *Benefits of testing and diversion.* While the primary purpose of testing is to obtain an indication of the effectiveness of the farm's SE prevention measures, the testing and diversion program would also directly reduce SE infection by preventing SE-positive eggs from reaching consumers. To the extent that SE-positive eggs are diverted to pasteurization, the number of these eggs that reach the consumer in an untreated form would decline. We estimate the benefits from diversion using the experience of the States.

The first key measure to be determined is the probability that the environment of a flock will test positive. We use two sources to estimate the current prevalence of SE-positive houses. Our first source is the Layers study (Ref. 27), which recruited 200 farm sites to be tested across the United States. We also use estimates based on the experience of testing under quality assurance plans.

The Layers study estimates that 7.1 percent of all houses are positive for SE. Regionally, SE prevalence ranges from a low of 0 percent in the Southeast to a high of 17.2 percent in the Great Lakes region. Nonetheless, because only 200 of an original sample of 526 farm sites chose to participate in this phase of the study, we are hesitant to rely solely on this figure for SE prevalence.

Regional quality assurance programs have also collected data on SE prevalence on the farm. As an upper bound, Pennsylvania experienced a prevalence of 40 percent in the early 1990's (Ref. 132). As a lower bound, we use 1 to 3 percent, which is the current prevalence of houses with SE-positive environments in Maine (Ref. 133). We believe that Pennsylvania's current prevalence of 7 to 9 percent (Ref. 131) is a likely prevalence for the nation as a whole.[63] When we put this data into a Beta-Pert probability distribution using a uniform distribution over 1 to 3 percent as the lower bound, 40 percent as the upper bound, and a uniform distribution over 7 to 9 percent as the mode, or most likely value, we estimate a national prevalence rate of 12.3 percent.

We assume that the Layers study and quality assurance program estimates are equally likely to be valid. Therefore, we put these values in a uniform distribution (7 to 12.3 percent) to estimate that 9.7 percent of farms would currently test SE-positive. Based on the experience of Pennsylvania, we estimate that 26 percent of houses that are environmentally positive also will have eggs that test positive (Ref. 131).

These figures imply that 502 million eggs from farms with more than 3,000 layers and 10 million eggs from farms

[62] All estimates related to plan design, review, and recordkeeping are based on estimates used to calculate the cost of HACCP for juice producers (63 FR 24253 at 24275 to 24285, May 1, 1998).

[63] This assumption is based on the fact that the number of outbreaks in the Northeast (where Pennsylvania is located) has fallen to a level equivalent with the rest of the nation (Ref. 7).

with less than 3,000 layers,[64] a combined 0.7 percent of all shell eggs,[65] would be diverted each year following the initial effective date. Of these eggs, we expect eggs to be positive at a rate of 2.75 per 10,000 (Ref 39). Consequently, within the pool of all diverted eggs, we estimate that an average of 138,000 SE positive eggs from farms with more than 3,000 layers and 2,800 SE-positive eggs from farms with fewer than 3,000 layers would be diverted annually. Given a total estimated number of positive eggs of 1.5 million, we can estimate that diversion would decrease the number of SE-related illnesses by 9.4 percent. This translates to potentially 46 cases of SE per year prevented by farms with fewer than 3,000 layers and 8,883 illnesses prevented by farms with more than 3,000 layers. For farms with 3,000 or fewer layers the cost is $571,800 per SE case prevented. For farms with more than 3,000 layers the cost is $2,000 per SE case prevented.

o. *Summary of costs and benefits potential on-farm SE prevention measures.* Table 28 summarizes the costs and benefits of the potential on-farm SE prevention measures. Some features of these summary estimates are worth addressing here. First, because the effectiveness of rodent and pest control is strongly linked to biosecurity and cleaning and disinfecting practices, we estimated the benefits of these provisions jointly. Second, we derive benefits without taking into account the interdependence of all proposed provisions. Therefore, table 28 reflects the incremental effects of each provision starting from a baseline of no new regulation. For example, the benefits of testing and diversion alone for large farms is 8,883 illnesses avoided annually at a cost of $1,800 per SE case avoided. As shown in table 4, a typical case of SE costs society roughly $17,700, assuming the VSL=$5 million, QALY=$300 thousand, and a 7 percent discount rate. Therefore, net benefits of testing and diversion alone are $141 million annually (8,883 cases avoided* ($17,700 - $1,800)). The benefits reported for the provisions in table 28 can be added together, mixed and matched, to achieve a rough upper bound estimate of the effectiveness of different combinations of provisions. Because there is some substitutability in benefits between some of the provisions, particularly between diversion and rodent and pest control, the actual benefits of combinations of provisions, as well as the proposed rule, will be somewhat smaller than what is reflected in table 28. A rough lower bound estimate of the incremental effect of each provision when combined with another is shown in table 33. Third, we estimate costs and benefits separately for farms with fewer than 3,000 layers and for farms with more than 3,000 layers.

TABLE 28.—ANNUAL COSTS, ILLNESSES AVERTED, AND COST PER ILLNESS AVERTED OF POTENTIAL ON-FARM MEASURES, BY FARM SIZE

	Farm Size	
	<3,000 Layers	>3,000 Layers
Costs (thousands of dollars)		
Rodent and Pest Control	$3,008	$21,019
Biosecurity	$7,100	$15,954
Cleaning and Disinfecting	$1,372	$2,441
SE Monitored Chicks and Pullets	$0.5	$87
SE Negative Feed	$138	$27,363
Vaccination	$188	$29,261
Refrigeration	$5,718	$18,120
Environmental Tests (Row Based Sampling)	$5,006	$3,460
Environmental Tests (Random Sampling)	$47,353	$8,922
Egg Tests	$0	$4,608
Diversion	$103	$5,133
Review of SE Prevention Measures	$871	$444
Cases of SE Averted (eventual)		
Rodent and Pest Control	142	25,701
Biosecurity	Included in Rodent Control	
Cleaning and Disinfecting	Included in Rodent Control	
SE Monitored Chicks and Pullets	< 1	10

[64] The total cost of diversion is divided by the cost of diversion per egg to obtain the number of eggs diverted.

[65] The percent of shell eggs that is diverted is determined by dividing the number of eggs diverted by the total number of shell eggs produced (69,771 million) as published in the USDA's Chicken and Eggs report (Ref. 98).

TABLE 28.—ANNUAL COSTS, ILLNESSES AVERTED, AND COST PER ILLNESS AVERTED OF POTENTIAL ON-FARM MEASURES, BY FARM SIZE—Continued

	Farm Size	
	<3,000 Layers	>3,000 Layers
SE Negative Feed	Theoretical	
Vaccination	Uncertain	
Refrigeration	10	2,162
Testing and Diversion	46	8,883
Other Benefits		
Rodent Control (Feed Savings - thousands of dollars)	$3.8	$696
Cost per Case of SE Averted (eventual - thousands of dollars)		
Rodent and Pest Control	$80.8	$1.5
Biosecurity	Included in Rodent Control	
Cleaning and Disinfecting	Included in Rodent Control	
SE Monitored Chicks and Pullets	$0.9	$8.7
SE Negative Feed	Theoretical	
Vaccination	Uncertain	
Refrigeration	$571.8	$8.4
Testing and Diversion	$559.4	$1.8

2. Administrative Measures

FDA has considered a number of administrative requirements that could be applied to farms. The provisions that we considered are examined below. Some, but not all, of the provisions are in the proposed rule. The costs and benefits of the provisions that are in the proposed rule are summarized in section V.F.

a. *Plan design and recordkeeping.* i. *Plan design and recordkeeping provisions.* We consider a provision that each farm site that sells raw eggs to the table egg market, other than directly to the consumer, design and monitor an SE prevention plan. If required, this prevention plan would include all measures the farm is taking to prevent SE in its flock. The following information includes potential components of the plan: (1) Chicks and pullets, (2) biosecurity, (3) rodent and other pest control, (4) cleaning and disinfecting, (5) feed, and (6) refrigeration. Recordkeeping may also be a provision of the plan. Records could be required for each of the provisions included in the plan, as well as for testing results. Farms may be required to have a trained or experienced supervisor that would be responsible for overseeing the plan.

ii. *Current industry practices—plan design and recordkeeping.* We assume that those farms that are currently operating according to recognized industry or State quality assurance plans are already largely in compliance with the plan design and recordkeeping provisions discussed in this section, and therefore would not experience additional costs to comply with record keeping provisions. Using data from the Layers study (Refs. 25 and 26), we find that 59 percent of farms with more than 50,000 layers are currently members of State or industry quality assurance plans. Fewer than 8 percent of farms with fewer than 50,000 layers are currently members of quality assurance plans.[66] The estimated number of farms and houses affected by plan design and recordkeeping provisions is shown in table 29 of this document.

TABLE 29.—FARMS AFFECTED BY PLAN DESIGN AND RECORDKEEPING PROVISIONS

Farm Size (No. of layers)	No. of Farms	Houses Per Farm	Percent of Farms on a QA Program	Farms Affected by the Proposal	Houses Affected by the Proposal
Fewer than 3,000	33,824	1.0	0.0	33,824	33,824
3,000 to 19,999	2,337	1.4	4.9	2,223	3,000
20,000 to 49,999	940	1.4	27.7	680	952
50,000 to 99,999	359	2.4	58.0	151	361

[66] We do not have data on participation by farms with fewer than 3,000 layers. We assume that none of these farms are currently members of recognized quality assurance programs.

TABLE 29.—FARMS AFFECTED BY PLAN DESIGN AND RECORDKEEPING PROVISIONS—Continued

Farm Size (No. of layers)	No. of Farms	Houses Per Farm	Percent of Farms on a QA Program	Farms Affected by the Proposal	Houses Affected by the Proposal
100,000 or more	443	7.4	59.7	179	1,322
All Farms	37,903	1.1	97.8	37,055	39,459

As table 29 of this document shows, we expect that a total of 37,055 farm sites with 39,459 poultry houses would be affected by plan design and recordkeeping provisions, if required.

iii. *Plan design costs.* In table 30 of this document we estimate the cost of designing a prevention plan and the corresponding cost of keeping records of plan performance. Because information on the costs of designing the QA plan for eggs is not available, we base these costs on assumptions used to analyze the design of HACCP programs (63 FR 24253 at 24275 to 24285, May 1, 1998). In particular, we assume that each farm measure will take approximately 20 hours to design. Farms with fewer than 3,000 layers are generally less complex. For these farms, we assume that it will take only 10 hours to design each component of the plan. We assume that the labor used to design the plan costs $18.14 an hour (Ref. 134). We double this figure to account for overhead. The cost of designing a plan with one component for a farm with less than 3,000 layers is expected to be $363, while the cost to larger farms is expected to be $726. Amortized over 10 years at 7 percent, the total cost of plan design to small farms is expected to be $1,747,100 per required provision, while the cost to larger farms will be $333,900 per provision. Amortized over 10 years at 3 percent, the total cost of plan design to small farms is expected to be $1,438,600 per required provision, while the cost to larger farms will be $274,900 per provision.

TABLE 30.—COST OF PLAN DESIGN PER PROVISION

Farm Size (No. of layers)	Farms Affected by the Proposal	Cost Per Farm	Total Costs
Fewer than 3,000	33,824	$363	$12,271,200
3,000 to 19,999	2,223	$726	$1,612,700
20,000 to 49,999	680	$726	$493,400
50,000 to 99,999	151	$726	$109,300
100,000 or more	179	$726	$129,585
All Farms	37,055		$14,616,100
Amortized Over 10 Years at 7%			$2,081,000

The total cost of plan design will depend on the number of on-farm provisions that are ultimately required by the proposed rule.

iv. *Recordkeeping costs.* In table 31 of this document, we estimate the cost of keeping records for one proposed provision for all poultry houses.

TABLE 31.—COST OF RECORDKEEPING FOR ONE PROVISION

Farm Size (No. of layers)	Houses Affected by the Proposal	Annual Cost Per House	Recordkeeping Costs
Fewer than 3,000	33,824	$472	$15,952,600
3,000 to 19,999	3,000	$943	$2,830,200
20,000 to 49,999	952	$943	$897,900
50,000 to 99,999	361	$943	$341,100
100,000 or more	1,322	$943	$1,246,600
All Farms	39,459		$21,268,400

We assume that the time required for recordkeeping is equivalent to the time necessary to monitor and document the provisions of a HACCP plan (63 FR 24253 at 24275 to 24286). Because the HACCP time estimate upon which we are basing our estimate involves multiple controls points and monitoring, this assumption tends to overstate the cost of recordkeeping for a provision of this proposal. In particular, we expect that, for each house affected,

recordkeeping will take one half an hour per week per required provision. At $18.14 an hour, doubled to reflect overhead costs, the cost of recordkeeping would be $943 ($18.14 x 52). We estimate that farms with fewer than 3,000 layers will have costs that are approximately half of those of larger farms. Our reasoning is further explained in section V.F.3 of this document.

b. *Training*. We are considering a provision that the person responsible for overseeing the SE prevention measures be trained or have equivalent job experience. A training course would last 2 to 3 days. The cost of taking a course consists of tuition, the cost of the supervisor's labor while in class, and any travel related expenditures that may be incurred.

The cost of a recent 3-day HACCP training course for egg processors was advertised to be $450 to $550 (Ref. 135). The cost of the supervisor's labor is estimated to be $1,161 (32 hours[67] x $36.28 an hour).

Travel expenditures consist of transportation, hotel, and miscellaneous expenses. These costs range from insignificant (reimbursement for minimal mileage) to $1,000 ($400 airfare + $400 hotel expenses + $200 expenses). We believe that most training will be relatively close to where producers are located. In addition, training is likely to take place in rural areas where lodging is relatively inexpensive. Therefore, we estimate that the most likely travel expense will be roughly $200 to $300. We use a Beta-Pert distribution to estimate that the expected cost of travel is $330.

The average cost of attending a training class is estimated to be $1,991 ($500 tuition + $1,161 labor + $330). Not all producers will have to send a supervisor to a class. The 12 percent of large farms already on quality assurance programs will have a trained supervisor already running the program. Of the remaining farms, some have experienced personnel who do not need formal training. Without better information, we assume that the true number of establishments that will need to formally train a supervisor will be uniformly distributed between 0 and 100 percent for all sizes of farms. Therefore, we expect 16,910 farms with fewer than 3,000 layers and 1,620 farms with 3,000 or more layers to incur training expenses. This cost will have to be incurred only at the outset of the program, and then again when a farm loses a trained supervisor. The total cost for all farms training a supervisor every 10 years, amortized at 7 percent, is estimated to be $4.8 million for very small farms and $0.5 million for larger farms. Amortized at 3 percent, the total cost is estimated to be $4.0 million for farms with less than 3000 layers and $0.4 million for larger farms.

c. *Registration*. Under this potential provision, all farms covered by any part of the proposed rule would be required to register with FDA. We estimate that approximately 33,820 farms with fewer than 3,000 layers and 4,080 farms with 3,000 or more layers would be covered by a registration provision. The cost of registration is composed of the labor cost of learning about, obtaining, filling out, and sending the registration form to FDA. We assume that the typical producer would spend a total of 30 minutes registering and that the value of labor is $18.14 per hour, doubled for overhead costs, for a total cost of $18.14 per producer. The total cost to the industry is $687,600 ($18.14 x 37,903). Amortized at 7 percent, the annual cost of registration is expected to be $97,900. The cost to farms with fewer than 3,000 layers would be $87,400, while the cost to farms with more than 3,000 layers would be $10,500. Amortized at 3 percent, the annual cost of registration is expected to be $80,600. The cost to farms with fewer than 3,000 layers would be $71,900, while the cost to farms with more than 3,000 layers would be $8,700.

d. *Summary of costs and benefits of administrative provisions*. The costs of administrative provisions are summarized in table 32 of this document. These provisions do not have independently quantifiable benefits. The provisions would be likely to generate benefits because administrative provisions help farmers verify whether SE prevention measures are being implemented appropriately. Early intervention on a plan that is not being implemented appropriately could result in corrective action to prevent SE that might otherwise occur. Furthermore, early troubleshooting in the event that SE is found on their farms would help farmers reduce any additional exposure from SE.

TABLE 32.—COSTS OF POTENTIAL ON-FARM ADMINISTRATIVE PROVISIONS (THOUSANDS OF DOLLARS)

	Farm Size	
	<3,000 Layers	>3,000 Layers
Costs (eventual)		
Plan Design	$1,747 per Provision	$334 per Provision
Recordkeeping	$15,953 per record kept	$5,316 per record kept
Training	$4,800	$459
Registration	$87	$11

3. Summary of On-Farm SE Prevention and Administrative Measures

Table 33 of this document shows the estimated costs and benefits for all of the on-farm SE prevention measures that we have considered. These totals include covering farms with fewer than 3,000 layers. The total costs and benefits of all of these prevention measures represent the costs and benefits of the regulatory option (described previously) of more extensive on-farm controls. Table 33 can also be used to illustrate the costs and lower bound incremental benefits of individual provisions or combinations of provisions. Because table 33 shows the effects of each provision when all are enacted, and the interdependence of rodent and pest control, biosecurity, cleaning and disinfecting, and testing and diversion is accounted for, these estimates can be added together, mixed and matched, to

[67] The number of hours is estimated as 24 hours of class time plus 8 hours of travel time.

achieve a rough estimate of the lower bound effects of different combinations of provisions. Between table 28 and table 33, a bounded estimate of the incremental effect of each provision is achieved. For example, testing and diversion will cost farms with more than 3,000 layers an incremental amount between $1,800 and $2,600 per illness avoided.

TABLE 33.—SUMMARY OF ANNUAL COSTS AND BENEFITS OF ON-FARM SE PREVENTION MEASURES (THOUSANDS OF DOLLARS)

	Farm Size	
	<3,000	>3,000
On-Farm Measures		
Costs (thousands of dollars)		
Rodent and Pest Control	$3,008	$21,019
Biosecurity	$7,100	$15,954
Cleaning and Disinfecting	$1,372	$2,441
SE Monitored Chicks and Pullets	$0.5	$87
SE Negative Feed	$138	$27,363
Vaccination	$188	$29,261
Refrigeration	$5,718	$18,200
Environmental Tests (Row Based Sampling)	$5,006	$3,460
Environmental Tests (Random Sampling)	$47,353	$8,922
Egg Tests	$0	$4,608
Diversion	$103	$5,133
Review of SE Prevention Plan	$871	$444
Cases of SE Averted (eventual)		
Rodent and Pest Control	142	25,701
Biosecurity		
Cleaning and Disinfecting		
SE Monitored Chicks and Pullets	<1	10
SE Negative Feed	Theoretical	Theoretical
Vaccination	Uncertain	Uncertain
Refrigeration	7	1,427
Testing and Diversion	33	6,296
Other Benefits		
Rodent Control (Feed Savings—thousands of dollars)	3.8	696
Cost per Case of SE Averted (eventual—thousands of dollars)		
Rodent and Pest Control	$80.8	$1.5
Biosecurity	Included in Rodent Control	Included in Rodent Control
Cleaning and Disinfecting	Included in Rodent Control	Included in Rodent Control
SE Monitored Chicks and Pullets	1	8.7
SE Negative Feed	Theoretical	Theoretical
Vaccination	Uncertain	Uncertain
Refrigeration	816.9	12.8

TABLE 33.—SUMMARY OF ANNUAL COSTS AND BENEFITS OF ON-FARM SE PREVENTION MEASURES (THOUSANDS OF DOLLARS)—Continued

	Farm Size	
	<3,000	>3,000
Testing and Diversion[1]	822.8	2.6
Administrative Measures		
Plan Design (Assumes 11 Provisions)	$19,217	$3,674
Recordkeeping (Assumes 7 Records Kept)	$111,671	$37,212
Training	$4,800	$459
Registration	$87	$11

[1] Assumes the average cost for environmental testing between random and row based sampling, assuming either type of test is equally likely.

4. Retail Provisions

a. *Coverage*. We considered whether Federal SE prevention measures should cover retail establishments that specifically serve highly susceptible populations. Establishments possibly covered would include nursing homes, child and adult day care centers, senior centers, and hospitals. The 2001 Model Food Code recommends additional safeguards for these establishments.

b. *SE prevention measures at retail*. i. *Provisions*. Under the measures we considered, establishments that specifically serve consumers from highly susceptible populations would be required to comply with certain provisions in the Food Code that we describe in section IV.D of this document. Those provisions for which we have adequate information to estimate costs and benefits would require that the previously mentioned establishments:

- Use only eggs that are clean, sound, contain no more restricted eggs than the proportion allowed in U.S. Consumer Grade B, and have been transported at an ambient temperature of 45 °F or below;
- Use pasteurized eggs or egg products in dishes that will be undercooked; and
- Substitute pasteurized eggs or egg products for raw shell eggs in dishes in which two or more eggs are broken and combined, unless the eggs are broken, combined, thoroughly cooked, and served immediately or are broken, combined, and used immediately as an ingredient in products (such as cookies or muffins) that will be thoroughly cooked.

ii. *Current state and industry practices—institutions serving highly susceptible populations*. These potential provisions are currently contained in the 2001 FDA Food Code (Refs. 136, 137, and 138). To date, 41 of 56 states and territories have adopted some version (1993 or later) of the FDA Food Code. Actual coverage is complicated, because the states and territories that have adopted the FDA Food Code do not necessarily follow all of the provisions, and states that have not adopted the FDA Food Code may have other regulations that have provisions that provide the same level of protection for highly susceptible populations.

iii. *Costs of retail SE prevention measures*. Two costs would occur if the retail SE prevention measures applicable to establishments that specifically serve highly susceptible populations were included in a final rule. First, covered retail establishments would incur increased costs from using pasteurized eggs and egg products in place of raw shell eggs. Second, covered retail establishments would incur costs from training employees to hold, prepare, and cook raw eggs properly.

If retail establishments used pasteurized shell eggs in place of unpasteurized shell eggs, they would pay more for their eggs ($0.35 per dozen) (Ref. 139). We do not know how many establishments would choose to do so. Alternatively, retail establishments could choose to use pasteurized egg products in place of unpasteurized shell eggs. If this option were chosen, the cost of this provision would be the cost differential between shell eggs and pasteurized egg products. We ask for comments regarding what these costs would be.

While there are no provisions that specifically require the training of food service industry employees, we believe that employers would choose to train their employees to hold, prepare, and cook raw eggs in accordance with these provisions. We also ask for comments regarding what these costs would be.

iv. *Benefits of retail SE prevention measures*. If all establishments serving highly susceptible populations were to implement these SE prevention measures through either Food Code adoption by states and territories (or other governments) or Federal regulations, we would expect to largely eliminate SE illnesses due to eggs and egg dishes served at these establishments. The USDA *Salmonella* Enteritidis Risk Assessment estimated that 24.7 percent of egg-related SE illness occurs from eggs consumed in institutions (Ref. 15). We assume this proportion to hold for highly susceptible and other consumers. The SE risk assessment also calculates that 50.4 percent of the population that becomes ill from SE comes from the highly susceptible population.[68] We therefore expect that a total of 12.4 percent (24.7 percent x 50.4 percent) of SE illnesses fall into the category of highly susceptible consumers who ate contaminated egg dishes at institutions. We do not know where highly susceptible consumers eat the eggs that make them ill. If we assume that half of these illnesses occur in institutions that specifically serve highly susceptible populations, these retail provisions would reduce illness due to SE contaminated eggs by 6.2 percent. We do not have robust estimates of the costs and benefits associated with those provisions.

F. Summary of Benefits and Costs of the Proposed Rule

In the previous section of this document, we described and estimated the benefits and costs of all of the SE

[68] The *Salmonella* Enteritidis Risk Assessment's ''susceptible'' populations and the Food Code's ''highly susceptible'' populations served by institutions are roughly equivalent. The SE risk assessment defines susceptible populations to include pregnant women, infants, the elderly, and immunocompromised persons. Children, the elderly, and immunocompromised persons could all be in institutions serving highly susceptible populations.

prevention measures we have considered. Here, we summarize and estimate the benefits and costs of the proposed rule.

1. Coverage

The proposed rule would only apply to farms with at least 3,000 layers that do not have all of their eggs treated, do not sell all of their eggs directly to consumers, and produce shell eggs for the table market. Farms in this category would be required to comply with all parts of the proposed rule. No retail establishments are directly affected by the proposed rule, because no retail establishments would be covered by the proposed rule.

2. Provisions in the Proposed Rule

a. *On-Farm preventive controls.* Many of the on-farm preventive controls examined above are included in this proposed rule. Provisions included in the proposed rule are rodent and pest control, biosecurity, cleaning and disinfecting, and procurement of chicks and pullets from SE-monitored breeders.

b. *On-Farm SE prevention measures.* The proposed rule also contains most of the on-farm SE prevention measures described above. In particular, the refrigeration, sampling, testing, and diversion provisions are included in the proposed rule.

c. *Administrative provisions.* Some of the administrative provisions we considered are also required by the proposed rule. In particular, records for all environmental and egg sampling and testing must be kept. Furthermore, farms must keep records indicating compliance with diversion requirements.

Farms are required to use SE prevention measures but are not required to have a formal written SE prevention plan. We believe that many farms will choose to implement a written plan. Each farm is required to have a trained or otherwise qualified individual to administer the prevention measures required by the proposed rule.

3. Summary of Costs and Benefits

In table 34 of this document, we summarize the costs and illnesses averted of this proposed rule and its provisions. After the on-farm adjustment phase (up to 4 years), we expect costs to fall and illnesses averted to increase. Eventually, the proposed rule will prevent approximately 33,430 cases of SE per year at a cost of $2,200 per illness averted. This value is less than the most conservative estimate (one that does not account for the pain and suffering of arthritis) of the expected value of an SE related illness, shown in table 5 of this document. Furthermore, though not listed in table 34, we also calculated the cost per estimated QALY saved. Assuming a 7-percent discount rate, we estimate the proposed rule will save approximately 1,870 QALYs annually. Assuming a 3-percent discount rate the estimated number QALYs saved annually is 3,410. This translates to $39,400 per QALY saved using a 7 percent discount rate and $21,600 per QALY saved using a 3 percent discount rate.[69] Either estimate falls well below our most conservative estimate of $100,000 for the value of a quality adjusted statistical life year.

TABLE 34.—SUMMARY OF ANNUAL COSTS AND ILLNESSES AVERTED OF THE PROPOSED RULE (THOUSANDS OF DOLLARS)

Provision	Costs		Illnesses Averted		Cost per Illness Averted	
	Initial	Eventual	Initial	Eventual	Initial	Eventual
On-Farm Measures						
Procurement of SE-Monitored Chicks and Pullets	$87	$87	10	10	$8.7	$8.7
Rodent and Pest Control	$21,019	$21,019	12,851	25,703	$3.1	$1.5
Biosecurity	$15,594	$15,594	—[1]	—[1]		
Cleaning and Disinfecting	$2,899	$2,441	—[1]	—[1]		
Refrigeration	$18,200	$18,200	1,693	1,426	$10.8	$12.8
Environmental Testing (Average)	$5,861	$5,861	—[2,3]	—[2,3]		
Egg Testing	$5,487	$4,608	—[2]	—[2]		
Review of Program	$525	$444	—[2]	—[2]		
Diversion	$6,094	$5,133	7,559	6,294	$2.4	$2.5
Administrative Measures						
Program Management	$2,672	$2,672	—	—		
Recordkeeping	$5,316	$5,316	—	—		
Training	$459	$459	—	—		
Total	$84,213	$81,834	22,113	33,433	$3.8	$2.4

[1] Estimated rodent control benefits also include benefits from biosecurity and cleaning and disinfecting.
[2] The benefits from all elements of the testing and diversion program are reported jointly under diversion.
[3] The environmental testing cost number reported is the average of the costs of the random swab and row based sampling methods.

[69] QALD's were converted back to QALYs for each possible outcome by dividing by 365. Annual QALYs lost for a case chronic arthritis (0.14) and death (1.0) were summed and subsequently discounted (at 3 percent and 7 percent) over 50 years.

The mean estimated dollar values of the benefits, the complete range and discussion of which is presented in section V.E.4 of this document and shown in table 37 of this document, range from $82 million to $1.65 billion, depending on the assumptions made about VSL, QALY, and the discount rate. Although the lowest mean estimated benefits are close to the mean estimated costs, these estimated benefits do not capture the health effects of chronic reactive arthritis sufferers. The most plausible estimated benefits values lie between $250 million and $1 billion, well above expected costs. The mean of all of the estimates is $580 million and most closely corresponds to the assumption set with VSL = $5 million, VSLY = $300 thousand, and the discount rate = 7 percent. Thus, at the mean, net benefits are roughly $500 million annually. Considering the plausible range of benefits and costs, net benefits of the proposed rule could be as low as $130 million annually and as high as $950 million annually.

As noted previously, the benefits of some provisions in the proposed rule are slightly lower in table 34 of this document than are the benefits listed in the analysis of potential provisions. This difference arises from the fact that each provision in the proposed rule reduces the base line number of illnesses that is used to estimate the benefits of the next provision in the list. In the benefits estimates for potential provisions, by contrast, the base line number of illnesses due to SE in shell eggs is fixed at the total number of illnesses estimated for 2001.

Table 34 of this document illustrates that we have not explicitly determined the benefits for the administrative provisions. The administrative provisions enhance the effectiveness of the SE prevention measures mandated by the rule, and the benefits are therefore embedded in the benefits estimates for each control measure.

In table 34 of this document, we include a cost for program management, because we assume that some management will be necessary to plan and carry out the provisions of the proposed rule. We assume that program management costs will be roughly equal to the cost of the potential plan design with eight provisions. We ask for comment on this assumption.

The recordkeeping costs in table 34 of this document are based on the requirement to keep testing, sampling, and diversion records. The cost of this requirement is assumed to be equal to the cost of one record, as presented in table 31 of this document. As discussed in section V.E.2.a.iv of this document, this estimated cost is likely to overestimate the true cost of keeping testing and diversion records. The recordkeeping costs calculated above are estimated for the typical record that a farm might keep. A typical record is assumed to reflect routine monitoring of a facet of an SE prevention program. Sampling, testing, and diversion records are only collected at the time that testing or diversion is taking place. We ask for comment regarding the actual burden of keeping records associated with the testing and diversion provisions of the proposed rule.

4. Analysis of Uncertainty

In table 34 of this document and elsewhere we present the expected effects of the proposed rule as point estimates. While this is a convenient way to summarize the effects of individual provisions and alternative regulatory options, the use of point estimates neglects the large degree of uncertainty intrinsic to the underlying analysis. In table 35 of this document, we present the results of a Monte Carlo simulation of uncertainty for the eventual annual costs of the proposed rule. Results are reported for the 5th and 95th percentiles, as well as for the mean value. Because many uncertainties could not be measured, this table should not be seen as a complete characterization of the uncertainty underlying the analysis. Nonetheless, table 35 of this document is a good illustration of the effect of the uncertainties we know to exist. Based on the data for which we have been able to characterize uncertainty, we believe that the eventual annual cost of the proposed rule will lie between $50 million and $1.12 billion. We outline descriptions of the distributions used to measure the uncertainties accruing to each provision in appendix C of this document.

TABLE 35.—COSTS OF THE PROPOSED RULE: ANALYSIS OF UNCERTAINTY (THOUSANDS OF DOLLARS)

	5th Percentile	Mean	95th Percentile
On-Farm Measures			
SE Monitoring of Chicks and Pullets	$23	$87	$176
Rodent and Pest Control	$11,389	$21,019	$32,916
Biosecurity	$15,290	$15,594	$15,894
Cleaning and Disinfecting	$1,190	$2,441	$5,567
Refrigeration	$11,850	$18,120	$24,844
Environmental Testing	$2,361	$5,861	$10,794
Egg Testing	$3,407	$4,608	$9,186
Review of Program	$330	$444	$875
Diversion	$3,811	$5,133	$10,071
Administrative Measures			
Program Management	$2,672	$2,672	$2,672
Recordkeeping	$4,481	$5,316	$6,833
Training	$44	$459	$912

TABLE 35.—COSTS OF THE PROPOSED RULE: ANALYSIS OF UNCERTAINTY (THOUSANDS OF DOLLARS)—Continued

	5th Percentile	Mean	95th Percentile
Total	$54,924	$81,754	$123,407

In tables 36 and 37 of this document, we characterize the uncertainties associated with the benefits of the proposed rule. A description of the distributions underlying the estimates in tables 36 and 37 can be found in appendix C. The expected annual benefits in terms of illness averted from the proposed rule range from nearly 21,300 SE illnesses averted to more than 49,500 cases of SE illnesses averted.

TABLE 36.—ILLNESSES AVERTED BY THE PROPOSED RULE: ANALYSIS OF UNCERTAINTY

Provision	5th Percentile	Mean	95th Percentile
On-Farm Measures			
SE Monitoring of Chicks and Pullets	7	10	15
Rodent and Pest Control	16,329	25,703	38,082
Biosecurity	Included in Rodent Control		
Cleaning and Disinfecting	Included in Rodent Control		
Refrigeration	914	1,426	2,125
Testing and Diversion	4,020	6,294	9,281
Total	21,270	33,433	49,503

Table 37 of this document shows that the estimated annual benefits in constant 2001 dollars range from $52.4 million to $2.45 billion. The large range is due in great part to the uncertainties underlying the economic assumptions. Although the lower bound estimate of expected benefits overlaps the upper bound of expected costs, it is safe to say that nearly all of the estimated distributions of benefits exceed the expected costs. Under very reasonable economic assumptions, the expected benefits of the proposed rule exceed the expected costs.

TABLE 37.—ESTIMATED VALUE OF ALL ILLNESSES AVERTED, GIVEN DIFFERENT ECONOMIC ASSUMPTIONS (THOUSANDS OF DOLLARS)

	Discount Rate = 3%					
	VSL = $5 million			VSL = $6.5 million		
	5th percentile	Mean	95th percentile	5th prcentile	Mean	95th percentile
VSLY = $0	$56,276	$88,457	$130,975	$69,950	$109,950	$162,799
VSLY = $100 thousand	$252,790	$397,344	$588,333	—	—	—
VSLY = $300 thousand	$645,816	$1,015,119	$1,503,048	$659,490	$1,036,611	$1,534,872
VSLY = $500 thousand	—	—	—	$1,052,516	$1,654,385	$2,449,587

	Discount Rate = 7%					
	VSL = $5 million			VSL = $6.5 million		
	5th percentile	Mean	95th percentile	5th prcentile	Mean	95th percentile
VSLY = $0	$52,406	$82,373	$121,967	$66,079	$103,866	$153,791
VSLY = $100 thousand	$161,703	$254,170	$376,341	—	—	—
VSLY = $300 thousand	$380,296	$597,764	$885,087	$393,970	$619,257	$916,911
VSLY = $500 thousand	—	—	—	$612,564	$962,851	$1,425,657

[1] VSL means value of a statistical life.
[2] VSLY value of a statistical life year.

Tables 35 through 37 of this document present the results of Monte Carlo simulations that treat the costs and benefits as distributions rather that as point estimates. The tables show that the range of potential costs is much narrower than the range of potential benefits. One additional component of costs not captured in the simulation involves enforcement costs. If FDA or States devote additional resources to inspections as a result of this rule, then the costs of those increased resources must be included in the total costs of the rule. FDA estimates that the potential social cost of increased inspections carried out by FDA or by States in cooperation with FDA, including costs of inspections, re-inspections, egg testing, training, education, assistance, additional staff, and operating costs, is $8 million per year. The egg safety program costs increase the expected annual costs of the proposed rule to $90 million.

The monetary estimates of benefits cover a broad range. The range is largely generated by the different values placed on cases of chronic reactive arthritis that result from SE illness. The higher the value of a statistical life year used to value the health effects of chronic reactive arthritis, the higher the estimated monetary benefits of this proposed rule. If the health effects of reactive arthritis are excluded from the estimated benefits, as in the first 4 rows of table 37 of this document, then the benefits and cost of the proposed rule are of approximately the same magnitude: the distribution of costs and benefits overlap and we cannot definitively conclude that the benefits exceed costs. Once the health effects of preventing chronic reactive arthritis are included, however, even the 5th percentile estimated benefits easily exceed estimated costs.

VI. Initial Regulatory Flexibility Analysis

A. Introduction

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a proposed rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the proposed rule on small entities.

B. Economic Effects on Small Entities

1. Number of Small Entities Affected

The Small Business Administration (SBA) defines chicken and egg producers to be small if their total revenues are less than $9 million (65 FR 30836 at 30841, May 15, 2000). A producer that receives $0.45 per dozen eggs and has layers that produce 265 eggs per year would have to have over 900,000 layers in production to earn revenues of over $9 million. While there are a number of producers that fall into this category, the vast majority of the farms affected by this proposed rule are considered to be small by SBA standards.

We estimate that approximately 8 percent of producers that are identified by the standard industrial classification (SIC) codes and the North American Industry Classification System (NAICS) as chicken and egg producers are large by SBA definition.[70] However, because the smallest egg producers are not classified by SIC or NAICS codes, we believe that fewer than 8 percent of egg producers actually fit the SBA definition of ''large.''

2. Costs to Small Entities

The on-farm portion of the proposed rule will result in significant costs to small businesses. In this PRIA we have estimated costs by farm size. These costs are presented in table 38 of this document. For the industry as a whole, the annual cost of the proposed rule is estimated to be $2,157 per farm site. This translates into a cost of $0.32 per egg layer.

TABLE 38.—DISTRIBUTION OF COST BY FARM SIZE

Farm Size (No. of layers)	Per Farm Cost of Proposed Rule[1]	Per Layer Cost of Proposed Rule
Less than 3,000	$0	$0
3,000 to 19,999	$11,779	$1.01
20,000 to 49,999	$13,364	$0.47
50,000 to 99,999	$24,412	$0.35
100,000 or more	$74,266	$0.19
All Farms	$2,157	$0.32

[1] These figures are drawn from the Preliminary Regulatory Impact Analysis (PRIA). In the PRIA not all costs are explicitly broken out by farm size. In this case, we assume that costs are either: (1) Equal for all farms (training and registration), (2) scaled to the number of houses per farm site (cleaning and disinfecting for flocks with more than 3,000 layers, biosecurity, and plan review in the case of a positive), or (3) scaled to the number of layers per farm site (National Poultry Improvement Plan SE monitored chicks and feed).

C. Regulatory Options

1. Exemption for Small Entities

a. *Exemption for all small entities.* One possible approach to reduce the impact on small entities would be to exempt all small entities from the rule. Although this would significantly reduce costs, it would also significantly reduce benefits. As mentioned above, under the SBA size standards the vast majority of farms affected by this proposed rule are small. Small farms include not only farms with a few hundred layers, but also some larger farms with over 100,000 layers. This exemption would lead to a significant reduction in the benefits estimated for the proposed rule.

The alternative approach implemented in the proposed rule exempts farms with fewer than 3,000 layers.[71] While over 89 percent of the farm sites covered by this rule have fewer than 3,000 layers, less than 1 percent of the eggs produced in the

[70] Data are drawn from Dun and Bradstreet's financial records using the Dialog database (Ref. 140).

[71] An exemption for farms with fewer than 3,000 birds is consistent with the exemption given by the EPIA for egg farms that are also egg processors.

United States are produced on these farms.

FDA has decided to exempt all farms with fewer than 3,000 layers from all provisions of this proposed rule. By exempting these farms, we reduce expected benefits by less than one percent while reducing expected costs by half.

We also exempt from all parts of the proposed rule those farms that sell all of their eggs directly to consumers.

2. Longer Compliance Periods

We recognize that it may be more difficult for some small farms to learn about and implement these SE prevention measures than it will be for other farms. FDA is therefore proposing to give farm sites with 3,000 or more but fewer than 50,000 layers, 2 years (as opposed to 1 year for larger farm sites) to comply with this proposed rule.

D. Description of Recordkeeping and Recording Requirements

The Regulatory Flexibility Act requires a description of the recordkeeping required for compliance with this proposed rule. We require recordkeeping for the sampling, testing, and diversion provisions of the proposed rule. The cost of recordkeeping is exhibited in table 39 of this document. How recordkeeping costs are calculated is detailed in section V.E of this document.

TABLE 39.—COST OF RECORDKEEPING BY FARM SIZE

Farm Size (No. of layers)	Per Farm Cost of Recordkeeping	Per Layer Cost of Recordkeeping
Less than 3,000	$0	$0
3,000 to 19,999	$2,830	$0.11
20,000 to 49,999	$898	$0.05
50,000 to 99,999	$341	$0.03
100,000 or more	$1,247	$0.02
All Farms	$135	$0.02

E. Summary

FDA finds that, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), this proposed rule would have a significant impact on a substantial number of small entities. More than 1,000 small farms would be affected by the proposed rule.

VII. Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4) requires cost-benefit and other analyses for rules that would cost more than $100 million in a single year. The current inflation-adjusted statutory threshold is $115 million. Since the estimated annual cost for this proposed rule is less than $115 million, FDA has determined that this proposed rule, if it becomes a final rule as proposed, would not be a significant rule under UMRA.

VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132 on federalism. We have examined the effects of the requirements of this proposal for on-farm SE prevention measures for shell egg production on the relationship between the Federal Government and the States. The agency concludes that preemption of State or local rules that establish requirements for production of shell eggs that would be less stringent than Federal law is consistent with this Executive Order. Section 3(b) of Executive Order 13132 recognizes that Federal action limiting the policymaking discretion of States is appropriate ''where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance.'' The constitutional basis for FDA's authority to regulate the safety and labeling of foods is well established.

Section 4(a) of Executive Order 13132 expressly contemplates preemption where the exercise of State authority conflicts with the exercise of Federal authority under a Federal statute. Moreover, section 4(b) of Executive Order 13132 authorizes preemption of State law by rulemaking when the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute or there is clear evidence to conclude that Congress intended the agency to have the authority to preempt State law.

State and local laws and regulations that would impose less stringent requirements for production of shell eggs would undermine the agency's goal of ensuring that shell eggs are produced using measures that will prevent their contamination with SE and, thus, reduce the risk of foodborne illness. The proposed requirements for production of shell eggs are the minimal prevention measures that we believe are necessary to ensure safety.

The proposed rule would establish national minimum prevention measures with respect to production of shell eggs. However, the egg production requirements of this proposed rule do not preempt State and local laws, regulations, and ordinances that establish more stringent requirements with respect to production requirements. As required by the Executive order, States and local governments will be given, through this notice of proposed rulemaking, an opportunity to participate in the proceedings to preempt State and local laws. In addition, appropriate officials and organizations will be consulted before this proposed action is implemented; the agency plans to have public meetings specifically addressing the issue of implementation of these proposed regulations. The agency consulted with a working group comprised of State officials in developing the provisions of this proposed rule and plans to continue to consult with this group in the development of a final rule. In addition, we sent facsimiles of a **Federal Register** document announcing a public meeting on egg safety and the availability of egg safety ''current thinking'' documents prepared by FDA and USDA to Governors, State health and agriculture commissioners, State attorneys general, and State food program coordinators.

IX. Environmental Impact

The agency has determined under 21 CFR 25.30(j) that this action is of a type

that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in the following paragraphs with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, or other forms of information technology.

Title: Control of *Salmonella* Enteritidis in Shell Eggs During Production—Recordkeeping Provisions Under Proposed Part 118.

Description: FDA is proposing to require shell egg producers to implement SE measures to prevent SE from contaminating eggs on the farm. We are only proposing recordkeeping provisions for the sampling, testing and diversion requirements for shell egg producers.

We have tentatively concluded that recordkeeping is necessary for the success of the SE prevention measures. Records of testing and diversion will assist FDA in determining if the farm in question currently has a problem with SE and is making an effort to ameliorate any problem it might have. FDA's statutory authority for these proposed requirements is discussed in section III.L of this document.

Description of Respondents: Businesses or other for profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 40.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
118.10	5,635	1	5,635	26	146,510
Total					146,510

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimates in table 40 in this document are based on estimates of the total number of layer houses affected by this proposed rule from statistics obtained from the NASS. Individual burdens were obtained by estimating the number of layer houses affected by each portion of the proposed rule and multiplying it by the corresponding number of records required annually and the hours needed to complete the record. These burden estimates are an estimate of the hours needed to complete each record contained in the agency's PRIA prepared for this proposed rule.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to submit comments regarding information collection to OMB, via facsimile on 202–395–6974, Attn: Desk Officer for FDA.

XI. Comments

Submit written comments regarding this proposal to the Division of Dockets Management (see **ADDRESSES**), unless comments regard information collection. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit comments regarding information collection to OMB (see **ADDRESSES**). Submit a single copy of electronic comments or two copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

XII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 118

Eggs and egg products, Incorporation by reference, Recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under the authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR chapter I be amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

2. Section 16.5 is amended by adding paragraph (a)(5) to read as follows:

§ 16.5 Inapplicability and limited applicability.

(a) * * *

(5) A hearing on an order for diversion or destruction of shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264), and § 118.12 of this chapter.

* * * * *

3. Part 118 is added to read as follows:

PART 118—PRODUCTION AND STORAGE OF SHELL EGGS

Sec.

118.1 Shell egg producers covered by the requirements in this part.
118.3 Definitions.
118.4 *Salmonella* Enteritidis (SE) prevention measures.
118.5 Environmental testing for *Salmonella* Enteritidis (SE).
118.6 Egg testing for *Salmonella* Enteritidis (SE).
118.7 Sampling methodology for *Salmonella* Enteritidis (SE).
118.8 Testing methodology for *Salmonella* Enteritidis (SE).
118.9 Administration of the *Salmonella* Enteritidis (SE) prevention measures.
118.10 Recordkeeping requirements for the *Salmonella* Enteritidis (SE) prevention measures.
118.12 Enforcement and compliance.

Authority: 21 U.S.C. 321, 331–334, 342, 371, 381, 393; 42 U.S.C. 243, 264, 271.

§ 118.1 Shell egg producers covered by the requirements in this part.

If you are a shell egg producer with 3,000 or more laying hens at a particular farm that does not sell all of your eggs directly to consumers and that produces shell eggs for the table market, you are covered by some or all of the requirements in this part, as follows:

(a) If any of your eggs that are produced at the particular farm do not

receive a treatment as defined in § 118.3, you must comply with all of the requirements of this part for egg production on that farm.

(b) If all of your eggs that are produced at the particular farm receive a treatment as defined in § 118.3, you must comply only with the refrigeration requirements in § 118.4 for production of eggs on that farm.

§ 118.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the FFDCA) (21 U.S.C. 321) are applicable to such terms when used in this part, except where they are redefined in this part. The following definitions also apply:

Biosecurity means a program, including limiting visitors to poultry houses, keeping small animals out of poultry houses, and requiring personnel to wear protective clothing, to ensure that there is no introduction or transfer of *Salmonella* Enteritidis (SE) onto a farm or among poultry houses.

Farm means all poultry houses and grounds immediately surrounding the poultry houses covered under a single biosecurity program.

Flock means all laying hens within one poultry house.

Group means all laying hens of the same age within one poultry house.

Induced molting means molting that is artificially initiated.

Laying cycle means the period of time that a hen begins to produce eggs until it undergoes induced molting or is permanently taken out of production and the period of time that a hen produces eggs between successive induced molting periods or between induced molting and the time that the hen is permanently taken out of production.

Molting means a life stage during which hens stop laying eggs and shed their feathers.

Pest means any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

Positive flock means a flock that has had an egg test that was positive for SE and applies until that flock meets the egg testing requirements in § 118.6(b) to return to table egg production.

Positive poultry house means a poultry house from which there has been an environmental test that was positive for SE during any of the laying cycles of a group in the poultry house until that house is cleaned and disinfected according to § 118.4(d).

Poultry house means a building, other structure, or separate section within one structure used to house poultry. For structures comprising more than one section containing poultry, each section is enclosed and separated from the other sections, and each section has a biosecurity program in place to ensure that there is no introduction or transfer of SE from one section to another.

Producer means a person who maintains laying hens for the purpose of producing shell eggs for human consumption.

Shell egg (or egg) means the egg of the domesticated chicken.

Treatment means a technology or process that achieves at least a 5-log destruction of SE for shell eggs, or the processing of egg products in accordance with the Egg Products Inspection Act.

§ 118.4 *Salmonella* Enteritidis (SE) prevention measures.

You must have SE prevention measures that are specific for each farm where you produce eggs and that include, at a minimum, the following:

(a) *Chicks and pullets.* You must procure chicks and pullets that came as chicks from SE-monitored breeder flocks that meet the National Poultry Improvement Plan's standards for ''U.S. S. Enteritidis Monitored'' status (9 CFR 145.23(d)) or equivalent standards.

(b) *Biosecurity.* You must develop and implement a biosecurity program. The biosecurity program must include the grounds and all facilities at each farm. As part of this program you must:

(1) Limit visitors on the farm and in the poultry houses;

(2) Ensure that equipment that is moved among poultry houses is kept clean and is not a source of SE contamination;

(3) Ensure the proper hygiene of persons that move between poultry houses through use of protective clothing and sanitizing stations, or other appropriate means that will protect against cross contamination;

(4) Prevent stray poultry, wild birds, and other animals from entering grounds and facilities; and

(5) Not allow employees to keep poultry at home.

(c) *Rodents, flies, and other pest control.* You must develop and implement a pest and rodent control program to reduce the rodent, fly and other pest populations in your poultry house(s). As part of this program, you must:

(1) Monitor for rodents by visual inspection and mechanical traps or glueboards or another appropriate monitoring method and, when monitoring indicates unacceptable rodent activity within a poultry house, use appropriate methods to achieve satisfactory rodent control;

(2) Monitor for pests by spot cards, Scudder grills, or sticky traps or another appropriate monitoring method and, when monitoring indicates unacceptable pest activity within a poultry house, use appropriate methods to achieve satisfactory pest control.

(3) Remove debris within a poultry house and vegetation and debris outside a poultry house that may provide harborage for pests.

(d) *Cleaning and disinfection.* You must develop procedures for cleaning and disinfecting a poultry house as outlined in paragraphs (d)(1) through (d)(4) of this section. You must clean and disinfect the poultry house according to these procedures before new laying hens are added to the house, if you have had an environmental test or an egg test that was positive for SE at any point during the life of a flock that was housed in the poultry house prior to depopulation. As part of the cleaning and disinfection procedures, you must:

(1) Remove all visible manure;

(2) Dry clean the positive poultry house to remove dust, feathers, and old feed;

(3) Wet clean the positive poultry house, including washing with detergents. Use detergents according to label instructions, followed by recommended rinsing procedures; and

(4) Following cleaning, disinfect the positive poultry house with spray, aerosol, fumigation, or another appropriate disinfection method.

(e) *Refrigeration.* You must store eggs at or below 45 °F ambient temperature if you hold them for more than 36 hours after laying.

§ 118.5 Environmental testing for *Salmonella* Enteritidis (SE).

(a) *Environmental testing when laying hens are 40 to 45 weeks of age.* As one indicator of the effectiveness of your SE prevention measures, you must perform environmental testing for SE (as described in §§ 118.7 and 118.8) in a poultry house when any group of laying hens constituting the flock within the poultry house is 40 to 45 weeks of age.

(1) If an environmental test at 40 to 45 weeks is negative and your laying hens do not undergo induced molting, then you do not need to perform any additional environmental testing within that poultry house, unless the poultry house contains more than one group of laying hens. If the poultry house contains more than one group of laying hens, then you must perform environmental testing on the poultry house when each group of laying hens is 40 to 45 weeks of age.

(2) If the environmental test at 40 to 45 weeks is positive, then you must:

(i) Review and make any necessary adjustments to your SE prevention measures to ensure that all measures are being properly implemented and

(ii) Begin egg testing (described in § 118.6) within 24 hours of receiving notification of the positive environmental test, unless you divert eggs to treatment as defined in § 118.3 for the life of the flock in that poultry house.

(b) *Environmental testing after an induced molting period*. If you induce a molt in a flock or a group in a flock, you must perform environmental testing for SE in the poultry house approximately 20 weeks after the end of any molting process.

(1) If an environmental test approximately 20 weeks after the end of the molting process is negative and none of your laying hens in that poultry house is molted again, then you do not need to perform any additional environmental testing in that poultry house. Each time a flock or group within the flock is molted, you must perform environmental testing in the poultry house approximately 20 weeks after the end of the molting process.

(2) If the environmental test approximately 20 weeks after the end of a molting process is positive, then you must:

(i) Review and make any necessary adjustments to your SE prevention measures to ensure that all measures are being properly implemented; and

(ii) Begin egg testing (described in § 118.6) within 24 hours of receiving notification of the positive environmental test, unless you divert eggs to treatment as defined in § 118.3 for the life of the flock in that poultry house.

§ 118.6 Egg testing for *Salmonella* Enteritidis (SE).

(a) If you have an SE-positive environmental test at any time during the life of a flock, you must divert eggs to treatment (defined in § 118.3) for the life of the flock in that positive poultry house or conduct egg testing as specified in paragraphs (b) through (e) of this section.

(b) Eggs must be sampled as described in § 118.7 and tested using methodology as described in § 118.8.

(c) You must conduct four egg tests, using sampling and methodology in §§ 118.7 and 118.8, on the flock in the positive poultry house at 2-week intervals. If all four tests are negative for SE, you are not required to do further egg testing.

(d) If any of the four egg tests is positive for SE, you must divert, upon receiving notification of an SE-positive egg test, all eggs from that flock to treatment (defined in § 118.3) until the conditions of paragraph (c) of this section are met.

(e) If you have a positive egg test in a flock and divert eggs from that flock and later meet the negative test result requirements described in paragraph (c) of this section and return to table egg production, you must conduct one egg test per month on that flock, using sampling and methodology in §§ 118.7 and 118.8, for the life of the flock.

(1) If all the monthly egg tests in paragraph (e) of this section are negative for SE, you may continue to supply eggs to the table market.

(2) If any of the monthly egg tests in paragraph (e) of this section is positive for SE, you must divert eggs from the positive flock to treatment for the life of the flock or until the conditions of paragraph (c) of this section are met.

§ 118.7 Sampling methodology for *Salmonella* Enteritidis (SE).

(a) *Environmental sampling*. An environmental test must be done for each poultry house in accordance with § 118.5(a) and (b). Within each poultry house, you must sample the environment using a scientifically valid sampling procedure.

(b) *Egg sampling*. When you conduct an egg test required under § 118.6, you must randomly collect and test the following number of eggs from the positive poultry house.

(1) To meet the egg testing requirements of § 118.6(c), you must randomly collect 1,000 eggs from a day's production. The 1,000-egg sample must be tested according to § 118.8. You must randomly collect and test four 1,000-egg samples at 2-week intervals for a total of 4,000 eggs.

(2) To meet the monthly egg testing requirement of § 118.6(e), you must randomly collect 1,000 eggs from a day's production per month for the life of the flock. Eggs must be tested according to § 118.8.

§ 118.8 Testing methodology for *Salmonella* Enteritidis (SE).

(a) *Testing of environmental samples for SE*. Testing to detect SE in environmental samples must be conducted by the method entitled ''Detection of *Salmonella* in Environmental Samples from Poultry Houses'' dated January 19, 2001, (proposed for inclusion in FDA's Bacteriological Analytical Manual) or another method that is at least equivalent to the method cited previously in accuracy, precision, and sensitivity in detecting SE. The Director of the **Federal Register** approves the incorporation by reference ''Detection of *Salmonella* in Environmental Samples from Poultry Houses'' in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from Division of Dairy and Egg Safety (HFS–306), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Parkway, College Park, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html*.

(b) *Testing of egg samples for SE*. Testing to detect SE in egg samples must be conducted according to the pre-enrichment method described by Valentin et al., in the *Journal of Food Protection*, or another method that is at least equivalent to the method cited previously in accuracy, precision, and sensitivity in detecting SE. The egg sampling method is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from Division of Dairy and Egg Safety (HFS–306), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Parkway, College Park, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html*.

§ 118.9. Administration of the *Salmonella* Enteritidis (SE) prevention measures.

You must have one individual at each farm who is responsible for administration of the SE prevention measures. This individual must have successfully completed training on SE prevention measures for egg production that is at least equivalent to that received under a standardized curriculum recognized by the Food and Drug Administration or must be otherwise qualified through job experience to administer the SE prevention measures. Job experience

will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum. This individual is responsible for:

(a) Development and implementation of SE prevention measures that are appropriate for your specific farm and meet the requirements of § 118.4;

(b) Reassessing and modifying the SE prevention measures as necessary to ensure that the requirements in § 118.4 are met; and

(c) Review of records created under § 118.10. The individual does not need to have performed the monitoring or created the records.

§ 118.10 Recordkeeping requirements for the *Salmonella* Enteritidis (SE) prevention measures.

(a) *Records that egg producers are required to maintain.* You must maintain the following records:

(1) Records of environmental and egg sampling performed under § 118.7 and the results of SE testing performed under § 118.8 as required in §§ 118.5 and 118.6.

(2) Records indicating compliance with the diversion requirements in § 118.6.

(3) Records indicating that all of the eggs at a particular farm will be given a treatment as defined in § 118.3, if you are a producer complying with the requirements of this section as described in § 118.1(b).

(b) *General requirements for records maintained by egg producers.* All records required by § 118.10(a) must include:

(1) Your name and the location of your farm,

(2) The date and time of the activity that the record reflects,

(3) The signature or initials of the person performing the operation or creating the record, and

(4) Data and information reflecting compliance activities must be entered on records at the time the activity is performed or observed, and the records must contain the actual values observed, if applicable.

(c) *Length of time records must be retained.* You must retain all records required by this part at your place of business, unless stored offsite under § 118.10(d), for 1 year after the flock to which they pertain has been taken permanently out of production.

(d) *Offsite storage of records.* You may store the records required by this part offsite after 6 months following the date that the monitoring occurred. You must be able to retrieve and provide the records at your place of business within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(e) *Official review of records.* You must have all records required by this part available for official review and copying at reasonable times.

(f) *Public disclosure of records.* Records required by this part are subject to the disclosure requirements under part 20 of this chapter.

§ 118.12 Enforcement and compliance.

(a) *Authority.* This part is established under authority of the Public Health Service Act (the PHS Act). Under the FFDCA, the Food and Drug Administration (FDA) can enforce the food adulteration provisions under 21 U.S.C. 331 through 334 and 342. Under the PHS Act (42 U.S.C. 264), FDA has the authority to make and enforce regulations for the control of communicable diseases. FDA has established the following administrative enforcement procedures for the diversion or destruction of shell eggs and for informal hearings under the PHS Act:

(1) Upon a finding that any shell eggs have been produced or held in violation of this part, an authorized FDA representative or a State or local representative in accordance with paragraph (c) of this section may order such eggs to be diverted, under the supervision of said representative, for processing in accordance with the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*) or by a treatment that achieves at least a 5-log destruction of SE or destroyed by or under the supervision of an officer or employee of FDA, or, if applicable, of the State or locality in accordance with the following procedures:

(i) *Order for diversion or destruction under the PHS Act.* Any district office of FDA or any State or locality acting under paragraph (c) of this section, upon finding shell eggs that have been produced or held in violation of this regulation, may serve a written order upon the person in whose possession the eggs are found requiring that the eggs be diverted, under the supervision of an officer or employee of the issuing entity, for processing in accordance with the EPIA (21 U.S.C. 1031 *et seq.*) or by a treatment that achieves at least a 5-log destruction of SE or destroyed by or under the supervision of the issuing entity, within 10-working days from the date of receipt of the order, unless, under paragraph (a)(2)(iii) of this section, a hearing is held, in which case the eggs must be diverted or destroyed consistent with the decision of the Regional Food and Drug Director under paragraph (a)(2)(v) of this section. The order must include the following information:

(A) A statement that the shell eggs identified in the order are subject to diversion for processing in accordance with the EPIA or by a treatment that achieves at least a 5-log destruction of SE or destruction;

(B) A detailed description of the facts that justify the issuance of the order;

(C) The location of the eggs;

(D) A statement that these eggs must not be sold, distributed, or otherwise disposed of or moved except as provided in paragraph (a)(1)(iv) of this section;

(E) Identification or description of the eggs;

(F) The order number;

(G) The date of the order;

(H) The text of this entire section;

(I) A statement that the order may be appealed by written appeal or by requesting an informal hearing;

(J) The name and phone number of the person issuing the order; and

(K) The location and telephone number of the office or agency issuing the order and the name of its Director.

(ii) *Approval of District Director.* An order, before issuance, must be approved by FDA's District Director or the Acting District Director. If prior written approval is not feasible, prior oral approval must be obtained and confirmed by written memorandum as soon as possible.

(iii) *Labeling or marking of shell eggs under order.* An FDA, State, or local representative issuing an order under paragraph (a)(1)(i) of this section must label or mark the shell eggs with official tags that include the following information:

(A) A statement that the shell eggs are detained in accordance with regulations issued under section 361(a) of the PHS Act (42 U.S.C. 264(a)).

(B) A statement that the shell eggs must not be sold, distributed or otherwise disposed of or moved except, after notifying the issuing entity in writing, to:

(*1*) Divert them for processing in accordance with the EPIA or by a treatment that achieves at least a 5-log destruction of SE or destroy them, or

(*2*) Move them to an another location for holding pending appeal.

(C) A statement that the violation of the order or the removal or alteration of the tag is punishable by fine or imprisonment or both (section 368 of the PHS Act (42 U.S.C. 271)).

(D) The order number and the date of the order, and the name of the government representative who issued the order.

(iv) *Sale or other disposition of shell eggs under order.* After service of the order, the person in possession of the shell eggs that are the subject of the order must not sell, distribute, or otherwise dispose of or move any eggs subject to the order unless and until receiving a notice that the order is withdrawn after an appeal except, after notifying FDA's district office or, if applicable, the State or local representative, in writing, to:

(A) Divert or destroy them as specified in paragraph (a)(1)(i) of this section, or

(B) Move them to another location for holding pending appeal.

(2) The person on whom the order for diversion or destruction is served may either comply with the order or appeal the order to the Regional Food and Drug Director in accordance with the following procedures:

(i) *Appeal of a detention order.* Any appeal must be submitted in writing to FDA's District Director in whose district the shell eggs are located within 5 working days of the issuance of the order. If the appeal includes a request for an informal hearing, the hearing must be held within 5 working days after the appeal is filed or, if requested by the appellant, at a later date, which must not be later than 20 calendar days after the issuance of the order. The order may also be appealed within the same period of 5 working days by any other person having an ownership or proprietary interest in such shell eggs. The appellant of an order must state the ownership or proprietary interest the appellant has in the shell eggs.

(ii) *Summary decision.* A request for a hearing may be denied, in whole or in part and at any time after a request for a hearing has been submitted, if the Regional Food and Drug Director or his or her designee determines that no genuine and substantial issue of fact has been raised by the material submitted in connection with the hearing or from matters officially noticed. If the Regional Food and Drug Director determines that a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for denial.

(iii) *Informal hearing.* Appearance by any appellant at the hearing may be by mail or in person, with or without counsel. The informal hearing must be conducted by the Regional Food and Drug Director or his designee, and a written summary of the proceedings must be prepared by the Regional Food and Drug Director.

(A) The Regional Food and Drug Director may direct that the hearing be conducted in any suitable manner permitted by law and by this section. The Regional Food and Drug Director has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct an informal, fair, expeditious, and impartial hearing, and to enforce the requirements concerning the conduct of hearings.

(B) Employees of FDA will first give a full and complete statement of the action that is the subject of the hearing, together with the information and reasons supporting it, and may present oral or written information relevant to the hearing. The party requesting the hearing may then present oral or written information relevant to the hearing. All parties may conduct reasonable examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing.

(C) The hearing shall be informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views will be made or considered, but any party may comment upon or rebut any information and views presented by another party.

(D) The party requesting the hearing may have the hearing transcribed, at the party's expense, in which case a copy of the transcript is to be furnished to FDA. Any transcript of the hearing will be included with the Regional Food and Drug Director's report of the hearing.

(E) The Regional Food and Drug Director must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the Regional Food and Drug Director may give the parties the opportunity to review and comment on the report of the hearing.

(F) The Regional Food and Drug Director must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a recommended decision, with a statement of reasons.

(iv) *Written appeal.* If the appellant appeals the detention order but does not request a hearing, the Regional Food and Drug Director must render a decision on the appeal affirming or revoking the detention order within 5 working days after the receipt of the appeal.

(v) *Regional Food and Drug Director decision.* If, based on the evidence presented at the hearing or by the appellant in a written appeal, the Regional Food and Drug Director finds that the shell eggs were produced or held in violation of this section, he must affirm the order that they be diverted, under the supervision of an officer or employee of FDA for processing under the EPIA or by a treatment that achieves at least a 5-log destruction of SE or destroyed by or under the supervision of an officer or employee of FDA; otherwise, the Regional Food and Drug Director must issue a written notice that the prior order is withdrawn. If the Regional Food and Drug Director affirms the order, he must order that the diversion or destruction be accomplished within 10-working days from the date of the issuance of his decision. The Regional Food and Drug Director's decision must be accompanied by a statement of the reasons for the decision. The decision of the Regional Food and Drug Director constitutes final agency action, subject to judicial review.

(vi) *No appeal.* If there is no appeal of the order and the person in possession of the shell eggs that are subject to the order fails to divert or destroy them within 10-working days, or if the demand is affirmed by the Regional Food and Drug Director after an appeal and the person in possession of such eggs fails to divert or destroy them within 10-working days, FDA's district office or, if applicable, the State or local representative may designate an officer or employee to divert or destroy such eggs. It shall be unlawful to prevent or to attempt to prevent such diversion or destruction of the shell eggs by the designated officer or employee.

(b) *Inspection.* Persons engaged in production of shell eggs must permit authorized representatives of FDA to make, at any reasonable time, an inspection of the egg production establishment in which shell eggs are being produced. Such inspection includes the inspection and sampling of shell eggs and the environment, the equipment related to production of shell eggs, the equipment in which shell eggs are held, and examination and copying of any records relating to such equipment or eggs, as may be necessary in the judgment of such representatives to determine compliance with the provisions of this section. Inspections may be made with or without notice and will ordinarily be made during regular business hours.

(c) *State and local cooperation.* Under sections 311 and 361 of the Public Health Service Act, any State or locality that is willing and able to assist the agency in the enforcement of §§ 118.4 through 118.10, and is authorized to inspect or regulate egg production establishments, may, in its own jurisdiction, enforce §§ 118.4 through

118.10 through inspections under paragraph (b) of this section and through administrative enforcement remedies specified in paragraph (a) of this section unless FDA notifies the State or locality in writing that such assistance is no longer needed. When providing assistance under paragraph (a) of this section, a State or locality may follow the hearing procedures set out in paragraphs (a)(2)(iii) through (a)(2)(v) of this section, substituting, where necessary, appropriate State or local officials for designated FDA officials or may utilize comparable State or local hearing procedures if such procedures satisfy due process.

Dated: September 15, 2004.

Lester M. Crawford,

Acting Commissioner of Food and Drugs.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendix A to the PRIA: Costs of Alternative Testing and Diversion Scenarios

The costs of testing and diversion depend on a number of factors, including the probabilities of SE-positive results for environmental and egg tests, the costs of testing and diversion, and whether the layers are molted. FDA assumes that there are five possible scenarios for non-molted layers and seventeen possible scenarios for molted layers.

Non-molted layers—all scenarios. The environmental testing costs are calculated to be the laboratory cost of environmental testing (C_{NT}) plus the labor cost of collecting one test (C_{NL}) times the number of tests to be collected (N_{NT}), or: $Cost_{NT} = (C_{NT} + C_{NL}) \times N_{NTS}$.

Scenario 1: 40 to 45 week environmental test negative.

• In the first scenario, the 40 to 45 week environmental test is negative. No other tests are taken.

• There are no egg testing or diversion costs in this scenario.

• The first scenario occurs with a probability $PS_1 = (1 - p_{N1})$, where p_{N1} is the probability that the 40 to 45 week environmental test is positive.

Scenario 2: 40 to 45 week environmental test positive. Egg testing negative.

• In scenario two, a positive 40 to 45 week environmental test triggers egg testing. All 4 of the required egg tests come up negative. No other tests are performed.

• This is the first scenario under which eggs will have to be tested. The cost of an egg test is the sum of the laboratory (C_{GT}), labor (C_{GL}), and lost revenue (C_{GG}) costs for a 20-egg test times the number of 20 egg batches to be tested (N_{GT}) times the number of test collections (4). If 1,000 eggs were tested, they would be tested in 50 20-egg tests. The total cost of egg testing is therefore: $Cost_{GT2} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times 4$.

• There are no diversion costs in this scenario.

• The probability that this scenario will occur is equal to $PS_2 = p_{N1} \times (1 - p_{G1})$, where p_{G1} is the probability that the first egg test is positive.

Scenario 3: 40 to 45 week environmental and first egg test positive. Subsequent egg test negative.

• In this scenario, a positive 40 to 45 week environmental test triggers egg testing. One of the 4 required egg tests is positive, and the farmer must divert. The next 4 egg tests are negative, diversion is stopped, and eggs are tested monthly for the life of the flock without any additional positive results.

• In this case, there will be two sets of egg tests. In addition, the farm will be expected to test monthly for the remaining life of the flock (LF - 1).[1] The total cost of egg testing is therefore: $Cost_{GT3} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times (8 + LF_3 - 1)$.

• The cost of diversion is the price differential between a table egg and an SE-positive egg (DC) times the number of days diverted times the number of eggs produced per day by a typical bird (0.72) times the number of layers in a typical layer house (HS). We expect that a set of four 1,000-egg tests will occur over a total of 8 weeks including laboratory time. Therefore, the total number of days diverted is equal to 56. This figure assumes that only one egg positive will be found and that diversion will end after eight weeks of testing. The total cost of diversion is: $Cost_{D3} = DC \times 56 \times 0.72 \times HS$.

• The probability that this scenario will occur is equal to $PS_3 = p_{N1} \times p_{G1} \times (1 - p_{G2})$, where p_{G2} is the probability that the second egg test is positive.

Scenario 4: 40 to 45 week environmental and first two egg tests positive. Eventually test off diversion.

• In this scenario, a positive 40 to 45 week environmental test triggers egg testing. One of the first 4 1,000-egg tests comes up positive, and the farmer must divert. After the positive egg test, one of the next 4 egg tests is also positive, and the farmer continues to divert. However, the farmer eventually tests off diversion, and eggs are tested monthly for the life of the flock.

[1] The remaining test life of the flock is LF -1 (LF is the remaining number of months) because the last month of lay generally produces substandard eggs that are sent to the breaker regardless of SE status. Thus, this last month is omitted from our calculations.

• The cost of egg testing in this scenario builds on the cost of egg testing in scenario 3. In this case the cost is equivalent to that of the last case with the exception that testing continues to occur halfway to the end of lay. Mathematically, this is written as: $Cost_{GT4} = (C_{GT} + C_{GL} + C_{GG}) \times [(8 \times N_{GT}) + 2.17 \times (LF_4 - 1) \times N_{GT5} \div 2 + (LF_4 - 1) \times N_{GT} \div 2]$.

• The cost of diversion equals the cost of diversion in scenario 3 (DC x 56 x 0.72 x HS) plus the cost of diversion for half of the remaining lay period DC x $[30 \times (LF_4 - 1) \div 2] \times 0.72 \times HS$. After like terms are grouped, the total cost under this scenario can be written as: $Cost_{D4} = (DC \times 0.72 \times HS) \times (56 + 30 \times (LF_4 - 1) \div 2)$.

• The probability that this scenario will occur is equal to $PS_4 = p_{N1} \times p_{G1} \times p_{G2} \times (1 - p_{G3})$, where p_{G3} is the probability that the farm never tests out of diversion.

Scenario 5: 40 to 45 week environmental and first two egg tests positive. Farm stays on diversion for the life of the flock.

• In this scenario, a positive 40 to 45 week test triggers egg testing. One of the first 4 egg tests comes up positive, and the farmer must divert. One of the 4 subsequent 1,000-egg tests also comes up positive and the farmer continues to divert. Subsequent tests continue to be positive, and the farmer diverts for the life of the flock.

• The cost of egg testing is equivalent to the cost of testing every two weeks for the life of the flock following the first egg positive, or $Cost_{GT5} = 2 \times (C_{GT} + C_{GL} + C_{GG}) \times [(8 \times N_{GT}) + 2.17 \times (LF_5 - 1) \times N_{GT}$.

• The farm is forced to divert eggs for the life of the flock following the first egg positive, or $Cost_D = (DC \times 0.72 \times HS) \times (56 + 30 \times (LF_5 - 1))$.

• The probability that this scenario will occur is equal to $PS_5 = p_{N1} \times p_{G1} \times p_{G2} \times p_{G3}$.

a. Molted layers. The introduction of molted flocks complicates the analysis of testing costs by introducing new protocols for end of cycle testing. Molting increases the original 6 scenarios to 22. Also, molted flocks have a much longer life expectancy than do non-molted flocks. Any problems resulting from analyzing flocks with different life spans is dealt with in the latter part of this appendix where the costs are annualized. The method used to estimate the cost of testing and diversion for molted flocks is outlined below.

b. All scenarios. Under all scenarios with molted layers, the producer will have to conduct two sets of environmental tests. The costs of

environmental testing are: $Cost_{NT} = 2 \times (C_{NT} + C_{NL}) \times N_{NTS}$.

Scenario 1a: 40 to 45 week environmental test negative. Post-molt environmental test negative.

• In the first scenario for molted layers, both the 40 to 45 week and the post-molt environmental tests are negative. No further action is required.

• There are no egg testing or diversion costs in this scenario.

• The first scenario occurs with a probability $PS_{1a} = (1 - p_{N1}) \times (1 - p_{N3A})$, where p_{N1} is the probability that the 40 to 45 week environmental test is positive and p_{N3A} is the probability that the post-molt environmental test is positive.

Scenario 1b: 40 to 45 week environmental test negative. Post-molt environmental test positive. Egg test negative.

• In this scenario, the 40 to 45 week environmental test is negative. However, a positive post-molt test triggers egg testing. Further testing is avoided because all 4 egg tests are negative.

• As with non-molted flocks, the cost of an egg test is the sum of the laboratory (C_{GT}), labor (C_{GL}), and lost revenue (C_{GG}) costs for a 20-egg test times the number of 20-egg batches to be tested (N_{GT}) times the number of test collections (4). The total cost of egg testing is therefore: $Cost_{GT1b} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times 4$.

• There are no diversion costs in this scenario.

• This scenario occurs with a probability $PS_{1b} = (1 - p_{N1}) \times p_{N3A} \times (1 - p_{G1A})$, where p_{G1A} is the probability that the first set of egg tests, if taken, will be positive.

Scenario 1c: 40 to 45 week environmental test negative. Post-molt environmental test positive. First egg test positive. Second egg test negative.

• In this scenario, the 40 to 45 week environmental test is negative. However, a positive post-molt environmental test triggers egg testing. One of the first 4 post-molt eggs tests is positive, triggering diversion. The 4 post-molt tests are negative and diversion is stopped. Eggs are tested monthly for the life of the flock without any additional positive test results.

• In this case, there will be two sets of egg tests. In addition, the farm will be expected to test monthly for the remaining life of the flock ($LF_{1c} - 1$). The total cost of egg testing is therefore: $Cost_{GT1c} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times (8 + LF_{1c} - 1)$.

• The cost of diversion is the price differential between a table egg and an SE-positive egg (DC) times the number of days diverted times the number of eggs produced per day by a typical bird (0.72) times the number of layers in a typical poultry house (HS). We expect that a set of four 1,000-egg tests will occur over a total of 8 weeks including laboratory time. Therefore, the total number of days diverted is equal to 56. The total cost of diversion is: $Cost_{D1c} = DC \times 56 \times 0.72 \times HS$.

• This scenario occurs with a probability $PS_{1c} = (1 - p_{N1}) \times p_{N3A} \times p_{G1A} \times (1 - p_{G2A})$, where p_{G2A} is the probability that a second set of egg tests, if taken, will be positive.

Scenario 1d: 40 to 45 week environmental test negative. Post-molt environmental test positive. First two egg tests positive. Farm eventually tests out of diversion.

• In this scenario, the 40 to 45 week environmental test is negative. However, a positive post-molt environmental test triggers egg testing. One of the first 4 egg tests comes up positive, and the farmer must divert. One of the second four egg tests also comes up positive, and the farmer continues to divert. Eventually, however, the farm is able to test off diversion and diversion is stopped. Eggs are tested monthly for the life of the flock without any additional positive test results.

• In this case, there will be eight egg tests (occurring in 2 week intervals), tests every 2 weeks for half of the remaining life of the flock, and monthly tests for the remaining half of the life of the flock. The total cost of egg testing is therefore: $Cost_{GT1d} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times [8 + 2.17 \times (LF_{1d} - 1) \div 2 + (LF_{1d} - 1) \div 2]$.

• In this case, diversion costs will be borne by the producer for the 8 weeks of the second set of egg tests plus half of the remaining lay period. The total cost of diversion is: $Cost_{D1d} = DC \times 0.72 \times HS \times [56 + 30 \times (LF_{1d} - 1) \div 2]$.

• This scenario occurs with a probability $PS_{1d} = (1 - p_{N1}) \times p_{N3A} \times p_{G1A} \times p_{G2A} \times (1 - p_{G3A})$, where p_{G3A} is the probability that a farm with two positive sets of egg tests will not be able to test off of diversion.

Scenario 1e: 40 to 45 week environmental test negative. Post-molt environmental test positive. First two egg tests positive. Farm diverts to depopulation.

• In this scenario, the 40 to 45 week environmental test is negative. However, a positive post-molt environmental test triggers egg testing. One of the first four egg tests is positive, and the farmer must divert. One of the second four egg tests also comes up positive, and the farmer continues to divert. The farm is never able to test off diversion.

• The cost of egg testing is equivalent to the cost of testing every two weeks for the life of the flock following the first egg positive, or $Cost_{GT1e} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times [8 + 2.17 \times (LF_{1e} - 1)]$.

• In this case, diversion costs will be borne by the producer for the 8 weeks of the second set of egg tests plus all of the remaining lay period. The total cost of diversion is: $Cost_{D1e} = DC \times 0.72 \times HS \times [56 + 30 \text{ '} (LF_{1e} - 1)]$.

• This scenario occurs with a probability $PS_{1e} = (1 - p_{N1}) \times p_{N3A} \times p_{G1A} \times p_{G2A} \times p_{G3A}$.

Scenario 2a: 40 to 45 week environmental test positive. Pre-molt egg test negative. Post-molt environmental test is negative.

• The 40 to 45 week environmental test is positive. The 4 egg tests are negative. No action is taken until the post-molt environmental test, which is negative. Further testing is avoided.

• The 4 egg tests are done pre-molt at a cost of: $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times 4$.

• There are no diversion costs in this scenario.

• This scenario occurs with probability $PS_{2a} = p_{N1} \times p_{N2} \times (1 - p_{G1E}) \times (1 - p_{N3C})$, where p_{G1E} is the probability that a pre-molt egg test will be positive and p_{N3C} is the probability that the end of cycle environmental test will be positive.

Scenario 2b: 40 to 45 week environmental test positive. Pre-molt egg test negative. Post-molt environmental test positive. Egg test negative.

• The 40 to 45 week environmental test is positive. The four egg tests are negative. No action is taken until the post-molt environmental test, which is positive. All four post-molt egg tests are negative.

• In this case two sets of 4 1,000-egg tests are required. The cost of this testing is: $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times 8$.

• There are no diversion costs in this scenario.

• This scenario occurs with a probability $PS_{2b} = p_{N1} \times p_{N2} \times (1 - p_{G1E}) \times p_{N3C} \times (1 - p_{G1c})$, where p_{G1C} is the probability that the first set of post-molt egg tests will be positive.

Scenario 2c: 40 to 45 week environmental test positive. Pre-molt egg test negative. Post-molt environmental test positive. First egg test positive. Second egg test negative.

• The 40 to 45 week environmental test is positive. All four required egg tests are negative. No action is taken. The post-molt environmental test is positive, triggering egg testing. One of the four egg tests is positive, triggering diversion. All four of the second tests

are negative, and diversion is stopped. Eggs are tested monthly for the remaining life of the flock.

• In this case, there will be three sets of egg tests. In addition, the farm will be expected to test monthly for the remaining life of the flock (LF_{2c} - 1). The total cost of egg testing is therefore: $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times (12 + LF_{2c} - 1)$.

• The cost of diversion is the price differential between a table egg and a SE positive egg (DC) times the number of days diverted times the number of eggs produced per day by a typical bird (0.72) times the number of layers in a typical layer house (HS). We expect that a set of four 1,000-egg tests will occur over a total of 8 weeks, including laboratory time. Therefore, the total number of days diverted is equal to 56. The total cost of diversion is: $Cost_D$ = DC x 56 x 0.72 x HS.

• This scenario occurs with a probability $PS_{2c} = p_{N1} \times p_{N2} \times (1 - p_{G1E}) \times p_{N3C} \times p_{G1c} \times (1 - p_{G2C})$, where p_{G2C} is the probability that a second set of egg tests, if taken, will be positive.

Scenario 2d: 40 to 45 week environmental test positive. Pre-molt egg test negative. Post-molt environmental test positive. The first two egg tests positive. Farm eventually tests out of diversion.

• The 40 to 45 week environmental test is positive. All four pre-molt egg tests are negative. No action is taken. The post-molt environmental test is positive, triggering egg testing. One of the first four post-molt egg tests comes up positive, and the farmer must divert. One of the second four post-molt egg tests also comes up positive, and the farmer continues to divert. The farm is eventually able to test off of diversion. Eggs are tested monthly for the remaining life of the flock.

• In this case, there will be 12 egg tests (occurring in 2 week intervals), tests every 2 weeks for half of the remaining life of the flock, and monthly tests for the remainder of the life of the flock. The total cost of egg testing is therefore: $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times [12 + 2.17 \times (LF_{2d} - 1) \div 2 + (LF_{2d} - 1) \div 2]$.

• In this case, diversion costs will be borne by the producer for the 8 weeks of the second set of egg tests plus half of the remaining lay period. The total cost of diversion is: $Cost_D$ = DC x 0.72 x HS x [56 + 30 x (LF_{2d} - 1) ÷ 2].

• This scenario occurs with a probability $PS_{2d} = p_{N1} \times p_{N2} \times (1 - p_{G1E}) \times p_{N3C} \times p_{G1c} \times p_{G2C} \times (1 - p_{G3C})$, where p_{G3C} is the probability that a farm with two positive sets of egg tests will not be able to test off of diversion.

Scenario 2e: 40 to 45 week environmental test positive. Pre-molt egg test negative. Post-molt environmental test positive. First two egg tests positive. Farm diverts until depopulation.

• The 40 to 45 week environmental test is positive. All four pre-molt egg tests are negative. No action is taken. The post-molt environmental test is positive, triggering egg testing. One of the first four post-molt egg tests comes up positive, and the farmer must divert. One of the second 4 post-molt egg tests also comes up positive, and the farmer continues to divert. The farm is never able to test out of diversion.

• The cost of egg testing is equivalent to the cost of testing every 2 weeks for the life of the flock following the first egg positive, or $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times [12 + 2.17 \times (LF_{2e} - 1)]$.

• In this case, diversion costs will be borne by the producer for the 8 weeks of the second set of egg tests plus all of the remaining lay period. The total cost of diversion is: $Cost_D$ = DC x 0.72 x HS x [56 + 30 x (LF_{2e} - 1)].

• This scenario occurs with a probability $PS_{2e} = p_{N1} \times p_{N2} \times (1 - p_{G1E}) \times p_{N3C} \times p_{G1c} \times p_{G2C} \times p_{G3C}$.

Scenario 3a: 40 to 45 week environmental test positive. First pre-molt egg test positive. Second pre-molt egg test negative. Post-molt environmental test is negative.

• The 40 to 45 week environmental test is positive. On of the first four pre-molt egg tests is positive, triggering diversion. All four of the second pre-molt tests are negative, ending diversion. No further action is taken until the post-molt environmental test, which is negative. Further testing is avoided.

• Two sets of egg tests are carried out pre-molt. Also, monthly egg tests must be taken for the life of the flock. The cost of egg testing is: $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times (8 + LF_{3a} - 1)$.

• Eggs are diverted between the first and second egg tests. We expect that a set of 4 1,000-egg tests will occur over a total of 8 weeks, including laboratory time. Therefore, the total number of days diverted is equal to 56. The total cost of diversion is: $Cost_D$ = DC x 56 x 0.72 x HS.

• This scenario occurs with probability $PS_{3a} = p_{N1} \times p_{N2} \times p_{G1E} \times (1 - p_{G2E}) \times (1 - p_{N4D})$, where p_{G2E} is the probability that the second set of pre-molt egg tests will be positive and p_{N3D} is the probability that the end of cycle environmental test will be positive.

Scenario 3b: 40 to 45 week environmental test positive. First pre-molt egg test positive. Second pre-molt egg test negative. Post-molt environmental test positive. Egg test negative.

• The 40 to 45 week environmental test is positive. One of the first four pre-molt egg tests is positive, triggering diversion. All four of the second pre-molt egg tests are negative, ending diversion. No action is taken until the post-molt environmental test, which is positive. The first four post-molt egg tests are negative.

• In this case, three sets of egg tests are required. Furthermore, monthly egg testing is required for the life of the flock. The cost of this testing is: $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times (12 + LF_{3b} - 1)$.

• Eggs are diverted between the first and second egg tests. We expect that a set of four 1,000-egg tests will occur over a total of 8 weeks, including laboratory time. Therefore, the total number of days diverted is equal to 56. The total cost of diversion is: $Cost_D$ = DC x 56 x 0.72 x HS.

• This scenario occurs with a probability $PS_{3b} = p_{N1} \times p_{N2} \times p_{G1E} \times (1 - p_{G2E}) \times p_{N4D} \times (1 - p_{G1D})$, where p_{G1D} is the probability that the first set of post-molt egg tests will be positive.

Scenario 3c: 40 to 45 week environmental test positive. First pre-molt egg test positive. Second pre-molt egg test negative. Post-molt environmental test positive. First egg test positive. Second egg test is negative.

• The 40 to 45 week environmental test is positive. One of the first four pre-molt egg tests is positive, triggering diversion. The second 4 pre-molt egg tests are negative, ending diversion. No action is taken until the post-molt environmental test, which is positive. One of the first four post-molt egg tests is positive, triggering diversion. The second four post-molt egg tests are negative and diversion is stopped. Eggs are tested monthly for the remaining life of the flock.

• In this case, there will be four sets of egg tests. In addition, the farm will be expected to test monthly for the remaining life of the flock (LF_{3c} - 1). The total cost of egg testing is therefore: $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times (16 + LF_{3c} - 1)$.

• Twice in the life of this flock eggs have tested positive in one test and negative in the next. We expect that a set of four 1,000-egg tests will occur over a total of 8 weeks, including laboratory time. Therefore, the total number of days diverted is equal to 56. The total cost of diversion is: $Cost_D$ = DC x 112 x 0.72 x HS.

• This scenario occurs with a probability $PS_{3c} = p_{N1} \times p_{N2} \times p_{G1E} \times (1 - p_{G2E}) \times p_{N4D} \times p_{G1D} \times (1 - p_{G2D})$, where

p_{G2D} is the probability that a second set of egg tests, if taken, will be positive.

Scenario 3d: 40 to 45 week environmental test positive. First pre-molt egg test positive. Second pre-molt egg test negative. Post-molt environmental test positive. First two egg tests positive. Farm eventually tests out of diversion.

• The 40 to 45 week environmental test is positive. One of the first four pre-molt egg tests is positive, triggering diversion. The second four pre-molt egg tests are negative, ending diversion. No action is taken until the post-molt environmental test, which is positive. One of the first four post-molt egg tests comes up positive, and the farmer must divert. One of the second four post-molt egg tests also comes up positive, and the farmer continues to divert. The farm is eventually able to test off of diversion. Eggs are tested monthly for the remaining life of the flock.

• In this case, there will be eight egg tests (occurring in 2 week intervals), tests every 2 weeks for half of the remaining life of the flock, and monthly tests for the remainder of the life of the flock. The total cost of egg testing is therefore: $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times [16 + 2.17 \times (LF_{3d} - 1) \div 2 + (LF_{3d} - 1) \div 2]$.

• In this case, diversion costs will be borne by the producer for the 8 weeks of the second set of egg tests plus half of the remaining lay period. The total cost of diversion is: $Cost_D = DC \times 0.72 \times HS \times [112 + 30 \times (LF_{3d} - 1) \div 2]$.

• This scenario occurs with a probability $PS_{3d} = p_{N1} \times p_{N2} \times p_{G1E} \times (1 - p_{G2E}) \times p_{N4D} \times p_{G1D} \times p_{G2D} \times (1 - p_{G3D})$, where p_{G3D} is the probability that a farm with two positive sets of egg tests will not be able to test off of diversion.

Scenario 3e: 40 to 45 week environmental test positive. First pre-molt egg test positive. Second pre-molt egg test negative. Post-molt environmental test positive. First two egg tests positive. Farm diverts until depopulation.

• The 40 to 45 week environmental test is positive. One of the first four eggs tests is positive, triggering diversion. and the second four pre-molt tests are negative, ending diversion. No action is taken until the post-molt environmental test, which is positive. One of the first four post-molt egg tests comes up positive, and the farmer must divert. One of the second four post-molt egg tests also comes up positive, and the farmer continues to divert. The farm is never able to test out of diversion.

• The cost of egg testing is equivalent to the cost of testing every 2 weeks for the life of the flock following the first egg positive, or $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times [16 + 2.17 \times (LF_{3e} - 1)]$.

• In this case diversion costs will be borne by the producer for the 16 weeks following each second set of egg tests plus the remaining lay period. The total cost of diversion is: $Cost_D = DC \times 0.72 \times HS \times [112 + 30 \times (LF_{3e} - 1)]$.

• This scenario occurs with a probability $PS_{3e} = p_{N1} \times p_{N2} \times p_{G1E} \times (1 - p_{G2E}) \times p_{N4D} \times p_{G1D} \times p_{G2D} \times (1 - p_{G3D})$.

Scenario 4: 40 to 45 week environmental test positive. First pre-molt egg test positive. Second pre-molt egg test positive. Farm eventually tests out of diversion.

• The 40 to 45 week environmental test is positive. One of the first four pre-molt egg tests is positive, triggering diversion. One of the second four pre-molt egg tests is also positive. Because the farm is already under diversion at the time of molt no post-molt test is needed. However, the farm eventually tests out of diversion. Eggs are tested monthly for the remaining life of the flock.

• In this case there will be eight egg tests (occurring in 2 week intervals), tests every 2 weeks for half of the remaining life of the flock, and monthly tests for the remainder of the life of the flock. The total cost of egg testing is therefore: $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times [8 + 2.17 \times (LF_4 - 1) \div 2 + (LF_4 - 1) \div 2]$.

• Diversion costs will be borne by the producer for the 8 weeks of the second set of egg tests plus half of the remaining lay period. The total cost of diversion is: $Cost_D = DC \times 0.72 \times HS \times [56 + 30 \times (LF_4 - 1) \div 2]$.

• This scenario occurs with a probability $PS_4 = p_{N1} \times p_{N2} \times p_{G1E} \times p_{G2E} \times (1 - p_{G3E})$, where p_{G3e} is the probability that a farm with two positive sets of egg tests will not be able to test off of diversion.

Scenario 5: 40 to 45 week environmental test positive. First pre-molt egg test positive. Second pre-molt egg test positive. Farm diverts until depopulation.

• The 40 to 45 week environmental test is positive. One of the first four pre-molt egg tests is positive, triggering diversion. One of the second four pre-molt egg tests is also positive. Because the farm is already under diversion at the time of molt, no post-molt test is needed. The farm is never able to test out of diversion.

• The cost of egg testing is equivalent to the cost of testing every two weeks for the life of the flock following the first egg positive, or $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times [8 + 2.17 \times (LF_5 - 1)]$.

• In this case, diversion costs will be borne by the producer for the 16 weeks following each second set of egg tests plus the remaining lay period. The total cost of diversion is: $Cost_D = DC \times 0.72 \times HS \times [56 + 30 \times (LF_5 - 1)]$.

• This scenario occurs with a probability $PS_5 = p_{N1} \times p_{N2} \times p_{G1E} \times p_{G2E} \times p_{G3E}$.

Appendix B to the PRIA: The Expected Cost of Testing and Diversion

The expected cost of testing and diversion is found by summing over all scenarios the product of scenario cost and scenario probability. This can represented mathematically as follows:

Cost per house for non-molted layers:

Environmental testing costs for a given house $Env_S = \sum_{i=1}^{6}(Cost_{NTi} \times PS_i)$

Egg testing costs for a given house $Egg_S = \sum_{i=1}^{6}(Cost_{GTi} \times PS_i)$

Diversion Costs for a given house $Div_S = \sum_{i=1}^{6}(Cost_{Di} \times PS_i)$

Total testing and diversion costs $= \sum_{i=1}^{6}[(Cost_{NTi} + Cost_{GTi} + Cost_{Di}) \times PS_i] = Env_S + Egg_S + Div_S$

where, $\sum_{i=1}^{6} PS_i = 1$

Cost per house for molted layers:

Environmental testing costs for a given house $Env_S = \sum_{i=1a}^{6}(Cost_{NTi} \times PS_i)$

Egg testing costs for a given house $Egg_S = \sum_{i=1a}^{6}(Cost_{GTi} \times PS_i)$

Diversion costs for a given house $Div_S = \sum_{i=1a}^{6}(Cost_{Di} \times PS_i)$

Total testing and diversion costs $= \sum_{i=1a}^{6}[(Cost_{NTi} + Cost_{GTi} + Cost_{Di}) \times PS_i] = Env_S + Egg_S + Div_S$

where, $\sum_{i=1a}^{6} PS_i = 1$

Total cost of testing and diversion. The cost of environmental testing and diversion varies by house size. Thus, in our calculations we estimate these costs for the typical house on farms with less than 3,000 layers, 3,000 to 19,999 layers, 20,000 to 49,999 layers, 50,000 to 99,999 layers, and over 100,000 layers. This is done for both molted and non-molted flocks. The total costs of testing and diversion are calculated using the following equations:

Total cost of environmental testing $= \sum_{S=0}^{4}(Env_S \times N_S)$

Total cost of egg testing $= \sum_{S=0}^{4}(Egg_S \times N_S)$

Total cost of diversion $= \sum_{S=0}^{4}(Div_S \times N_S)$

Total cost of testing and diversion $= \sum_{S=0}^{4}[(Env_S \times Egg_S + Div_S) \times N_S]$

where, N_S = the number of houses in each size category.

Appendix C to the PRIA: Distributions Used in the Analysis of Uncertainty

DISTRIBUTIONS USED IN THE ANALYSIS OF UNCERTAINTY

Variable	@Risk Formula Used	Notes
Coverage of the Proposed Rule		
Farms Selling to Retail (50 to 99 layers)	Risk Uniform (0%, 50%)	Egg Safety Action Group Approved Assumption
Farms Selling to Retail (100 to 399 layers)	Risk Uniform (10%, 90%)	Egg Safety Action Group Approved Assumption
Farms Selling to Retail (400 to 3000 layers)	Risk Uniform (50%, 100%)	Egg Safety Action Group Approved Assumption
Farms Not Selling in Retail that Sell Directly to Consumers	Risk Uniform (0%, 100%)	Egg Safety Action Group Approved Assumption
Number of Houses per Farm Site (3,000 to 19,999 layers)	Risk Normal (1.7, 0.5)	From Layers 99
Number of Houses per Farm Site (20,000 to 49,999 layers)	Risk Normal (1.8, 0.2)	From Layers 99
Number of Houses per Farm Site (50,000 to 99,999 layers)	Risk Normal (2.4, 0.3)	From Layers 99
Number of Houses per Farm Site (Over 100,000 layers)	Risk Normal (7.4, 0.8)	From Layers 99
Egg Prices		
Wholesale Price of Table Eggs- North Atlantic	Risk Uniform ($0.66, $0.70)	USDA
Wholesale Price of Table Eggs- North Central	Risk Uniform ($0.57, $0.69)	USDA
Wholesale Price of Table Eggs- South Atlantic	Risk Uniform ($0.63, $0.76)	USDA
Wholesale Price of Table Eggs- South Central	Risk Uniform ($0.69, $0.83)	USDA
Wholesale Price of Table Eggs- West	Risk Uniform ($0.75, $0.95)	USDA
Value of Checks/UnderGrades - North Atlantic	Risk Uniform ($0.14, $0.19)	USDA
Value of Checks/UnderGrades - North Central	Risk Uniform ($0.15, $0.18)	USDA
Value of Checks/UnderGrades - South Atlantic	Risk Uniform ($0.14, $0.19)	USDA
Value of Checks/UnderGrades - South Central	Risk Uniform ($0.15, $0.18)	USDA
Benefits Estimation		
Percent of SE cases from Eggs	Risk Uniform (53%, 79%)	CDC Range from Outbreaks
Percent of Illnesses Resulting in Arthritis	Risk Pert (0%, 3%, 10%)	Range Estimated in Traceback Studies
Arthritis Cases that are Short-Term	Risk Beta (10, 19)	Based on Zorn and Klontz
Percent of SE Positive Eggs Diverted in First Four Years	Risk Uniform (6.7%, 9.4%)	Estimate is a Synthesis of 'Initial' and 'Eventual' Estimates from the Testing and Diversion Model
SE Monitored Chicks/Pullets		
Percent of Pullets in NPIP SE Monitored Program	Risk Normal (94.5%, 1.8%)	Layers 99
Biosecurity		
Percent of Large Houses with Footbaths	Risk Uniform (Risk Normal (24.5%, 5.4%), Risk Normal (24.6%, 6.4%))	Layers 99
Rodent and Pest Control - Primary Method of Fly Control		
Residual Spray (less than 20,000 layers)	Risk Normal (42.1%, 22.2%)	Layers 99
Baits (less than 20,000 layers)	Risk Normal (11.4%, 6.5%)	Layers 99
Larvicide (feed) (less than 20,000 layers)	Risk Normal (17.2%, 9.8%)	Layers 99
Biological Predators less than 20,000 layers)	Risk Normal (20.1%, 15.8%)	Layers 99

DISTRIBUTIONS USED IN THE ANALYSIS OF UNCERTAINTY—Continued

Variable	@Risk Formula Used	Notes
Other (less than 20,000 layers)	Risk Normal (2.4%, 2.3%)	Layers 99
None (less than 20,000 layers)	Risk Normal (6%, 4.8%)	Layers 99
Residual Spray (20,000 to 49,999 layers)	Risk Normal (14.2%, 7.4%)	Layers 99
Baits (20,000 to 49,999 layers)	Risk Normal (32.6%, 9.4%)	Layers 99
Larvicide (spot) (20,000 to 49,999 layers)	Risk Normal (0.9%, 0.6%)	
Larvicide (feed) (20,000 to 49,999 layers)	Risk Normal (26.6%, 12.6%)	Layers 99
Sprays/Foggers (20,000 to 49,999 layers)	Risk Normal (4.2%, 2.3%)	Layers 99
Other (20,000 to 49,999 layers)	Risk Normal (4%, 2%)	Layers 99
None (20,000 to 49,999 layers)	Risk Normal (17.5%, 6.9%)	Layers 99
Residual Spray (50,000 to 99,999 layers)	Risk Normal (24%, 7.2%)	Layers 99
Baits (50,000 to 99,999 layers)	Risk Normal (38.5%, 8%)	Layers 99
Larvicide (feed) (50,000 to 99,999 layers)	Risk Normal (12.8%, 6.1%)	Layers 99
Sprays/Foggers (50,000 to 99,999 layers)	Risk Normal (12.9%, 6.8%)	Layers 99
Biological Predators (50,000 to 99,999 layers)	Risk Normal (6.8%, 3.1%)	Layers 99
None (50,000 to 99,999 layers)	Risk Normal (5%, 2.1%)	Layers 99
Residual Spray (Over 100,000 layers)	Risk Normal (14%, 3.9%)	Layers 99
Baits (Over 100,000 layers)	Risk Normal (39.1%, 8%)	Layers 99
Larvicide (spot) (Over 100,000 layers)	Risk Normal (0.8%, 0.7%)	Layers 99
Larvicide (feed) (Over 100,000 layers)	Risk Normal (9.2%, 2.9%)	Layers 99
Sprays/Foggers (Over 100,000 layers)	Risk Normal (10.4%, 4%)	Layers 99
Biological Predators (Over 100,000 layers)	Risk Normal (12.9%, 6.4%)	Layers 99
Other (Over 100,000 layers)	Risk Normal (4.8%, 2.3%)	Layers 99
None (Over 100,000 layers)	Risk Normal (8.8%, 2.4%)	Layers 99
Rodent and Pest Control - Primary Method of Rodent Control		
Chemicals or Bait (less than 20,000 layers)	Risk Normal (63.6%, 17.6%)	Layers 99
Traps or Tape (less than 20,000 layers)	Risk Normal (17.6%, 15.7%)	Layers 99
Cats (less than 20,000 layers)	Risk Normal (18.8%, 10.3%)	Layers 99
Chemicals or Bait (20,000 to 49,999 layers)	Risk Normal (71.6%, 6.4%)	Layers 99
Traps or Tape (20,000 to 49,999 layers)	Risk Normal (7.4%, 3.6%)	Layers 99
Cats (20,000 to 49,999 layers)	Risk Normal (18%, 6.6%)	Layers 99
None (20,000 to 49,999 layers)	Risk Normal (3%, 2%)	Layers 99
Chemicals or Bait(50,000 to 99,999 layers)	Risk Normal (94%, 2%)	Layers 99
Traps or Tape (50,000 to 99,999 layers)	Risk Normal (2.2%, 1%)	Layers 99
Cats (50,000 to 99,999 layers)	Risk Normal (3.8%, 1.6%)	Layers 99
Chemicals or Bait (Over 100,000 layers)	Risk Normal (90.6%, 2.7%)	Layers 99
Traps or Tape (Over 100,000 layers)	Risk Normal (6.6%, 2.4%)	Layers 99
Cats (Over 100,000 layers)	Risk Normal (1.4%, 0.7%)	Layers 99

DISTRIBUTIONS USED IN THE ANALYSIS OF UNCERTAINTY—Continued

Variable	@Risk Formula Used	Notes
Other (Over 100,000 layers)	Risk Normal (1%, 0.5%)	Layers 99
None (Over 100,000 layers)	Risk Normal (0.4%, 0.3%)	Layers 99
Rodent and Pest Control - Other		
Cost of Fly Control (3,000 to 19,999 layers)	Risk Uniform ($3,028, $5,560)	RTI costs using assumptions of low and high severity fly problems
Cost of Fly Control (20,000 to 49,999 layers)	Risk Uniform ($5,342, $9,675)	RTI costs using assumptions of low and high severity fly problems
Cost of Fly Control (50,000 to 99,999 layers)	Risk Uniform ($9,873, $17,979)	RTI costs using assumptions of low and high severity fly problems
Cost of Fly Control (Over 100,000 layers)	Risk Uniform ($48,626, $88,228)	RTI costs using assumptions of low and high severity fly problems
Cleaning and Disinfecting		
Manure Removal - Between Each Flock	Risk Normal (96.6%, 1.6%)	Layers 99
Manure Removal - After 2 or More Flocks	Risk Normal (3.4%, 1.6%)	Layers 99
Dry Clean - Between Each Flock	Risk Normal (79.4%, 3.7%)	Layers 99
Dry Clean - After 2 or More Flocks	Risk Normal (1.1%, 0.6%)	Layers 99
Wet Clean - Between Each Flock	Risk Normal (30.6%, 4.5%)	Layers 99
Wet Clean - After 2 or More Flocks	Risk Normal (23%, 5.7%)	Layers 99
Disinfect - Between Each Flock	Risk Normal (44.5%, 5.4%)	Layers 99
Disinfect - After 2 or More Flocks	Risk Normal (20.6%, 5.9%)	Layers 99
Training		
Tuition	Risk Uniform ($450, $550)	Web Sources
Travel	Risk Pert ($0,$250,$1000)	See Text
Farms Not on a QA Plan that will be Affected by the Proposed Rule	Risk Uniform (0%, 100%)	Assumption
Testing and Diversion		
Current Positive Environmental Tests	Risk Uniform (7.1%, Risk Pert (2%, 8%, 40%))	See Text
Probability Random Swabbing Regime is Chosen by FDA	Risk Uniform (0%, 100%)	Assumption
Percent of Farms Adequately Testing Environments	Risk Uniform (0%, 52%)	52% are currently conducting some level of testing (Layers 99). Most of these farms will not be conducting an adequate level of testing.
Refrigeration		
Percent of Eggs Processed Off-Farm (3,000 to 19,999 layers)	Risk Normal (98.3%, 1.3%)	Layers 99
Percent of Eggs Processed Off-Farm (20,000 to 49,999 layers)	Risk Normal (96.3%, 1.4%)	Layers 99
Percent of Eggs Processed Off-Farm (50,000 to 99,999 layers)	Risk Normal (83.1%, 7.6%)	Layers 99
Percent of Eggs Processed Off-Farm (Over 100,000 layers)	Risk Normal (65.6%, 6%)	Layers 99
Percent of Eggs Stored at Less then 45 Degrees (3,000 to 19,999 layers)	Risk Normal (21.9%, 16.1%)	Layers 99

DISTRIBUTIONS USED IN THE ANALYSIS OF UNCERTAINTY—Continued

Variable	@Risk Formula Used	Notes
Percent of Eggs Stored at Less then 45 Degrees (20,000 to 49,999 layers)	Risk Normal (24.2%, 13.4%)	Layers 99
Percent of Eggs Stored at Less then 45 Degrees (50,000 to 99,999 layers)	Risk Normal (11.1%, 3.6%)	Layers 99
Percent of Eggs Stored at Less then 45 Degrees (Over 100,000 layers)	Risk Normal (27.3%, 8.6%)	Layers 99
Refrigeration		
Farms that Store Eggs at Greater than 60 Degrees (3,000 to 19,999 layers)	Risk Normal (42.7%, 22.7%)	Layers 99
Farms that Store Eggs at Greater than 60 Degrees (20,000 to 49,999 layers)	Risk Normal (22.6%, 8.8%)	Layers 99
Farms that Store Eggs at Greater than 60 Degrees (50,000 to 99,999 layers)	Risk Normal (37.7%, 10.5%)	Layers 99
Farms that Store Eggs at Greater than 60 Degrees (Over 100,000 layers)	Risk Normal (17.1%, 5.1%)	Layers 99
Farms that Store Eggs at 50 to 60 Degrees (3,000 to 19,999 layers)	Risk Normal (35.4%, 17.2%)	Layers 99
Farms that Store Eggs at 50 to 60 Degrees (20,000 to 49,999 layers)	Risk Normal (53.2%, 12.1%)	Layers 99
Farms that Store Eggs at 50 to 60 Degrees (50,000 to 99,999 layers)	Risk Normal (51.2%, 13%)	Layers 99
Farms that Store Eggs at 50 to 60 Degrees (Over 100,000 layers)	Risk Normal (55.6%, 17.4%)	Layers 99
Egg Room Construction (3,000 to 19,999 layers)	Risk Uniform ($3,723, $5,584)	RTI estimates for costs of $50 and $75 per square foot
Egg Room Construction (20,000 to 49,999 layers)	Risk Uniform ($8,036, $12,054)	RTI estimates for costs of $50 and $75 per square foot
Egg Room Construction (50,000 to 99,999 layers)	Risk Uniform ($15,936, $23,903)	RTI estimates for costs of $50 and $75 per square foot
Egg Room Construction (Over 100,000 layers)	Risk Uniform ($69,625, $104,438)	RTI estimates for costs of $50 and $75 per square foot

Note. We list the formulas used by @Risk, the program we used to run the simulations. Risk Uniform generates a uniform distribution with parameters representing minimum and maximum values. Risk Normal is the normal distribution, with the parameters representing mean and standard deviation. Risk Pert is the Beta-Pert Distribution; the three parameters represent the minimum, most likely, and maximum values. Risk Beta is a Beta distribution with parameters based on the number of successes (adjusted for prior) and the number of failures (adjusted for prior).

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