DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 118

[Docket No. FDA–2000–N–0190] (Formerly Docket No. 2000N–0504)

RIN 0910–AC14

Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule that requires shell egg producers to implement measures to prevent *Salmonella* Enteritidis (SE) from contaminating eggs on the farm and from further growth during storage and transportation, and requires these producers to maintain records concerning their compliance with the rule and to register with FDA. FDA is taking this action because SE is among the leading bacterial causes of foodborne illness in the United States, and shell eggs are a primary source of human SE infections. The final rule will reduce SE-associated illnesses and deaths by reducing the risk that shell eggs are contaminated with SE.

DATES: This final rule is effective September 8, 2009. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in new 21 CFR 118.8 as of September 8, 2009. *Please see* section II.C of this document for the compliance dates of this final rule. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by August 10, 2009 (*see* the ''Paperwork Reduction Act of 1995'' section of this document).

FOR FURTHER INFORMATION CONTACT: John Sheehan, Center for Food Safety and Applied Nutrition (HFS–315), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1488.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

A. FDA's Proposed Rule

On September 22, 2004, FDA proposed a rule to prevent SE contamination in shell eggs during production (the proposed rule) (69 FR 56824). The proposed rule set out several measures to be taken by egg producers to prevent the contamination of shell eggs with SE during egg production, such as implementation of biosecurity and pest control programs, environmental and egg testing requirements, and requirements concerning refrigerated storage of eggs at the farm and diversion from the table egg market of eggs from flocks in which SE has been detected (69 FR 56824).

In addition, in the proposed rule we solicited comments on whether we should include additional requirements in the final rule, particularly in two areas. First, we asked whether we should expand the proposed recordkeeping requirements to include a written SE prevention plan and records documenting compliance with the SE prevention measures (69 FR 56824 at 56825 and 56841 through 56842). Second, we asked whether the safe egg handling and preparation practices in FDA's Food Code (*see http://www.cfsan.fda.gov/~dms/fc05-toc.html* (accessed December 14, 2006)) should be federally mandated for establishments that specifically serve a highly susceptible population (such as nursing homes, hospitals, and daycare centers) (69 FR 56824 at 56825 and 56849 through 56852).

The proposed rule had a 90-day comment period, which ended on December 21, 2004. To discuss the proposed rule and solicit comments from interested stakeholders, FDA held three public meetings in 2004. Based on comments received in response to the proposed rule, FDA reopened the comment period on May 10, 2005, for the limited purpose of receiving comments and other information regarding industry practices and programs that prevent SE-monitored chicks from becoming infected by SE during the period of pullet rearing until placement into laying hen houses (70 FR 24490). The term ''pullet'' refers to a chicken less than 20 weeks of age. On May 24, 2005, FDA received a request for an extension of the reopened comment period from two of the major trade associations representing egg producers and others affected by this

rule. We agreed to extend the reopened comment period until July 25, 2005.

B. What Are Salmonella and SE Infection?

As we described in greater detail in the proposed rule (69 FR 56824 at 56825 through 56827), *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. 1–2).

All people are at risk for salmonellosis, although the severity of the infection is influenced by a person's age and immune status. *Salmonella* infections are characterized by diarrhea, fever, abdominal cramps, headache, nausea, and vomiting. Symptoms 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 diarrhea can be severe, and the person may be ill enough to require hospitalization. In some patients, 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). These complications associated with an infection are more likely to occur in children, the elderly, and persons with a weakened immune system.

In addition, about 2 percent of those who recover from salmonellosis may later develop recurring joint pain and reactive arthritis (Ref. 3, 4).

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 reported to State health departments, and the *Salmonella* isolates are referred to State Public Health laboratories for serotyping (a method of distinguishing related organisms by their antigens). Each case and each serotyped isolate is reported to the U.S. Centers for Disease Control and Prevention (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 *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 occur 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 estimates that there are 38 cases of salmonellosis for every reported culture-confirmed case (Ref. 5). The overall burden of salmonellosis in 2001 was estimated to be 1,203,650 cases, including 14,000 hospitalizations, and 494 deaths (Refs. 6 and 7). Updated *Salmonella* surveillance data for 2004 indicate that the burden of salmonellosis in 2004 was somewhat higher, estimated to be 1,376,514 cases, including 14,264 hospitalizations, and 427 deaths (Refs. 5 and 8).

CDC surveillance data list close to 600 different *Salmonella* serotypes that have caused illness in the United States. Since 1995, *Salmonella enterica* serotype Enteritidis (SE) has been the second most frequently reported cause of *Salmonella* infection (Ref. 9). CDC reported that in 2008 SE was the leading reported cause of *Salmonella* infections, accounting for 20.1% of all of the *Salmonella* isolates that were serotyped (Ref. 10). The rate of SE isolates reported to CDC increased from 0.6 per 100,000 population in 1976 to 3.6 per 100,000 population in 1996 (Ref. 11–12). In 2001 the isolation rate for SE was 2.0 per 100,000 population, and the annual contribution of SE (corrected for underreporting) to salmonellosis was estimated to be 193,463 illnesses, including 2,004 hospitalizations and 60 deaths (Refs. 5 and 8). Estimated incidence of *Salmonella* infection in 2008 did not change significantly compared with estimates for the preceding 3 years, and in particular the apparent increase in *Salmonella* infections was not significant. However, the incidence of SE did increase by 19% (CI = 3%–39%) (Ref. 10). These data confirm the continued significance of SE as a cause of human infection in the United States.

In 1985, States reported to CDC 26 SE-related outbreaks (i.e., occurrences of 2 or more cases of a disease related to a common source); by 1990 the number of SE-related outbreaks reported to CDC had increased to 85. The number of outbreaks began declining in the 1990s; in 1995 there were 56 confirmed outbreaks of SE infection, in 2000 there were 50, and in 2002 there were 32 (Ref. 13). The number of outbreaks has remained roughly constant since 2002; in 2004 there were 28, in 2005 there were 35, and in 2006 there were 26 SE outbreaks in the United States (Ref. 13). Although these data indicate that there has been a decrease in reported outbreaks (and associated illness) linked to SE infection since the mid-1990s, the incidence of SE infection in the United States remains much higher than in the 1970s (Ref. 14), and the decrease in reported outbreaks of SE illness since 1999 has appeared to slow or stop compared to decreases seen in the mid-1990s (Ref. 15). CDC recently reported that, of the four pathogens with HP2010 targets, *Salmonella,* with 16.2 cases per 100,000 in 2008, is the farthest from its 2010 target (6.8) (Ref. 10). If current trends continue, we will fall short of the public health and foodborne illness gains required to meet the Healthy People 2010 goal of a 50 percent reduction from the 1997 baseline in both the number of SE foodborne outbreaks and the rate of isolation in the population of foodborne *Salmonella* infections (Ref. 16).

C. What Is the Connection Between Salmonella and Shell Eggs?

CDC established an epidemiological and laboratory association between eggs and *Salmonella* outbreaks in the mid-1980s (*see* 69 FR 56824 at 56826 through 56827). Shell eggs are 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 1985 and 2002, a total of 53 percent of all SE illnesses identified through CDC 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 (Ref. 17). These data are in accord with a published analysis by CDC researchers reporting that between 1990 and 2001, 78 percent of vehicle-confirmed SE outbreaks were associated with eggs, primarily raw or undercooked (Ref. 15). Over that decade, 14,319 illnesses were attributed to SE associated with shell eggs (Ref. 15). Most of these attributed illnesses occurred before 1995 (10,406 illnesses), but 3,913 occurred during 1996 through 2001. We believe egg quality assurance programs (EQAPs), consumer and retailer education, and Federal regulations requiring egg refrigeration have contributed to the decrease in SE

illness since the mid-1990s, but that further reductions in SE illness and foodborne salmonellosis cannot be accomplished without additional Federal measures to address SE contamination of shell eggs.

The surface of an egg can become contaminated with any microorganism that might be excreted by a laying hen or through contact with contaminated nesting materials, dust, feedstuff, shipping and storage containers, human beings, and other animals. The likelihood of trans-shell penetration increases with the length of time that the eggs are in contact with contaminating materials. This mechanism of contamination was previously considered the source of all SE contamination of eggs.

However, 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. Although 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. 18 and 19). The site of contamination is usually the albumen (the egg white).

Researchers believe 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. 20). In a farm-to-table risk assessment of SE in eggs which was conducted by FDA and the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) (''the 1998 joint SE risk assessment'') (Ref. 21), we 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. 21). FDA and FSIS updated this risk assessment in 2005 and derived this same estimate (Ref. 22). This figure is based on data compiled from 1991 to 1995 (Ref. 23).

D. The U.S. Egg Industry

On a per capita basis, Americans consume about 234 eggs per year (Ref. 24). U.S. production is relatively stable and has increased only slightly over time. For example, it was at about 60 billion eggs in 1984 and at 67.3 billion eggs in 1998 (Ref. 25). 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. 26).

E. Current On-Farm Practices

In the proposed rule we described in detail current farm practices to address the risk of SE contamination (69 FR 56824 at 56830 through 56831). Most of the information we provided came from a 1999 study (the Layers 99 study) (Refs. 27, 28, and 29) by USDA's Animal and Plant Health Inspection Service (APHIS) National Animal Health Monitoring System (NAHMS), as well as information on voluntary EQAPs, which are discussed more fully in section I.G of this document.

The Layers 99 study was designed to include information from States that account for at least 70 percent of the animal and farm population in the United States (Refs. 27, 28, and 29). Each operation participating in the study had more than 30,000 laying hens. The study found that egg laying operations varied considerably in size and style of poultry house; approximately 34 percent of the houses 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 six or more layer houses. The study also found wide variability within the poultry houses with respect to style of housing and number and level of cages, although less than one percent were cage-free. Manure handling varied with house style and also varied regionally.

The study found that, when a poultry house is repopulated with new laying hens (also known as ''layers''), most of the new layers come from a pullet raising facility. 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. Most (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 monitoring programs for many avian diseases and pathogens, including SE. Chicks are SE-monitored if they are hatched from eggs from flocks that are certified through NPIP as ''U.S. S. Enteritidis Clean'' breeder flocks (9 CFR 145.23(d)).

Many pullet-raising facilities in the Layers 99 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 and/or vaccines to protect pullets against SE.

The study found that 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). 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 non-molted flocks ended production at 74 weeks of age.

Approximately two-thirds of farms had biosecurity measures that did not allow visitors without a business reason to enter poultry houses. Sixty-two percent of farms that allowed visitors allowed business visitors provided they had not been on another poultry farm that day. Of the farms that allowed visitors in the layer house, most farms (76 percent) required that visitors wear clean boots. The majority of farms prohibited employees from being around other poultry and from owning their own birds.

With respect to pest control, the Layers 99 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 for rodent control by 93 percent of farms. 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.

The Layers 99 study found 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.

The Layers 99 study showed that, in 1997, 58 percent of farms tested for SE. The number of farms testing for SE varied by region. The number and regional distribution of farms doing testing for SE is very similar to the number and distribution of farms participating in an EQAP.

F. Voluntary EQAPs

The Layers 99 study found that 51 percent of all farm sites participated in an EQAP sponsored by a State or commodity group (e.g., United Egg Producers). The *Salmonella* Enteritidis Pilot Project (SEPP), begun in 1992 by USDA with special funding from Congress, was one of the first EQAPs in the United States (in 1994, SEPP became the Pennsylvania Egg Quality Assurance Program (PEQAP)). Currently, there are at least nine voluntary EQAPs operated and administered by States or other organizations (Refs. 30 through 36). In addition, certain egg companies operate an EQAP within their own facilities (Ref. 28).

Currently, EQAPs are voluntary for producers. These programs have similar requirements, but vary in how they implement these requirements. All programs require use of NPIP ''U.S. S. Enteritidis Clean'' chicks or equivalent, biosecurity, rodent control, and cleaning and disinfection of poultry houses. Although most programs require some environmental testing, the amount varies from once to four or five times during the life of a flock. If an environmental test is SE-positive (i.e., SE is detected at any level in any sample), 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 programs have some educational programs for participants.

G. The Food Code

FDA regularly publishes the Food Code, which provides guidance on food safety, sanitation, and fair dealing that can be uniformly adopted by State and local governments for the retail segment of the food industry. The Food Code provisions are not Federal requirements; however, 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 its text into a legal requirement.

Beginning with the 1993 edition, the Food Code was issued in its current format and was revised every 2 years. In 2002, with the support of the Conference for Food Protection, FDA decided to move to a 4-year interval between complete Food Code revisions. FDA published the 2005 Food Code, which is the first full edition to publish since the 2001 edition. During the 4-year interim period, a Food Code Supplement that updated, modified, and clarified certain provisions was made available. The provisions relevant to egg safety at establishments serving highly susceptible populations can be found in the 2001 Food Code in sections 3–202.11(C), 3–202.13, 3–202.14(A), 3–401.11(A)(1)(a) and 3–801.11(B)(1), (B)(2), (D)(1), (D)(2), (E)(1), and (E)(2). These Food Code provisions include the use of pasteurized eggs in recipes where eggs are raw or undercooked (e.g., Caesar salad, hollandaise sauce, eggnog), and if eggs are combined, unless the eggs are cooked to order and immediately served or combined immediately before baking and thoroughly cooked. The 2001 provisions all substantively remain the same in the 2005 Food Code, but sections 3–801.11(D)(1) and (D)(2) are now designated as 3–801.11(C)(1) and (C)(2), and sections 3–801.11(E)(1) and (E)(2) are now designated as 3–801.11(F)(1) and (F)(2). In addition, FDA amended the definitions of ''Eggs'' and ''Egg Products'' in the 2005 edition of the Food Code to clarify the difference between ''egg'' (shell egg) and ''egg product'' (liquid, frozen, or dry egg). Also, FDA clarified that baluts and reptile eggs are excluded from the egg-related provisions of the Food Code.

Through careful examination of State retail food codes, FDA has identified 47 States and territories (out of 56 States and territories) that have either adopted the 2005 Food Code or provisions that require the same prevention measures for highly susceptible populations (Ref. 37).

H. Rationale for the Final Rule

This rule is the most recent in a series of farm-to-table egg safety efforts begun by FDA and FSIS in the 1990s. These efforts are described in more detail in the proposed rule (69 FR 56824 at 56827 through 56829). Among these initiatives was the FDA and FSIS 1998 joint SE risk assessment (Ref. 21), discussed in detail in the proposed rule (69 FR 56824 at 56829), which 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 production-to-consumption continuum. In 2004, after FDA's proposed rule was published, FSIS published a draft risk assessment for SE in shell eggs and *Salmonella* spp. in egg products. This risk assessment was then published as final in October 2005 (Ref. 22).

There are currently several Federal regulations related to egg safety at the food service level. These regulations include a final rule issued by FSIS for refrigeration and labeling of eggs during transport and storage when packed for the ultimate consumer (63 FR 45663, August 27, 1998) and an FDA final rule that requires labeling of eggs and refrigeration of eggs at retail establishments (65 FR 76092, December 5, 2000). However, this is the first and only Federal rule that addresses the introduction of SE into the egg during production. Interventions that can reduce the number of SE-contaminated eggs at the production phase are of particular interest. Because progress in reducing the number of illnesses and outbreaks appears to have slowed or stopped, these additional preventive measures are needed to reduce further the risk of SE illnesses and meet our public health goals. Because eggs remain the primary source of SE infections, continued actions to improve egg safety are the most effective way to reduce the overall number of SE infections and outbreaks and to achieve our public health goals.

II. Highlights of the Final Rule and Summary of Significant Differences Between the Proposed and Final Rules

A. Highlights of the Final Rule

The provisions in the final rule are described briefly in the following paragraphs, and are discussed in more detail later in the preamble of this document.

- Persons who produce shell eggs from a farm operating with 3,000 or

more laying hens, unless that farm sells all of its eggs directly to consumers or does not produce shell eggs for the table market, are subject to this final rule (21 CFR 118.1(a)).

- Shell egg producers need only comply with refrigeration and registration requirements if all of their shell eggs from a particular farm receive a treatment as defined in the final rule (§ 118.1(a)(2)).
- Persons who transport or hold shell eggs for shell egg processing or egg products facilities are required to comply with the refrigeration requirements of this final rule (§ 118.1(b)).
- Shell egg producers are required to use the following SE prevention measures:
- Have and implement a written SE prevention plan that includes all mandatory SE prevention measures (21 CFR 118.4);
- Procure pullets that are SE-monitored, or raise pullets under SE-monitored conditions (§ 118.4(a));
- Use a biosecurity program, meaning a program that includes limiting visitors on the farm and in poultry houses; maintaining personnel and equipment practices that will protect against cross-contamination from one poultry house to another; preventing stray poultry, wild birds, cats, and other animals from entering poultry houses; and prohibiting employees from keeping birds at home (§ 118.4(b));
- Use a program to control rodents, flies, and other pests that includes monitoring for pest activity and removing debris and vegetation that may provide harborage for pests (§ 118.4(c)); and
- Clean and disinfect poultry houses before new laying hens are added if an environmental or egg test was positive for SE during the life of the flock; cleaning and disinfecting must include removing all visible manure, dry cleaning to remove dust, feathers, and old feed, and disinfecting (§ 118.4(d)).
- Shell eggs being held or transported are required to be refrigerated at or below 45 degrees Fahrenheit (°F) ambient temperature beginning 36 hours after time of lay (§ 118.4(e)).
- Shell egg producers must conduct environmental testing for SE when laying hens are 40 to 45 weeks of age and 4 to 6 weeks after molt (21 CFR 118.5).
- Shell egg producers must conduct egg testing for SE when an environmental test is positive for SE (21 CFR 118.6).
- Administration of the SE prevention measures requires having one or more supervisory personnel, who do not have to be onsite employees, who are responsible for ensuring compliance with each farm's SE prevention plan (21 CFR 118.9).
- Shell egg producers must maintain a written SE prevention plan and records documenting compliance with the requirements in the plan (21 CFR 118.10).
- Shell egg producers must retain records for 1 year after the flock to which they pertain has been taken permanently out of production (§ 118.10(c)).
- Shell egg producers must make records available within 24 hours from the time of receipt of the official request (§ 118.10(d)).
- Shell egg producers must register with FDA (21 CFR 118.11).

B. Significant Differences Between the Proposed and Final Rules

The final rule reflects the following significant changes from the proposed rule:

- Persons who transport or hold shell eggs for shell egg processing or egg products facilities must comply with the refrigeration requirements. Only shell egg producers were subject to the proposed refrigeration requirements.
- Shell egg producers are required to have and implement written SE prevention plans.

The proposed rule did not require that plans be written.

- The requirements for protective clothing and sanitizing stations have been removed from biosecurity program requirements.
- The requirement to ''wet clean the positive poultry house'' has been removed.
- Egg processors are now permitted to equilibrate refrigerated eggs to room temperature just prior to processing.
- The requirement to begin egg testing within 24 hours after notification of a positive environmental test has been changed to require that results of egg testing be obtained within 10 calendar days after receiving notification of the positive environmental test.
- The required time period to perform environmental testing for SE after molting has been changed from 20 weeks to 4 to 6 weeks after molt.
- Diverted eggs must have labeling on the shipping container, and all documents accompanying the shipment must state ''Federal law requires that these eggs must be treated to achieve at least a 5-log destruction of *Salmonella* Enteritidis or processed as egg products in accordance with the Egg Products Inspection Act, 21 CFR 118.6(f).''
- The requirement that one onsite supervisor at each farm be responsible for administration of the SE prevention measures has been changed to allow for more than one supervisor and for offsite supervisors to be responsible.
- Shell egg producers must document that pullets were SE-monitored or raised under SE-monitored conditions.
- ''SE monitored'' has been defined to mean that pullets are raised under SE control conditions that prevent SE, including the following: (1) Procurement of chicks from SE-monitored breeder flocks that meet NPIP's standards for ''U.S. S. Enteritidis Clean'' status (9 CFR 145.23(d)) or equivalent standard, (2) environmental testing, and (3) cleaning and disinfection of the environment as needed based upon the results of the environmental testing.
- Shell egg producers must maintain records documenting compliance with each of the SE prevention measures.
- Shell egg producers must maintain records documenting review and modifications of the SE prevention plan and corrective actions.
- Shell egg producers must register with FDA.

C. Compliance Dates

The compliance date is July 9, 2010; except that, for producers with fewer than 50,000 but at least 3,000 laying hens, the compliance date is July 9, 2012. The compliance date for persons who must comply with only the refrigeration requirements is July 9, 2010.

III. Comments on the Proposed Rule

FDA received approximately 2,000 timely submissions in response to the initial comment period on the proposed rule. In addition, approximately 20 timely submissions were received in response to the reopened comment period. The majority of submissions came from individuals and groups advocating animal welfare issues that, for reasons discussed later in this document, are outside the scope of this rulemaking. The remaining comments came from various trade associations, State government agencies, industry, consumer groups, scientific associations, and individual consumers. These comments raised approximately 60 major issues. To make it easier to identify comments and our response to the comments, the word ''Comment'' will appear in parentheses before the description of the comment, and the word ''Response'' will appear in parentheses before our response. We have also numbered each comment to make it easier to identify a particular comment. The number assigned to each comment is purely for organizational

purposes and does not signify the comment's value or importance or the order in which it was submitted.

A. General Comments

1. Enforcement by Voluntary EQAPs

(Comment 1) Several comments stated that FDA should implement what some comments referred to as a ''recognition regime,'' under which parts of the final rule would not apply to (or would be presumptively complied with by) State and industry EQAPs with standards equivalent to the Federal rule. Some comments suggested that all shell egg producers should be subject to the testing and diversion requirements of the final rule, but that egg producers participating in recognized EQAPs would have to meet only the on-farm SE control measures specified by the EQAP. The comments suggested that, as part of the recognition of the EQAPs, FDA should also recognize audits and inspections conducted by State agencies to measure compliance with those programs, rather than conducting separate Federal inspections.

(Response) FDA recognizes that existing voluntary EQAPs have been successful in reducing SE contamination in poultry houses in certain States (*see* discussion in section I.G of this document). However, for several reasons, we do not agree that States with EQAPs that are recognized by FDA should not be subject to this rule.

First, as discussed, these programs are not uniformly administered or equally comprehensive in their prevention measures. In addition, currently the EQAPs that exist are voluntary for shell egg producers. Although the existing EQAPs all have similar requirements, they vary in how those requirements are implemented. This rule will establish uniform, nationwide requirements to prevent SE in shell eggs during production, storage, and transportation. FDA believes that these requirements will further reduce SE illness and deaths associated with egg consumption.

On the other hand, we agree that we can enlist the assistance of existing EQAP organizations and officials in implementing FDA's regulation. The rule provides that a State or locality may, in its own jurisdiction, enforce this rule by carrying out inspections under § 118.12(b) (21 CFR 118.12(b)) and by using the administrative remedies in § 118.12(a) unless FDA notifies the State or locality in writing that its assistance is no longer needed. FDA plans to provide guidance to States and localities through an enforcement and implementation guidance subsequent to this final rule.

2. Vaccination of Layers Against SE

(Comment 2) Some comments agreed with FDA's conclusion, discussed in the proposed rule, that there is insufficient scientific support for a requirement that layers be vaccinated against SE (69 FR 56824 at 56847). Some of these comments stated that FDA should encourage voluntary vaccination efforts by, for example, allowing producers that can demonstrate the effectiveness of their vaccination programs to follow an alternative protocol for environmental testing before depopulation. One comment encouraged the use of SE vaccinations as an added prevention measure against SE contamination of shell eggs and recommended that an option of using a vaccination program should be available to shell egg producers. In support, the comment stated that data exists from the United States and Europe that the comment said demonstrates the efficacy of vaccination programs. The comment did not provide additional data in support of these statements.

Another comment stated that the available research and field evidence support a conclusion that vaccines used with other SE control measures will reduce SE.

(Response) FDA agrees with the comments supporting only voluntary vaccination of layers. As we stated in the proposed rule, there are insufficient data on the efficacy of vaccines, particularly data reflecting field trials under ''real world'' conditions, to support a mandatory vaccination requirement (69 FR 56824 at 56847). We also believe that data on the efficacy of vaccines are insufficient to allow substitution of vaccination for any of the SE prevention measures required in this final rule. If individual producers have identified vaccines that are effective for their particular farms, we encourage the use of the vaccine as an additional SE prevention measure.

3. Delegation of Inspection Responsibilities to Other Federal or State Agencies

(Comment 3) Two comments urged FDA to delegate farm inspection responsibilities to USDA's FSIS and Agricultural Marketing Service (AMS) or the State Departments of Agriculture, because these agencies are already involved in oversight of various aspects of egg production. Similarly, another comment stated that APHIS and FSIS are more qualified than FDA to address disease and pathogen risk reduction in live animal production operations.

(Response) FDA disagrees with the suggestion that we should delegate inspection responsibilities under this rule to USDA or the States. Although we coordinate our respective egg safety efforts with FSIS and AMS, each agency has distinct responsibilities and skills, all of which benefit consumers of shell eggs and egg products. These responsibilities and skills do not necessarily overlap as a practical matter (for example, AMS personnel are in certain shell egg packing plants, but not in the layer houses). Furthermore, the rule provides that any State or locality that is willing and able to assist FDA in enforcing the rule may do so in its own jurisdiction.

4. Induced Molting

(Comment 4) Several comments responded to the request in the proposed rule for comment and data concerning induced molting (69 FR 56824 at 56846 through 56847). We received a number of comments encouraging FDA to ban induced molting of laying birds. These comments stated that this practice stresses the immune function of chickens, resulting in the promotion of SE contamination in shell eggs and egg products; that it leads to plucking and consumption of feathers that may be contaminated with *Salmonella;* and that the plucking may itself also stress the immune system. The comments provided some references for these assertions. Another comment stated that USDA supports elimination of forced molting to reduce SE contamination and that the American Veterinary Medical Association also opposes the practice.

Other comments supported the absence in the proposed rule of provisions addressing molting. These comments stated that the research on which claims about post-molt SE shed are based have primarily been laboratory, rather than field research, involving large challenge doses of SE that would not be duplicated in the field and strains of chickens different from those common in commercial laying operations. The comments stated that there is only emerging research into how to use a variety of diets to control the natural process of molting in the egg production setting.

(Response) We addressed the issue of induced molting at length in the proposed rule (69 FR 56824 at 56846 through 56847). We discussed the limitations of studies cited to support the assertion that induced molting increases SE contamination of eggs and stated that we did not believe that we had 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. Although the proposed rule specifically requested comment and data related to our discussion of induced molting, we did not receive any new data on the relationship between induced molting and SE contamination of the laying environment and of eggs. As a result, we do not have adequate evidence to support including a prohibition on induced molting in the final rule.

5. Indemnification

(Comment 5) One comment suggested that we research whether the Public Health Service Act (the PHS Act) would allow us to indemnify persons whose economic interests are adversely affected by this rule, for example, as a result of diversion of shell eggs to breaker facilities. The comment suggested that, should we conclude that we lack such legal authority, we should consider whether to request it from Congress. Another comment suggested that a Federal compensation package may be needed for smaller producers that lack pasteurization capability.

(Response) Unlike APHIS, FDA is not required or explicitly authorized by Federal statute to compensate persons whose economic interests are adversely affected by certain Agency actions.[1] Further, FDA notes that although some producers will face economic costs from the diversion of eggs to the table market, as discussed in section V of this document (Analysis of Economic Impacts), the economic benefit from illnesses averted is expected to greatly exceed the cost of this rule. The suggestion that FDA seek statutory authority to pay compensation to indemnify producers is outside the scope of this rule.

B. Comments on ''Shell Egg Producers Covered by the Requirements in This Part'' (Proposed and Final § 118.1)

Exemption of Producers With Small Flocks

(Comment 6) Several comments addressed our proposed exemption of shell egg producers with small flocks, defined as flocks of less than 3,000 laying hens at a particular farm. Most of these comments argued that these small flocks are less likely to have adequate SE prevention measures and that excluding them would be contrary to the public health goal of the rule. The comments suggested that smaller facilities are less likely to have adequate refrigeration capacity, effective rodent control, an effective biosecurity program, measures in place to limit laying hens' exposure to manure on building floors and exposure to the outdoors; that they may pose a greater risk that they will transport and hold eggs without proper refrigeration; and that they may be less likely to obtain replacement pullets or chicks from breeders who participate in the SE prevention programs. One comment similarly suggested that eggs from these smaller producers might be associated with a disproportionate share of sporadic illnesses and even some outbreaks. The comments did not provide data to support these concerns; one comment from one of the larger trade associations stated that it was not aware of research that would support any conclusion that smaller operations would be either more or less likely to have an SE problem than larger, commercial operations.

One comment proposed that FDA reduce the exemption to producers with less than 500 chickens or require all producers not selling directly to consumers to comply with the rule. This comment suggested that FDA may not be aware of outbreaks associated with eggs from these producers because the eggs are not likely to be shipped interstate.

One comment cited our $1.01 per hen ($0.05 per dozen) estimate of the cost to farms with between 3,000–19,999 layers as an illustration of the large financial burden that the rule imposes on these farms.

(Response) We do not believe that there is at this time sufficient evidence to warrant extending the rule's coverage to producers with fewer than 3,000 laying hens. As we explained in the proposed rule (69 FR 56824 at 56832), because producers with fewer than 3,000 layers do not contribute significantly to the table egg market, imposing any one or all of the restrictions on them will have little measurable impact on the incidence of SE. We have no information documenting that there is an elevated risk of sporadic illness or outbreaks associated with eggs sold directly from farmer to consumer or from a producer with fewer than 3,000 laying hens.

FDA disagrees with the statement that we may be unaware of outbreaks associated with eggs from small producers because these producers are less likely to ship eggs interstate. The outbreak data relied on by FDA is in general submitted by State Departments of Health to CDC. As noted earlier, cases of salmonellosis must be reported to local health departments, who in turn provide information to States and to CDC.

FDA recognizes that the cost per hen is higher for smaller farms. However, though not specifically broken out in the regulatory impact analysis, for farms with between 3,000 and 19,999 layers, the public health benefits of the rule exceed the costs by more than $90 million annually and costs do not exceed benefits for any of the individual provisions of the rule. There are a number of features of the rule itself and in our plans for implementation to facilitate smaller farms' compliance with the rule. For example, this final rule has a staggered compliance schedule, which provides smaller egg producers (those with between 3,000 and 49,999 layers) 3 years to comply with the final rule. FDA will continue to evaluate the impact of this rule on smaller farms and will consider taking appropriate steps to mitigate those impacts, where it is possible to do so without reducing safety. In addition, FDA intends to provide guidance on the recordkeeping and other provisions of the rule, including small entity compliance guidance. We plan to use guidance, to the extent feasible, as a vehicle to identify areas where compliance could be achieved via flexible approaches that would mitigate the financial impact while preserving the public health benefits of the rule. We plan to solicit public and industry input on this guidance.

Therefore, FDA has retained the exemption from all provisions of this final rule for farms with fewer than 3,000 layers.

C. Comments on ''Definitions'' (Proposed and Final § 118.3)

1. Poultry House

(Comment 7) One comment questioned the proposed definition of a poultry house, which requires that different sections of a single building separated by walls be considered as separate houses. The comment noted that the definition would not address the risk of airborne transmission of SE. The comment stated that ''there is considerable evidence that SE can be transmitted through dust and other airborne particles,'' citing three references in support. The comment noted that the proposed rule did not require that separate sections in a building have separate ventilation systems, but did require biosecurity

[1] Under the Animal Health Protection Act, USDA is required to compensate the owner for any animal, article, or means of conveyance that the Secretary of Agriculture requires to be destroyed (7 U.S.C. 8306(d)). Under the Plant Protection Act, USDA is authorized to pay compensation to any person for economic losses incurred as a result of action taken by the Secretary of Agriculture under a declaration of extraordinary emergency (7 U.S.C. 7715).

procedures to ensure that there is no introduction or transfer of SE from one section to another. The comment suggested that the definition of a poultry house should clarify that the biosecurity procedures should include transfer through airborne particles.

(Response) FDA recognizes that SE may be transmitted through dust and other airborne particles. However, FDA does not believe that separate ventilation for each section of a house should be mandated because there is great variation in design and placement of houses and ventilation systems, and separate ventilation may not be necessary in every circumstance. Depending on the layout of a farm and the type and number of houses, a producer should decide whether ventilation needs to be addressed as part of farm-specific biosecurity measures to prevent the introduction or transfer of SE from one section to another.

The proposed definition of ''poultry house'' stated ''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.*'' (Emphasis added.) The final phrase has been removed from this section and added as an introduction to § 118.4(b) (biosecurity) to make clear that you must ''take steps to ensure that there is no introduction or transfer of SE into or among poultry houses,'' and that ''[a]mong such biosecurity measures you must, at a minimum'' include a number of specific measures in the biosecurity plan. If the design of a farm and its poultry houses needs an additional measure of ventilation to prevent cross-contamination, then such a measure should be added to the biosecurity plan.

In addition, in the final rule we have revised the definition of ''poultry house'' to clarify that ''[f]or structures comprising more than one section containing poultry, each section that is separated from other sections is considered a separate house.''

2. Treatment

(Comment 8) Some comments stated that a survey of egg processors to determine their current pasteurization practices supports a 5-log reduction, although many processors achieve a substantially greater pathogen reduction. The comments stated that the survey indicated that 50 percent of survey respondents reported that they achieve a 5-log reduction, and the other 50 percent reported a 7-log or greater reduction. The comments stated that the current 5-log reduction requirement appears to provide an adequate margin of safety, because specified temperatures and holding times do not take into account the additional kill achieved in the product while it is heating up to, and cooling down from, the pasteurization temperature.

(Response) FDA agrees with the comments that a 5-log reduction in SE via pasteurization or an alternative approach or the processing of egg products to achieve an equivalent level of protection is appropriate to ensure the safety of shell eggs. Therefore, we have retained the definition for the term ''treatment'' (or ''treated'') in § 118.3 of the final rule as ''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. We established this standard in 1997, in response to a USDA/AMS request to FDA on criteria for shell egg pasteurization. AMS then published this standard in its **Federal Register** notice on official identification of pasteurized shell eggs on September 24, 1997 (62 FR 49955).

Additionally, both FDA and FSIS 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 complimentary.

D. Comments on ''Salmonella Enteritidis (SE) Prevention Measures'' (Proposed and Final § 118.4)

1. Chicks and Pullets (§ 118.4(a))

FDA reopened the comment period on May 10, 2005, to seek further comment and information on industry practices and programs that prevent SE-monitored chicks from becoming infected by SE during the period of pullet rearing until placement into laying hen houses (70 FR 24490). We received approximately 20 submissions that provided additional information and data on the specific questions that FDA presented.

(Comment 9) Several comments stated that on-farm prevention practices must address each stage in the life of laying flocks, including the pullet-rearing stage. These comments stated that applying the FDA-mandated practices to layers only after they have been placed in layer hen houses may be too late to ensure protection against SE, as the layers' ovaries may already be contaminated with the pathogen. The comments urged FDA to make clear in the rule that all of the SE prevention practices apply to both pullet rearing houses and layer houses. The comments noted that this approach would be consistent with the practice of existing EQAPs SE prevention measures that are applicable specifically to pullets.

Many comments suggested that FDA add a new requirement that producers certify that pullets they procure have come from a facility that has an SE-monitoring program. The comments recommended that pullet houses undergo environmental tests for SE for each flock at approximately 10 weeks of age. The comments stated that, if the test is positive, the producer could still accept the pullets, but the producer should be required to test environmentally after placement. In addition, the comments suggested that FDA require that pullet houses should be cleaned and disinfected prior to placement of the next pullet flock. Finally, the comments suggested that FDA require testing for layers used to backfill (replacing dead or diseased layers with other layers) and older flocks that are moved to another facility.

(Response) We agree that SE prevention measures should be in place during the pullet phase of shell egg production and have modified the rule accordingly. We believe this will reduce the risk of placing infected birds into poultry houses. The final rule requires producers to procure pullets from sources where the environment has been tested and found environmentally negative prior to introduction into the laying flock. The environmental testing is required of pullets at 14 to 16 weeks of age and cleaning and disinfection of the pullet environment is required if the environmental test is positive. The cleaning and disinfection procedures include removing all manure, dry cleaning the positive pullet house to remove dust, feathers, and old feed, and following cleaning, disinfecting of the positive pullet house with spray, aerosol, fumigation, or another appropriate disinfection method. Additionally, if the environmental test is positive for SE, producers must begin egg testing within 2 weeks of the start of egg laying. The requirements also include procuring chicks from SE-monitored breeder flocks that meet standards set by NPIP for ''U.S. S. Enteritidis Clean'' status or equivalent standard.

FDA does not agree that a specific requirement is needed to test birds used to backfill and to test older flocks that are moved to another facility. Section 118.5(a) of the final rule requires

producers to perform environmental testing for SE in a poultry house when any group of laying hens constituting the flock within the poultry house is 40 to 45 weeks of age. Therefore, any layers used to backfill and older layers moved into a poultry house will be, or would have been, environmentally tested at 40 to 45 weeks of age, as are all other layers.

(Comment 10) Several comments supported the proposed requirement that all pullets and chicks be procured from a hatchery or breeding flock that participates in NPIP. These comments noted that NPIP participants have developed effective strategies that have reduced the prevalence of many poultry diseases including SE.

(Response) We have retained the requirement that pullets that are purchased be procured as chicks from SE-monitored breeder flocks that meet NPIP's standards for ''U.S. S. Enteritidis Clean'' status or an equivalent standard.

2. Biosecurity (§ 118.4(b))

(Comment 11) Some comments stated that FDA should revise its biosecurity requirements to allow egg producers greater flexibility. In addition, some comments challenged specific biosecurity measures as being insufficiently supported by data demonstrating their effectiveness in controlling or preventing SE contamination. Specifically, comments questioned the value of requiring personal protective equipment and sanitizing stations between houses on one farm, limiting visitors, controlling movement of workers from house to house, preventing employees from having poultry at home, and preventing stray poultry, wild birds, and other animals from entering the grounds. According to the comments, on a farm it is the presence of mice near chickens that maintains the SE infection and contributes to SE spread from building to building. One comment asserted that biosecurity efforts on the farm should be focused on ''rodents and other issues threatening to introduce or maintain SE.'' The comment does not explain what ''other issues'' the commenter is referring to. The comment also asserted that PEQAP does not have a biosecurity requirement.

(Response) FDA agrees with the comments that biosecurity measures could be more flexible in the final rule without jeopardizing the effectiveness of the SE prevention measures. Specifically, we believe egg producers may be able to devise and implement effective means other than protective clothing and sanitization stations to prevent cross-contamination between houses. For example, in some circumstances placing footbaths and farm-specific footwear at the entrance to a complex, maintaining house specific equipment, or using non-street clothing in the layer houses may be sufficient to prevent cross-contamination between houses. Therefore, we have removed from the biosecurity provisions the requirements for the use of protective clothing and sanitizing stations between houses. This change addresses the diverse poultry housing situations that exist throughout the country by allowing each producer to implement biosecurity practices and procedures appropriate for a particular farm and situation. We also agree that it is impractical to require egg producers to prevent stray animals from entering the grounds. Therefore, we have narrowed the provision for stray animals to apply only to the poultry houses.

However, FDA disagrees with the comments questioning the value of other specific biosecurity requirements. As discussed in the proposed rule (69 FR 56824 at 56835), limiting visitors on the farm and in poultry houses, maintaining practices that will protect against cross-contamination when persons move between poultry houses, and prohibiting employees from keeping birds at home are all vital biosecurity provisions that are commonly in use. According to the Layers 99 study (Ref. 29), 66 percent of farm sites already practice some form of biosecurity; that study found that poultry houses where visitors were not allowed were less likely to test positive for SE.

Biosecurity is a critical part of a farm's SE prevention measures. You must implement these biosecurity measures to prevent the introduction or transmission of SE into or between poultry houses. Furthermore, contrary to the comment, PEQAP requires all participants to maintain an acceptable biosecurity program (Ref. 30). As discussed in section I.G of this document, all current EQAPs require use of NPIP ''U.S. S. Enteritidis Clean'' chicks or equivalent, biosecurity, rodent control, cleaning and disinfection of poultry houses, and many programs require some environmental testing as well.

We will make further specific recommendations for biosecurity steps and options for achieving these steps, based on current science and best practices, in a guidance that we plan to issue subsequent to this final rule. We emphasize, however, that biosecurity is an important and integral part of any poultry farm's SE prevention program, and that the biosecurity requirements in the final rule are minimum standards; egg producers may incorporate additional biosecurity measures into their SE prevention plans if they believe such measures are warranted.

(Comment 12) One comment stated that if FDA insists on a biosecurity requirement, it should address the movement of pullets, spent hens (hens that have permanently ceased egg production), people, equipment, eggs, flats (a receptacle for storing or transporting eggs most often constructed of cardboard or plastic), and egg shells.

(Response) The comment was not specific as to how these matters should be addressed and did not provide any supporting data concerning the need for particular requirements. However, it was not our intention that the proposed rule's biosecurity provisions addressing the risk of cross-contamination from visitors or the movement of ''equipment'' be interpreted as an exclusive list of measures to take to prevent the introduction of SE into or among poultry houses. We have amended § 118.4(b) to make this clear, by adding general introductory language, moved from the proposed definition of ''poultry house,'' that producers must ''take steps to ensure that there is no introduction or transfer of SE into or among poultry houses.''

(Comment 13) One comment suggested that the proposed rule is premised on a mistaken belief by FDA that biosecurity alone can prevent the introduction and spread of SE.

(Response) As reflected in the rule, FDA understands that biosecurity is only one element of the measures that a producer must have to prevent SE. Producers must follow additional SE prevention measures, including pullet measures; rodent, fly and other pest control; cleaning and disinfection; and refrigeration.

(Comment 14) One comment questioned whether organic poultry producers would be able to comply with the requirement in the proposed rule (§ 118.4(b)(4)) that requires egg producers to ''prevent stray poultry, wild birds, and other animals from entering grounds and facilities.'' The comment stated that this requirement is in conflict with a requirement under the USDA National Organic Program (7 CFR part 205) that organic poultry producers must provide outside access for all livestock. The comment also stated that farms that are based on a pastured poultry system, which typically provides a substantial percentage of the birds' diet from pasture, would have difficulty complying with this requirement.

(Response) We agree that it would be difficult to prevent stray poultry and

other animals from entering the grounds of the farm, and we believe it is sufficient to keep stray animals out of the poultry house. Therefore, in the final rule, we have changed the requirement for stray animals so that it applies only to poultry houses rather than the entire grounds. Further, we have consulted with AMS, which administers the National Organic Program, and AMS has informed us that this requirement would not make it impossible for eggs to qualify as organic (Ref. 38).

3. Pest Control (§ 118.4(c))

(Comment 15) Some comments supported the rodent control program requirement in proposed § 118.4(c)(1), but questioned the role of flies in the spread of SE and recommended elimination of the pest monitoring under proposed § 118.4(c)(2). The comments further stated that if measured outside the poultry house, the fly count might reflect flies that are present from external locations, such as animal housing at adjacent properties.

(Response) FDA disagrees that the provision for monitoring flies in § 118.4(c)(2) should be removed or modified. In the proposed rule we described research by FDA and others showing that flies harbor SE within the poultry house environment (69 FR 56824 at 56835). According to the Layers 99 study, flies, like rodents, have access to feed troughs on nearly all farms. Further, the fly monitoring procedure can be performed inside the layer house, thus creating an accurate reflection of the presence of flies there.

For clarification, FDA has replaced the term ''pest'' in § 118.4(c)(2) in the final rule with ''flies'' because ''pest,'' which is defined to mean any objectionable animal including, but not limited to, rodents, flies, and larvae, is too broad in the context of this specific provision.

(Comment 16) One comment stated that PEQAP addresses rodent control, but does not address fly control. The comment recommended that fly control be included in the FDA regulation, but that the States individually and independently decide the number of flies allowed for maintaining compliance with the regulation. The comment suggested that under State or local requirements or when a farm has a problem, the spot cards be used to determine the numbers and, therefore, the appropriate control program.

(Response) FDA disagrees with the comment that the States should individually and independently decide the number of flies allowed for maintaining compliance with the regulation. This rule establishes minimum national standards based on measures that have been shown to prevent SE. The comment did not provide any rationale for addressing flies on a State-by-State basis. Further, the rule provides flexibility in how fly presence is determined, allowing not just spot cards, but also Scudder grills, sticky traps, or other appropriate monitoring methods. FDA intends to publish guidance on the requirement to monitor for flies and on the level of fly activity considered acceptable.

The literature suggests that 50 or fewer hits on a spot card or sticky trap per week or a count of less than 20 on a Scudder grill indicate satisfactory fly control ((Refs. 39 and 40).

4. Cleaning and Disinfection (§ 118.4(d))

(Comment 17) One comment suggested that mandatory cleaning and disinfection measures should not require removal of ''all visible manure'' in a hen house following a positive environmental test and depopulation, but should allow for flexibility with respect to manure removal. The comment stated that complete removal of all manure would destroy biological controls for flies (such as parasitic wasps). The comment also argued that this requirement is impractical, because many producers only remove manure from the houses during those times of year when they can immediately apply it to fields. Several comments stated that the requirement to remove all visible manure is impractical for large, complex poultry farming operations, because commercial in-line, multi-tiered cage layer houses with related accessories and equipment for watering, feeding, egg collection, manure deflection, storage, and removal might be impossible to bring into compliance. The complex machinery (some electrical) is very difficult to clean at best and is just not compatible with wet cleaning. It would also be difficult to accomplish this cleaning in very cold climates because of freezing, in that the layers were an important source of house heat until they were removed for replacement. The comment also noted it might be difficult to enforce a requirement such as ''removal of all visible manure.''

(Response) We disagree that flexibility should be allowed with respect to manure removal after a positive environmental test. First, even if it is true that complete removal of all manure would ''destroy biological controls for flies'' (presumably, by removing parasitic wasp larvae), the wasp population could be restored by the firm, if biological controls are an intended and effective component of the firm's fly control efforts. Data available to FDA indicate that there are non-biological methods of control available to producers (i.e., chemical and mechanical methods) and that these methods are used by most laying hen houses. Moreover, the available data indicate that the role of parasitic wasps in controlling flies is currently being debated in the scientific literature, with most of the work being done in cattle feedlots. Meyer *et al.* (1990) (Ref. 41) and Andress and Campbell (1994) (Ref. 42) found parasite treatments had no apparent affect on adult fly populations, while Weinzierl and Jones (1998) (Ref. 43) concluded that parasitism significantly reduced the fly population. In the one study we are aware of concerning the use of parasitic wasps to control flies in the context of poultry facilities, variable results were obtained (Kaufman *et al.,* 2001) (Ref. 44).

Furthermore, limited data suggest that total cleanout of manure is feasible even where parasitic wasps are used to control flies. A study by Hinton and Moon (2003) (Ref. 45) on the effect of a total cleanout on fly control in chicken houses compared the effect of a total cleanout of manure from chicken houses to two partial cleanout methods. Initially, the increase in flies was greatest in those houses with total cleanout, but subsequent differences between the three cleaning methods were small and the fly densities remained relatively stable for 3 months in all houses. Although this study did not specifically evaluate parasitic wasps, it supports a finding that total cleanout of poultry houses will not adversely affect fly control efforts (Ref. 45).

Second, the fact that manure cannot always be applied to fields does not mean that it should not be removed from poultry houses. Manure removed from a house can be composted, stored in a manure barn, or spread on a field depending on the time of year that it is removed.

Finally, we do not understand why manure removal at a large operation would be impractical. We acknowledge that a large operation has more manure to handle, but FDA has visited large operations that do clean out the manure, and we are unaware of any unique problems for such operations.

Because manure is a reservoir of SE that has been shed by infected laying hens, once a poultry house has had an SE-positive environmental or egg test, it is important that all visible manure be removed. Removing all visible manure before new laying hens are placed into a house will help to prevent the SE from

infecting the replacement flock via the manure and rodents.

Therefore, FDA concludes that, to prevent the spread or perpetuation of SE from one flock to another, a producer must remove all visible manure from a poultry house before new laying hens are added to the house when an environmental test was positive for SE at any point during the life of the flock that was housed in the poultry house prior to depopulation. The agency realizes that the floor in a concrete-floored house could appear light gray, but we do not expect to see any accumulation of manure in a house that has had the manure removed, and we do not anticipate practical difficulties in our ability to enforce this requirement. We plan to publish guidance on acceptable manure removal subsequent to this final rule.

(Comment 18) Several comments objected to the wet cleaning requirement in the proposed rule and suggested alternatives such as allowing flexibility so long as the cleaning and disinfection procedures are sufficient to eliminate SE. The comments stated that wet cleaning is impractical during the coldest months in some States; that it can encourage the growth of SE by creating an environment for growth of microorganisms in the poultry house; and that wet cleaning will harm some mechanical and electrical parts of equipment and cages. The comments argued that there is no scientific consensus in favor of wet cleaning.

(Response) We agree that wet cleaning may not be practical in all situations and have removed the requirement from the final rule. As discussed in the proposed rule (69 FR 56824 at 56836), it is important that, once a poultry house has had an SE-positive environmental or egg test, a producer 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. The final rule retains the requirement in this circumstance to dry clean the poultry house to remove dust, feathers, and old feed prior to the addition of new laying hens to the house and following cleaning, to disinfect the positive poultry house with spray, aerosol, fumigation, or another appropriate disinfection method.

5. Refrigeration (§ 118.4(e))

(Comment 19) Several comments raised concerns about the requirement in § 118.4(e) of the proposed rule that egg producers should refrigerate shell eggs if they are held longer than 36 hours. Some comments urged FDA to change the time at which refrigeration is required to 72 hours after production. The comments noted that 72 hours would accommodate shell egg production over weekends and smaller producers that have pickups less frequent than daily, while at the same time ensuring that eggs are not accumulated and held over long periods without refrigeration.

One comment argued that the requirement to refrigerate eggs within 36 hours could actually be counter-productive with respect to the safety of eggs destined for use in the table market. The comment reasoned that more checks and cracks will occur when previously refrigerated eggs are washed due to the greater change in temperature. The comment recommended that FDA not set a prescriptive time requirement for refrigeration of table eggs unless further research justifies the need, but that if a time limit for refrigeration must be set, it should be set at 72, not 36, hours.

(Response) We disagree that eggs should remain unrefrigerated for up to 72 hours after laying. Our proposed requirement that eggs be refrigerated if stored more than 36 hours was based on data indicating that, although fresh shell eggs provide an inhospitable environment for *Salmonella* 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 (69 FR 56824 at 56836 through 56887). As they degrade, shell eggs provide an increasingly more hospitable environment for the growth of SE. Studies have shown that SE, when inoculated into the albumen (whites) of whole shell eggs, multiplied to high numbers if the eggs were not properly refrigerated (Refs. 46, 47, and 48).

The 36-hour limit for unrefrigerated holding is supported by a model, contained in the 1998 joint SE risk assessment (Ref. 21), which was developed to examine the relationship among holding time, holding temperature, and yolk membrane breakdown as an indicator of SE risk. (The yolk membrane separates the nutrient-rich yolk and any SE bacteria that might be present in the albumen; breakdown or loss of the yolk membrane results in rapid growth of SE present in the albumen.) The model showed that, at 70 to 90 °F (i.e., temperatures that might be observed in unrefrigerated egg holding areas in farms or warehouses or in transport vehicles), there was much less breakdown of yolk membrane in eggs held no longer than 36 hours than in eggs held no longer than 72 hours. According to the model, eggs held at 70 °F will experience at least a 16-percent breakdown of yolk membrane after 36 hours and a 25-percent breakdown after 72 hours. Eggs held at 80 °F will suffer at least a 22-percent breakdown after 36 hours and a 39-percent breakdown in the yolk membrane at 72 hours. At 90 °F, there is at least a 33-percent breakdown after 36 hours and at least a 62-percent breakdown of the yolk membrane after 72 hours. In the 2005 FSIS risk assessment (Ref. 22), refrigeration was modeled again; this risk assessment found that limiting eggs to just 12 hours without refrigeration, the shortest timeframe between laying and refrigeration that was evaluated, provided the greatest public health benefit among the time frames studied.

Although, as we stated in the proposed rule, we believe that it is very important that eggs be placed into refrigerated storage as soon as possible after they are laid, we recognize that this may not be practical for all producers. It may take several hours or longer after the eggs are laid before they are collected or picked up for transport. According to the Layers 99 study (Ref. 28), almost half of the farm sites surveyed had egg pickups every 1 to 2 days. In light of all of these data, we are retaining in the final rule the requirement of 36 hours as the maximum amount of time eggs may be held unrefrigerated on the farm.

(Comment 20) Several comments questioned the proposed refrigeration temperature requirement of 45 °F. One comment stated that holding eggs at 45 °F would result in two problems related to egg quality and safety. First, the comment stated that ambient moisture would condense on the cold eggs and cause them to ''sweat'' before they are washed/sanitized, increasing the chance of surface contamination penetrating the eggs. Second, the comment stated that when cold eggs are moved into the egg washer, which uses hot water, checks or cracks can develop in the shell, lowering the quality of the egg and increasing the risk of future surface bacterial or fungal contamination getting into the interior of the eggs.

(Response) FDA does not agree that a 45 °F refrigeration requirement is too low. This requirement is consistent with FDA's final rule on refrigeration of shell eggs at retail (65 FR 76092), and like that requirement, the rule is based on research demonstrating that *Salmonellae* do not grow well or rapidly at temperatures less than or equal to 45 °F. FDA finds that the scientific evidence on the growth of SE in eggs shows that control of storage temperature of shell eggs can significantly reduce the rate of

multiplication of any SE present (Refs. 46, 47, and 48).

FDA agrees that there can be quality and safety problems such as thermal checks (hairline cracks in the shell) associated with refrigerating eggs immediately prior to processing into either table eggs or egg products. Therefore, FDA is modifying the rule to allow an equilibration step (a step during which the eggs reach room temperature) before eggs are processed. Specifically, under § 118.4(e) of the final rule, shell eggs that have been refrigerated may be held at room temperature for no more than 36 hours just prior to processing to temper them, which will reduce the risk of hairline cracks in the shell that could contribute to bacteria entering the egg during washing if the egg is too cold. We believe the benefits of refrigeration accompanied by equilibration outweigh any possible risk associated with sweating of the eggs.

(Comment 21) One comment stated that the rule is silent on the refrigeration of eggs that are segregated at the grading operation for processing at egg products plants. These are the eggs that do not meet grade requirements, are checked (that is, the shell is cracked, but the shell membrane is intact), or have dirt on the shell. The comment explained that the last two types of eggs pose a significant food safety risk if handled improperly and can be processed only in a USDA-inspected egg products plant. Additionally, the comment stated it may take several days to accumulate a quantity of checked and dirty eggs for shipment. Similarly, the comment stated that surplus eggs produced by hatchery flocks are accumulated and sent to egg products plants for processing and could present a hazard if not properly refrigerated. The comment noted that most shell egg packers and hatcheries currently refrigerate these eggs, but the comment urged FDA to amend the proposed rule to require that eggs segregated at grading operations and at hatcheries and intended for further processing also be subject to the refrigeration requirements proposed for on-farm storage.

Another comment noted that USDA only requires refrigeration at the packer's facility after packing for the consumer. The comment stated that nest run eggs (eggs that are packed as they come from the production facilities without having been washed, sized, and/or candled for quality) and restricted eggs, (eggs whose use is limited by FSIS under the Egg Products Inspection Act because they are, for example, checked or dirty) are not required to be refrigerated. This comment further stated that to maintain the maximum benefit of SE illness reduction from refrigeration, eggs should be refrigerated throughout the distribution chain.

(Response) We sought comment in the proposed rule 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 further stated that we would 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).

FDA agrees with the comment that the refrigeration requirement in the proposed rule only addresses eggs held at the farm for more than 36 hours after time of lay. The proposed requirement does not address nest-run eggs, surplus hatching eggs sent to the table egg market, eggs shipped to egg products facilities and then sent to the table egg market, or any other eggs that are held or transported at locations other than at the producer's layer farm. Holding or transporting these eggs without refrigeration allows growth of any SE that may be present in the eggs. We also agree with the comment that, to maintain the maximum benefit of SE illness reduction from refrigeration, eggs should be refrigerated throughout the distribution chain. Therefore, to reduce this potential growth of harmful bacteria, we have modified § 118.4(e) in the final rule to require refrigeration during all storage and transportation beginning at 36 hours after time of lay.

Following are three examples of eggs requiring refrigeration under the final rule, which would not have required refrigeration previously: (1) Unwashed eggs more than 36 hours old from a farm with 3,000 or more layers that have left the producer's farm and are being transported to or are at a shell egg processing facility or are being held in a warehouse; (2) eggs from a farm with 3,000 or more layers that are more than 36 hours old and are being shipped from an egg products facility (USDA-inspected plant) to a shell egg processing facility; and (3) eggs from a hatchery that are more than 36 hours old, were never used for hatching, and are now being transported to a shell egg processing facility. For clarification, in the final rule we are defining ''egg products facility'' as ''a USDA-inspected facility where liquid, frozen, and/or dried egg products are produced,'' and ''shell egg processing facility'' as ''a facility that processes (e.g., washes, grades, packs) shell eggs for the table egg market.''

In addition, as discussed in response to comment 20, for those eggs to be processed as table eggs but which are not processed for the ultimate consumer within 36 hours from the time of lay and therefore are required to be held and transported under refrigeration, we are permitting an equilibration step.

E. Comments on ''Environmental Testing for Salmonella Enteritidis (SE)'' (Proposed and Final § 118.5)

(Comment 22) Several comments challenged the proposed requirement that egg producers conduct environmental testing when a flock has reached 40 to 45 weeks of age, and if the flock has molted, 20 weeks after the end of the molting process. The comments suggested that instead FDA follow the practice of some EQAPs, which require testing of the layer house environment at the end of the laying period, prior to depopulation. One comment stated that environmental samples should be obtained anytime within the time period of active production, or between the 40th and 60th week of production. In addition, the comment stated that if the environmental samples taken at this time are negative there is no need to conduct additional samples for those birds that have undergone an induced molt.

Another comment stated that the 1998 joint SE risk assessment (Ref. 21), as well as draft 2004 USDA risk assessment (Ref. 49) support a revision to the proposed testing time for post-molt layers from 20 weeks, as proposed, to a 4 to 6 week range post-molt. In support of this suggestion, the comment noted that the 2004 FSIS draft risk assessment finds the greatest risk of infected eggs immediately after molt, but at this time hens are laying few eggs. As a result, the comment estimated that if the increased risk used in the draft risk assessment is multiplied by expected lay post-molt, the greatest number of infected eggs from infected molted flocks will occur between 4 to 6 weeks post-molt.

(Response) We do not agree that the timing for environmental testing of unmolted flocks should be modified. As stated in the proposed rule, environmental testing for SE is an indicator of whether SE prevention measures are working effectively. Testing provides an opportunity for producers to evaluate the SE status of their poultry houses and to take appropriate action if their prevention measures are not preventing SE. Information from an EQAP 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. 50). Additionally, the Layers 99 study found that flocks less than 60 weeks of age (younger flocks) were five times more likely to test positive for SE than older flocks (Refs. 27 through 29). In the absence of any new data, we are retaining in the final rule the requirement 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. 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 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.

FDA does, however, agree that the post-molt environmental test should be moved from 20 weeks post-molt to 4 to 6 weeks post-molt. As the comment noted, the FSIS 2004 draft risk assessment (Ref. 49) (as well as the final version of the risk assessment, Ref. 22, published in 2005) described research by Ebel and Schlosser (Ref. 23) that indicated that ''[e]vidence from field studies suggests that molted flocks, in the first 20 weeks of post-molt production, will produce SE-contaminated eggs more frequently than non-molted flocks'' (Ref. 22 at page 29). As FSIS explained in the draft and final risk assessments, ''[t]he stress of molting is thought to result in an increased susceptibility of hens to SE infection'' (Id.). FSIS relied in its analysis on data contained in the ''*Salmonella* Enteritidis Pilot Project Progress Report'' (Ref. 51) and the study by Holt on immunological factors in laboratory hens (Ref. 52), which were referenced in the proposed rule. As we stated in our response to comment 4, the data underlying the FSIS risk assessment, which we reviewed in the proposed rule, do not support a prohibition on induced molting. However, these data do suggest that there may be some elevated risk that hens may become infected with SE in the post-molt period, before 20 weeks have passed. In light of these studies, we have decided that it would be prudent to conduct environmental SE testing earlier post-molt than was proposed. Therefore, to evaluate the status of a laying hen house post-molt to determine the effectiveness of SE prevention measures during the post-molt laying cycle, we have amended § 118.5(b) to require an environmental test at 4 to 6 weeks after the end of any molting process.

(Comment 23) Several comments suggested that FDA revise the proposed rule to make the environmental sampling plan flexible.

In support of this suggestion, some comments stated that because the rule would cover very diverse egg laying facilities in the United States (e.g., free-range farms and confinement operations using cages or nesting boxes), one single sampling plan would not be effective. One comment recommended a different sampling plan requirement for each operation type. The comment suggested that all confinement ''barns'' could be sampled under the same plan, and recommended that for such operations FDA require that a minimum of one manure drag sample be obtained from each bank of cages. The comment stated that more research is needed to determine the most appropriate sample sites for operations that are cage-free, pasture-raised, or free-range. Another comment noted that the sampling plan should also be flexible because of variations in operations within geographic areas and across geographic regions, for example, difference in manure collection/disposal systems.

(Response) FDA agrees that because the final rule covers very diverse egg laying facilities, the same sampling plan may not be practical for all operations and that the sampling plan requirement should be flexible to accommodate variations in housing styles. The proposed rule did not specify a particular plan; rather it provided at § 118.7(a) that ''[w]ithin each poultry house, you must sample the environment using a scientifically valid sampling procedure.'' In the final rule, to make more clear that the appropriateness of a sampling plan depends on the house being sampled, we have modified the language in § 118.7(a) to require ''a sampling plan appropriate to the poultry house layout.'' Specific sampling instructions have been incorporated into the environmental testing method, ''Environmental Sampling and Detection of *Salmonella* in Poultry Houses.''

(Comment 24) One comment questioned whether FDA could appropriately determine whether a producer is using a ''scientifically valid sampling procedure,'' as required in proposed § 118.7(a). The comment suggested that, for example, there might be no reason to believe that sampling every cage row is more effective than sampling 32 random sites in a laying house. Another comment stated that the only ways to generate drag samples that can be compared across the various types of poultry house are the two discussed in the proposal: Drag swabbing the aisles (the ''whole aisle'' method) and swabbing a certain number of feet of egg belt (the ''limited feet from 32 sites'' method) because eggs are collected by hand in only a few houses. Another comment stated that while the procedure for sampling manure pits in a high rise facility with caged layers is fairly straightforward, nonconfinement operations do not have a clear direction on what is the most appropriate sampling site. The comment asserted that it would be unreasonable to expect an operation with 10,000 layers to develop a scientifically valid sampling program when FDA cannot define what is scientifically valid.

(Response) In the proposal FDA described the ''whole aisle'' and ''limited feet from 32 sites'' swabbing methods and acknowledged differences in the types of poultry houses and the challenges involved in sampling all houses representatively and consistently. We asked for comments about the appropriateness of different methods of drag swabbing and received no comments that would support one method over the other. To specifically acknowledge differences between poultry houses, the rule now requires ''a sampling plan appropriate to the poultry house layout.'' FDA believes that there are sufficient data for producers to develop sampling plans for all poultry environments. Over the past ten years, FDA has performed environmental sampling in a variety of poultry houses, which have contained from 3,500 to 250,000 birds and have varied from high rise to shallow pit to sunken water pit houses. The results of this sampling indicate that the manure area and eggbelts are the two best areas to sample (Ref. 53). FDA has incorporated specific sampling instructions into the environmental testing method, ''Environmental Sampling and Detection of *Salmonella* in Poultry Houses.''

(Comment 25) One comment stated that because it is common for producers in Hawaii to have multi-age flocks in one poultry house, it would be difficult to perform SE testing for specific flocks that reach the age at which testing is required. The comment further stated that if there is an environmental positive test result for a typical farm in Hawaii (5 to 10 acres), there would be no space to store the eggs to wait for egg

test results. The comment argued that a positive environmental test result could mean depopulation of the entire farm and, even if the egg tests are negative, it could still mean the end of the farm.

(Response) The comment reflects a misunderstanding of the rule. Section 118.5 requires environmental testing of the entire poultry house when any group of laying hens in that house is 40 to 45 weeks of age. If multi-age flocks are housed in the same poultry house, egg producers must perform environmental testing on the entire house whenever any group of laying hens in that house reaches 40 to 45 weeks of age. Furthermore, upon finding an environmental sample positive for SE, there is no requirement to store or otherwise hold the eggs. The eggs from a flock in a house that has tested environmentally positive for SE may continue to be marketed as table eggs until the producer is notified that an egg test is determined positive for SE. At that point, the producer must divert those eggs to treatment.

(Comment 26) One comment argued that a testing regulatory scheme would not be effective in preventing illnesses from SE. This comment stated that environmental and egg testing only indicates the status of the house at the time of the test.

(Response) Environmental and egg testing alone do not prevent SE, but instead serve as an indicator and verification step that the SE prevention plan is working properly. Further, a positive egg test can prevent contaminated eggs from reaching consumers and thereby protect the public health.

Diversion (§§ 118.5 and 118.6)

(Comment 27) We received many comments on our proposed requirement that eggs from a SE-positive layer house environment must be diverted to pasteurization, unless testing of four pools of 1,000 eggs each yields SE-negative results. One comment supported the diversion requirement as a reasonable way to keep higher-risk eggs out of the table egg market, but stated that the requirement could pose an economic risk to shell egg producers that do not have their own egg pasteurization capabilities. Other comments similarly noted that this requirement could have an economic impact on egg producers that lack ready access to egg pasteurization facilities, because they will have to sell their eggs to ''breakers'' who already have an adequate supply of eggs (through ownership of laying houses or pre-existing contacts with such houses). As a result of this arrangement, egg producers will have to take whatever price they can get from the breakers and the price will inevitably be much lower than the price they would have gotten if the eggs had not come from an SE-positive layer house. Some comments expressed concern that egg product buyers might not want to purchase product known to have come from eggs diverted because of SE, further reducing the breaker's incentive to buy the diverted eggs.

Thus, these comments expressed concern that this diversion would result in a cost to the industry much greater than that projected by FDA in the proposal. One comment stated that, even if they were willing to buy the diverted eggs, breakers might offer a price too low to make it economically feasible to retain the flock. That same comment noted that diversion to the pet food supply chain would not be an option because SE-positive eggs would have to be run through the processing plant, and stated that destruction may be the only alternative in most cases.

(Response) FDA recognizes that diversion of eggs may be expensive or impracticable. We do not agree that we have underestimated these costs. Further, these costs are outweighed by the public health benefit realized by diverting contaminated eggs.

In addition, FDA believes there may be some confusion about the diversion requirement. Under the rule, diversion is required under the following three scenarios: (1) When the environment tests positive for SE, and the producer chooses not to test eggs from that house to determine whether the eggs are also positive; (2) when the eggs in a house test positive for SE; and (3) by order of an FDA, State, or local representative after a finding that shell eggs have been produced or held in violation of this regulation.

(Comment 28) One comment requested that FDA include hard cooking as an acceptable method of diversion.

(Response) If diversion is required, you do not necessarily have to send the eggs to a breaker. You may instead divert them to an alternative process that achieves at least a 5-log reduction in SE, using, for example, in-shell pasteurization of shell eggs or hard cooking of shell eggs.

In the proposed rule, FDA defined treatment as ''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.'' We have retained this definition in the final rule. Thus, as long as the hard-cooking process achieves at least a 5-log destruction of SE, it is an acceptable method of diversion.

(Comment 29) One comment stated that Hawaii has no egg breaking facilities, and that the costs of shipping diverted eggs to breaking facilities in California or elsewhere in the continental United States would be prohibitive. The comment also noted that in the past some breaking facilities on the West coast have refused to accept eggs from Hawaii. The comment requested that the rule be made more flexible to address the situation facing Hawaii and other States with inadequate or no egg diversion capacity.

(Response) FDA recognizes that there is regional variation in the cost of diversion for eggs. For a full discussion of this variation, see section V.F of this document. We understand that there are currently no breaking facilities in Hawaii and that it may not be economically feasible to ship diverted eggs to the continental United States or Canada. For egg producers in Hawaii, and for others also unable to avail themselves of breaker facilities, the cost of diversion per egg is the lost value of a table egg. In the proposed rule, we estimated that the price to a producer for one dozen diverted eggs in Hawaii is $0.53, or $0.044 per egg. We recognize that this cost is more than double the cost of diversion for egg producers in other regions; however, per our usual approach for public health regulations promulgated under the FFDCA and the PHS Act, we are establishing minimum national standards that will equally apply to all States. We acknowledge that diversion for egg producers in situations such as those in Hawaii may be particularly financially challenging. As discussed above, we will use guidance as appropriate to mitigate the impacts associated with implementation of the rule.

F. Comments on ''Egg Testing for Salmonella Enteritidis (SE)'' (Proposed and Final § 118.6)

(Comment 30) One comment agreed with the sampling protocol established in § 118.6(c) for egg testing for SE, but stated that 24 hours is not a practical timeline to begin egg testing after a positive environment is found. The comment suggested that § 118.6(c) require egg producers to immediately notify the appropriate state agency of the positive environmental findings and that egg sampling commence within 2 weeks after the environmental test results are received. Another comment suggested that FDA revise the time period allowed between receiving a positive environmental sample and conducting the required egg testing from

24 to 72 hours to allow for weekends or holidays when laboratory facilities would most likely not be available to complete the tests. Several comments further argued that the 24-hour requirement for initiating egg testing is impossible, as even collecting the eggs within 24 hours might be difficult at times. In addition, the comments argued that to arrange testing for 1,000 eggs requires scheduling of several items, including people, labs, and media, and cannot be done in 24 hours.

(Response) For the reasons identified in the comments, FDA agrees that 24 hours may not be practical to begin egg testing. Therefore, we have modified § 118.5(a)(2)(ii) and (b)(2)(ii) in the final rule. Rather than setting a time when egg testing must begin, the rule establishes a deadline for conducting and completing such testing and receiving the results. The final rule requires that the results of egg testing for the first 1000 eggs must be obtained within 10 calendar days of receiving notification of the positive environmental test. This time period allows for the farm to obtain a laboratory to do the work and collect the eggs and for the laboratory to perform and complete the tests.

(Comment 31) Two comments stated that the egg sampling procedure should be witnessed by a regulatory agency, such as a State Department of Agriculture.

(Response) FDA disagrees. Other FDA regulations, such as Hazard Analysis and Critical Control Point (HACCP) Procedures for the Safe and Sanitary Processing and Importing of Juice (21 CFR part 120) and Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products (21 CFR parts 123 and 1240), do not require sampling and other testing to be overseen by FDA or State officials to be effective. The egg sampling requirement is expected to be routine and a regular component of the on-farm plan to prevent SE.

Furthermore, to assist FDA in ensuring compliance, the final rule requires that each facility establish and maintain records of plan activities, including egg sampling. Such records will assist FDA in determining whether sampling was performed appropriately.

G. Comments on ''Sampling Methodology for Salmonella Enteritidis (SE)'' (Proposed and Final § 118.7)

(Comment 32) One comment stated that FDA should distinguish between a sampling plan used to verify or monitor an on-farm program and a sampling plan used for an SE outbreak trace back. The comment also asked for clarification of the scientific justification for the requirement in § 118.7 that egg producers pull a 1,000 egg sample, regardless of the size of the operation. The comment questioned whether sampling for monitoring purposes needs to be as extensive as that undertaken for outbreak trace back situations.

Another comment noted that due to potential breakage, a sample size of 1,050 eggs would eliminate the problem of having to use cracked or broken eggs (i.e., the laboratory can select 1,000 eggs from this 1,050 egg pool).

(Response) The rule requires egg testing after receipt of notification of a positive environmental test (unless the eggs are treated). Sampling after a positive environmental test is intended to effectively detect SE-positive eggs from a flock.

The rule requires that egg producers collect and deliver for testing a minimum of 1,000 intact eggs representative of a day's production four times at 2-week intervals, resulting in a total test of 4,000 eggs over an 8-week period. This sampling scheme is based on data from the SE risk assessment indicating that an SE-contaminated flock may be producing SE-contaminated eggs with a prevalence of 1 in 1,400 (Ref. 54). The sampling scheme would result in a 95 percent probability of accurately detecting an SE-positive egg from a flock producing contaminated eggs with the prevalence calculated in the risk assessment (Ref. 54).

We agree with the potential for breakage raised in the comment concerning the sample size for egg testing and have modified § 118.7(b) in the final rule so that the requirement is to ''collect and deliver for testing a minimum of 1,000 *intact* eggs representative of a day's production'' (Emphasis added).

With regard to the comment regarding making a distinction between a sampling plan for monitoring SE on the farm and for an SE outbreak trace back, FDA notes that this final rule does not address SE outbreak trace backs and is solely designed for the prevention of SE in shell eggs during production, storage and transportation. SE outbreak trace back is beyond the scope of this regulation and will not be addressed here.

H. Comments on ''Testing Methodology for Salmonella Enteritidis (SE)'' (Proposed and Final § 118.8)

(Comment 33) One comment recommended that FDA modify its required environmental testing method to conform to the methods currently being used by the industry, states and laboratories. One such method is that used by the NPIP. The comment stated that the proposed environmental testing method requires the use of an extra selective agar, bismuth sulfate (BS) agar, which has not been proven to be effective in isolating SE from environmental samples. The comment argued that BS agar is the agar of choice for isolating S. Typhi from clinical samples, but that it is not effective for environmental samples of SE. The comment suggested that the isolation with BS agar is an unnecessary step that should be eliminated from the method.

(Response) The method we proposed for environmental testing is set forth in ''Detection of *Salmonella* in Environmental Samples from Poultry Houses,'' which was proposed for inclusion in FDA's Bacteriological Analytical Manual (BAM), or an equivalent method with respect to accuracy, precision, and sensitivity in detecting SE. The environmental testing method FDA proposed was very similar to the NPIP environmental testing method. For example, it included the same pre-enrichment and enrichment broth. It was different only in that it specified what specific plating agars should be used, and it required the use of three, not two, plating agars. The selective plating agars identified in the proposed rule method were brilliant green with novobiocin (BGN), xylose-lysine tergitol 4 (XLT4), and BS. BGN and XLT4 are two of the selective plating agars that have been used by some laboratories using the NPIP method.

With respect to the use of BS, FDA has performed additional plating with layer house environmental SE colonies on BS agar and has reconsidered the method for conducting environmental testing. As a result of this review FDA has eliminated the use of BS for environmental testing in the final rule and has changed the method to reflect the elimination of the BS agar. The method specified in the final rule, ''Environmental Sampling and Detection of Salmonella in Poultry Houses,'' requires only two agars, BGN and XLT4.

The comment did not challenge the specification that BGN and XLT4 be the plating agars used, and we have not changed this specific requirement in the final rule. As in the proposed rule, if other methods are at least equivalent to the specified method in accuracy, precision and sensitivity in detecting SE, they may be used instead of the method specified.

(Comment 34) With respect specifically to environmental testing, a

comment noted that the test does not allow for pooling of samples, which the comment stated would reduce the number of samples the laboratory would have to run with no loss in sensitivity of the test. The comment stated that pooling would reduce costs by 75 percent.

(Response) Although there are data showing that pooling of food samples, under specified conditions, does not compromise method sensitivity, we are not aware of any data, and the comment did not provide any such data, to support pooling for environmental sampling. Until such data become available, it would be imprudent of FDA to specify a test that includes compositing of environmental swabs.

(Comment 35) One comment raised concerns about the proposed egg testing method. The comment stated that the method proposed by FDA differs from the method used by APHIS, as well as other methods used by industry, states and laboratories. In addition to the concern that the method that we proposed is not the same as that used by APHIS, the comment identified two other specific concerns with the proposed egg testing method. First, the comment stated that the proposed egg testing method requires the use of BS, an isolation media that is the media of choice for isolating *Salmonella* Typhi from clinical samples. Second, the comment stated that only two selective agar plates should be inoculated (BGN and XLT4) instead of the five proposed in the method for egg testing.

(Response) Neither the description of the method discussed in the preamble of the proposed rule nor the reference to the method contained in the codified portion of the proposed rule are correct for the egg testing methodology. The method referred to in the codified portion of the proposed rule was actually a comparison study involving varying media and pre-enrichment. The method for testing eggs adopted in the final rule is the method in the BAM, chapter 5, ''*Salmonella*.''

Addressing the comments in turn, we disagree that we should adopt the APHIS egg testing method. Like the BAM method, the APHIS method first involves the disinfection of eggs and then the cracking, pooling and mixing of eggs. The two methods diverge at the third step, which is incubation: In the BAM method the pools are incubated at room temperature for 96 hours, while in the APHIS method the pools are incubated for only 72 hours.

The two methods also are different in subsequent steps. In the BAM method, there is a pre-enrichment step in which a portion of the egg pool is enriched with trypticase soy broth supplemented with ferrous sulfate and incubated for 24 hours, after which the pre-enriched sample is placed into 2 selective enrichment broths (tetrathionate and Rappaport-Vassiliades), and subsequent inoculation onto three selective media: BS, xylose lysine desoxycholate (XLD), and Hektoen enteric (HE). In the APHIS method, there is no pre-enrichment step. Instead, egg samples from the incubated eggs are inoculated onto 2 selective agars (brilliant green and XLD). In both methods colonies that grow on the agar plates are sampled to characterize the organism as *Salmonella* by the reaction on two agar slants.

FDA believes that, for the purposes of this final rule, its method is preferable to the APHIS ''Egg Sampling Method'' (58 FR 41048, August 2, 1993). First, the addition of ferrous sulfate at the pre-enrichment step in FDA's method provides iron, which is needed by *Salmonella* for growth and which may not be present in sufficient quantity in the egg; thus, this step may increase the likelihood of detection. Second, the two selective enrichment media (tetrathionate and Rappaport-Vassiliades) used in FDA's method contain agents that are selective (inhibitory) against the non-*Salmonella* organisms. The inhibition of non-*Salmonella* organisms enhances the test by reducing competition and possible overgrowth from other organisms. Third, the use of three, rather than two, selective plating agars maximizes the possibility of detecting as many SE strains as possible. We note that the APHIS egg sampling method was developed and has been in use since 1993. While it has been and remains a valid sampling method, the FDA method is more sensitive and can better detect the presence of *Salmonella* in food, and our adoption of this newer and more sensitive test will better support the public health goals of this rule. In summary, FDA believes that the specific method prescribed for egg testing in this final rule is tailored to the goals of the rule.

With respect to the two more specific comments, FDA does not agree with the recommendation to eliminate BS in the method for egg testing, for the reasons explained in the previous paragraphs. Nor do we agree that the other two selective agar plates should be BGN and XLT4, rather than HE and XLD. In a comparison study of selective plating agars using selected high moisture foods (Ref. 55), the newer selective plating agars performed comparably with the BAM recommended agars (BS, HE, and XLD) but offered no advantage. The BAM is a collection of procedures preferred by analysts in FDA laboratories for the detection in food and cosmetic products of pathogens and microbial toxins. With some limited exceptions, these methods have been used and peer reviewed by FDA scientists as well as by scientists outside FDA. A new agar such as that proposed in the comments would be added to the BAM only after research indicated superior performance in the context of a variety of foods, and where the agar has been validated by collaborative studies. Therefore, the final rule does not deviate from the proposal in recommending the use of the BAM-recommended plating agars. However, we note that another test that is equivalent to the specified test in accuracy, precision and sensitivity for detecting SE may be used.

(Comment 36) One comment recommended that FDA allow for improvements in the methodology for *Salmonella* testing to be easily and quickly adopted by the industry upon validation of the new method, and that FDA work with other Federal agencies with approved testing methods, such as APHIS and FSIS, to facilitate approval of methods and to reduce the need for one facility to use several different methods for *Salmonella* testing. The comment stated that APHIS, FSIS, and scientific organizations all have approved methods for detecting *Salmonella* and SE. The comment further stated that methods need to provide consistent results, yet be flexible enough to allow the industry to adapt quickly when improvements are made. For example, rapid testing methods are available and approved by some Federal agencies (e.g., FSIS). The comment argued the current proposed rule would not allow a producer to use a rapid method for testing of environmental or egg samples. The comment recommended that FDA conduct a literature review and, if necessary, additional research to determine what methods are appropriate to detect SE in the environment and egg samples, with the goal of identifying methods that are appropriate for the purpose of the testing and less costly (in both time and money) to the industry.

(Response) In the final rule, FDA is allowing for other methods to be used for both environmental and egg testing, provided they are equivalent to the methods we specify in accuracy, precision, and sensitivity in detecting SE.

I. Comments on ''Administration of the Salmonella Enteritidis (SE) Prevention Measures'' (Proposed and Final § 118.9)

(Comment 37) Several comments suggested that FDA modify the requirement in proposed § 118.9 that one qualified individual at each farm have training equivalent to a standardized curriculum recognized by FDA or be otherwise qualified through job experience to administer the SE prevention measures. The comments proposed instead that FDA require training of a qualified individual responsible for each farm, even if that person is not an onsite employee. These comments noted that many producers employ one individual to oversee multiple farm locations, and that this person generally has more experience and training than the onsite employees and can provide better oversight on developing and implementing SE prevention measures.

(Response) We agree and are amending the language in § 118.9 in the final rule to allow for one or more supervisory personnel, who do not have to be onsite employees, to be responsible for ensuring compliance with each farm's SE prevention measures.

(Comment 38) One comment expressed concern about the burden small producers may experience in complying with the proposed requirement that at least one individual at each farm must successfully complete standardized FDA-curriculum or equivalent training of up to 2 to 3 days on SE prevention measures for egg production. The comment requested that FDA consider developing a training program that could be implemented without requiring travel from the egg operation. Further, the comment requested that FDA not impose deadlines for such training that could be difficult for such small producers to meet.

(Response) FDA plans to work with trade associations, State regulatory officials, and academia/extension officials to develop and offer training opportunities at venues that should satisfy the needs of small, medium, and large size facilities. Further, in the final rule, FDA has reduced the burden of the training requirement by allowing one or more supervisory personnel to serve as the trained administrator for all of the firm's facilities rather than requiring a dedicated, trained individual at each facility. FDA believes this will substantially reduce the burden for small producers to comply. Finally, FDA notes that the rule provides that equivalent job experience can be substituted for training.

J. Comments on ''Recordkeeping Requirements for the Salmonella Enteritidis (SE) Prevention Measures'' (Proposed and Final § 118.10)

(Comment 39) In the proposed rule, FDA proposed certain recordkeeping requirements and solicited comments on whether additional recordkeeping measures should be required for a comprehensive SE prevention plan, and whether a written SE prevention plan should be required. Several comments supported the proposed recordkeeping requirements but did not comment on expanding them; one comment stated that there is no need for FDA to expand its recordkeeping requirements beyond those proposed. In addition, several comments supported expanding the proposed recordkeeping requirements to include a written SE prevention plan and records for compliance with SE prevention measures. Several comments noted that such records have been very useful in conducting inspections of facilities to determine compliance with the egg quality assurance program requirements and for identifying problems in the producer's SE prevention plan when a test is positive. Another comment stated that records documenting compliance with all aspects of the SE prevention plan will be essential for a producer to determine if their plan is effective and in making adjustments to improve their plan. One comment opposed the requirement of a written SE prevention plan, stating that while a written plan would undoubtedly be an important management tool, and indeed many operations have such a plan, it is not necessary for FDA to mandate such a document. The comment stated FDA should not place undue emphasis on paperwork, as opposed to actual results. The comment suggested that FDA work with interested parties to develop a model SE prevention plan that could be provided to egg producers for their use.

(Response) FDA agrees with the comments that the final rule should require a written SE prevention plan as well as records to document the effective implementation of that plan. This written SE prevention plan will set forth a producer's plan to implement the regulation's prevention, testing, and diversion measures. A written plan is necessary for producers to ensure that they have effectively and consistently implemented SE prevention measures. Further, a written plan greatly facilitates FDA inspection. SE prevention measures may be quite different among farms, given different facility design and size, and yet be equally effective in preventing SE contamination. Knowledge of the specific prevention measures taken on a farm, as discussed in an SE prevention plan, will assist FDA to assess compliance with the prevention measures.

In addition, reviewing records of implementation of a facility's specific SE prevention measures is the best mechanism for FDA to use to determine whether preventive measures have been implemented over a period of time. These required documents include records of implementation and compliance with all SE prevention measures. Such documents, for example, would include documents that pullets were SE monitored or raised under SE monitored conditions, records of SE environmental and egg testing, and records of activities required by the rule, such as treatment or diversion of eggs, as well as records indicating review of the plan and any changes or modifications made to the plan. Keeping careful written records will help producers ensure that they have effectively and consistently implemented SE prevention measures and will also assist FDA in determining whether the plan is being followed and in identifying problems in the producer's plan when a test is positive. If changes or modifications need to be made, recording such changes or modifications will help ensure such changes are implemented.

Therefore, under § 118.10, FDA is requiring that egg producers covered by all of the requirements in the rule (§ 118.1(a)(1)) maintain the following records documenting their SE prevention measures: (1) A written SE prevention plan; (2) documentation that pullets were ''SE-monitored'' or were raised under ''SE-monitored'' conditions, including environmental testing records for pullets; (3) records documenting compliance with the SE prevention measures; and (4) records of review and of modifications of the SE prevention plan and corrective actions taken. FDA intends to issue guidance regarding the recordkeeping requirement.

(Comment 40) Two comments stated that FDA should require purchasers of diverted eggs (e.g., egg breaking facilities, shell pasteurization facilities, hard-cooked operations, or other facilities where the eggs could be treated) to maintain records indicating that the diverted eggs have been treated. These comments, submitted by an agricultural department and poultry and livestock commission of two major shell egg producing states, argued that without records there would be no

ability to ensure the purchaser would treat the eggs and not simply divert them back to the table egg market.

(Response) FDA agrees with the comments' concern that purchasers of diverted eggs might resell them for the table egg market without treating them and that buyers might not know that the eggs must receive a treatment. To address this concern, FDA has modified this final rule by adding § 118.6(f), which requires that when shell egg producers divert eggs, the pallet, case, or other shipping container must be labeled and all documents accompanying the shipment must contain the following statement: ''Federal law requires that these eggs must be treated to achieve at least a 5-log destruction of *Salmonella* Enteritidis or processed as egg products in accordance with the Egg Products Inspection Act, 21 CFR 118.6(f).'' The statement must be legible and conspicuous. FDA believes this additional requirement will help reduce the likelihood that these eggs will end up on the market without having been treated. We note that USDA–FSIS, not FDA, regulates egg-breaking facilities under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

The costs and benefits of this provision are addressed in section V of this document, Regulatory Impact Analysis.

(Comment 41) One comment questioned the proposed rule to the extent it did not require an SE prevention plan until a producer has a positive environmental test. The comment stated that this delay increases the risk of producing SE-positive eggs that are distributed into the table egg market prior to the test and increases the difficulty of the producer reducing or eliminating SE from the environment and the flock.

(Response) The assertion in the comment that the proposed rule did not require an SE prevention plan until a producer has a positive environmental test is incorrect. Neither the proposed nor final rules make having an SE prevention plan contingent upon a positive environmental test.

(Comment 42) One comment commended FDA's statement that ''we intend to consider records that come into our possession under this rule as generally meeting the definition of a trade secret or commercial confidential materials'' (69 FR 56824 at 56841). However, the comment requested that FDA identify in the final rule what information will be considered confidential commercial information (CCI) or a trade secret, and under what legal authority FDA will defend this designation against any legal challenges.

(Response) FDA's regulations in 21 CFR part 20 govern the disclosure of information under the Freedom of Information Act (FOIA), including the disclosure of CCI and trade section information. The agency's general policies, procedures, and practices relating to the protection of confidential information received from third parties apply to information received under this rule. It is not necessary that FDA designate information upfront as CCI or trade secret because these determinations can be made before releasing any information. If FDA denies a request under FOIA, it will rely on the provisions in that statute which permit the agency to withhold information.

(Comment 43) One comment questioned FDA's assertion that section 361 of the PHS Act (42 U.S.C. 264) gives it legal authority to inspect records. The comment argued that FDA's reliance upon section 361 of the PHS Act is misplaced and cannot be used to impose records inspection on food establishments where, according to the comment, such inspection is not allowed under section 704(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 374(a)).

(Response) In the final rule, FDA relies on sections 402(a)(4) and 701(a) of the FFDCA (21 U.S.C. 342(a)(4) and 371(a)) and sections 311, 361, and 368 of the PHS Act (42 U.S.C. 243, 264, and 271) to require access to certain records. FDA does not rely on section 704(a) of the FFDCA for authority to access records in this rule. Furthermore, the PHS Act provides authority for records access that is independent of the FFDCA. Specifically, section 361 of the PHS Act authorizes the Secretary of Health and Human Services (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.'' The basis for the recordkeeping requirements in the final rule is further explained in section IV of this document, Legal Authority.

(Comment 44) One comment encouraged FDA to incorporate an automated recordkeeping requirement into the proposed rule. The comment stated that an automated system would enhance and support the recordkeeping requirements outlined in the proposed rule. The comment argued that such a system could provide farm-specific data, and an efficient, cost-effective way to research compliance. The comment stated that an automated system would greatly reduce the recordkeeping burden placed upon egg producers as well as the time, frequency, and cost associated with FDA inspections.

(Response) FDA believes that the least burdensome way of implementing the recordkeeping requirements is to specify the information that must be contained in the records, but not the format in which the records are kept. Automated technology may not be available or within the means of all producers covered by the rule. We note that egg producers may choose to use automated recordkeeping as long as they maintain all of the required records.

K. Comments on Registration Requirements for Shell Egg Producers (Final § 118.11)

(Comment 45) In the proposed rule (69 FR 56841 at 56841 through 56842), FDA solicited comments about whether we should require that shell egg producers register with FDA. Several comments supported requiring registrations by egg producers covered by the SE prevention measures. These comments stated that registration of all producers covered by any of the SE prevention measures would be the most efficient method of obtaining the information needed to conduct annual inspections and allocate resources.

Further, several comments stated that such a requirement should be consistent with the program developed under the agency's bioterrorism regulations. The comments further stated that by identifying each farm's location and size, a registration requirement would enable more efficient inspection, as well as better management and oversight of a shell egg recall.

One comment stated that, to create a level playing field across the United States, registering all producers is necessary and that FDA may be able to cooperate with USDA/APHIS, which is presently developing a premises identification program for all animal premises in the United States.

(Response) FDA agrees with the comments and is requiring that egg producers who must comply with all of the SE prevention measures in this rule, and also those producers who must comply only with the refrigeration requirements in this rule, register with FDA and provide information on the name of each farm, its location, layer capacity, and the number of houses. Persons who transport or hold shell eggs for shell egg processing or egg products facilities but who are not egg producers are not required to register with FDA, although they are subject to the refrigeration requirements in § 118.4.

FDA intends to conduct inspections of egg farms 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. We will use the producer registration information to create a database used to efficiently conduct inspections and allocate inspection resources. Covered egg producers must register within 30 days of becoming an egg producer or, if already an egg producer, by the applicable effective date of the rule. Additionally, registered egg producers are required to notify FDA within 120 days of ceasing egg production (excluding seasonal egg producers or those who temporarily cease operation due to labor disputes, fire, natural disasters, or other temporary conditions).

Producers can register online via the Internet, by completing a paper form and mailing or faxing it to FDA, or by sending a CD–ROM containing the relevant registration information to FDA. If ceasing egg production, producers can notify FDA either online via the Internet or by completing a paper form and mailing or faxing it to FDA.

(Comment 46) One comment objected to requiring producers who pack eggs to register, stating that every producer with packing facilities is registered with the FDA under the registration rule and should not be required to register a second time. The comment agreed that producers that do not pack eggs, but sell eggs that will ultimately go into the table egg market, should be registered so that FDA can ensure these firms are following the on-farm production and testing requirements of the SE rule.

(Response) Farms are not required to register under FDA's Registration of Food Facilities regulation (21 CFR 1.226(b)). If a farm also has a packing or processing facility, then only the packing or processing facility is required to register under the registration rule if those packing and processing activities do not qualify under the farm exemption (see ''farm'' definition for activities that are covered in the farm exclusion under 21 CFR 1.227(b)(3)). Because the packing/processing facility registration information may not fully identify the farm location, FDA is requiring that information in this regulation. If the information that would be provided by an egg producer during registration has already been provided under the registration regulation, the producer may submit its registration number rather than registering again.

(Comment 47) One comment objected to the proposed registration requirement as an unnecessary burden and an unreasonable invasion of privacy. The comment argued that FDA only should check for compliance. The comment further argued that ''unexpected visits are not appropriate as a respect for other people and the reality is that no one can hide what you want to see in 24 hours.'' The comment further argued that registration will result in a loss of privacy for the producer and is unnecessary for the success of the program.

(Response) FDA disagrees with this comment. As stated above, registration will aid in the identification of egg producers for inspection and compliance purposes. We will use the producer registration information to create a database that we will use to efficiently conduct inspections and allocate inspection resources. With regard to ''unexpected visits,'' section 704 of the FFDCA (21 U.S.C. 374) authorizes FDA inspections without advance notice and FDA's practice of making such inspections precedes this rule and is independent of whether registration is required.

(Comment 48) One comment expressed concern that information submitted to register facilities would be subject to the Federal Freedom of Information Act (5 U.S.C. 552), and that public release of this information could result in a decrease of security at the producer sites. The comment stated that FDA has other means at its disposal to learn the site information needed to administer this program and still respect the need for security at the producer sites.

(Response) FDA recognizes that this information may be subject to disclosure under FOIA, unless there is statutory authority there or elsewhere that protects it. However, we disagree that the risk of such disclosure outweighs the public health benefits of collecting this information. As stated previously, registration will facilitate FDA's identification of egg producers for inspection and compliance purposes. We will use the producer registration information to create a database that we will use to efficiently conduct inspections and allocate inspection resources.

L. Comments on ''Enforcement and Compliance'' (Proposed and Final § 118.12)

There were no comments on this section.

M. Comments on Request for Comments as to Whether FDA Should Mandate Special Requirements for Food Establishments That Specifically Serve Highly Susceptible Populations

(Comment 49) We received a number of responses to our request in the proposed rule for comments on whether the current FDA Food Code system (under which states may adopt and implement provisions of the FDA Food Code) is adequate to protect highly susceptible populations from salmonellosis, or whether instead we should establish mandatory Federal standards for food establishments that serve eggs to highly susceptible populations, such as the elderly. Several of these comments supported the Federal codification of the egg-related Food Code provisions for food establishments specifically serving highly susceptible populations, and one comment opposed codification.

One comment supporting codification stated that egg producers do not have full control or responsibility for egg safety, and that food establishments and consumers must share in the responsibility for egg safety. The comment opposed to setting Federal standards stated that the egg safety goal cannot be achieved through mandatory Federal requirements at the food establishment level. The comment recommended continuing mandatory on-farm efforts while continuing educational efforts at retail and consumer levels.

(Response) FDA agrees that food establishments that specifically serve highly susceptible populations can play an important role in egg safety As we discussed in section I.H., a majority of states and territories have adopted into their own retail food codes the relevant egg-associated provisions of the FDA Food Code (sections 3–202.11(C), 3–202.13, 3–202.14(A), and 3–801.11(B)(1) and (B)(2), (C)(2), (E), and (F)(1) and (F)(2) of FDA's 2005 Food Code (see discussion under section I.H of this document regarding the changes made from the 2001 Food Code)). In addition, other state, local, Federal, or voluntary standards applicable to these facilities may have similar egg safety provisions, although we were not able to identify or quantify all such standards. We agree with the comment that encouraged us to continue education efforts at the retail and consumer levels. We also agree that codification of the FDA Food Code provisions is not a necessary exercise of our authority. Instead, we have determined that we will continue to encourage states to adopt the relevant provisions of the FDA Food Code.

(Comment 50) One comment suggested that we make mandatory those parts of the Food Code related to the pooling of eggs in all institutions, including but not limited to those serving specifically at-risk populations in section 3–8 of the Food Code. The comment stated that many of the large outbreaks have been related to commercial or government institutions that misuse eggs, especially when they break and pool large numbers of eggs. The comment stated that even if the eggs are delivered SE-free, the hand breaking and pooling of eggs can result in a contaminated pool due to inadequate hand washing, unclean utensils, temperature abuse during the breaking process and cross-contamination from other raw foods. The comment also stated that the FDA Food Code should be modified to incorporate a requirement that pasteurized egg products be substituted for shell eggs if the eggs are to be pooled, as a model for States to follow.

(Response) FDA has determined that the relevant egg safety provisions of the Food Code should not be mandatory, for the reasons discussed in the preceding response, including those provisions related to the pooling of eggs.

The comment concerning modification of the FDA Food Code is beyond the scope of this rule.

IV. Legal Authority

As outlined in section II.B of this document, after considering comments received in response to the proposal, FDA made changes in the final rule, including the addition of some requirements. The proposed rule contained an explanation of its legal basis under authorities in sections 311, 361, and 368 of the PHS Act (42 U.S.C. 243, 264, and 271) and sections 402(a)(4) and 701(a) of the FFDCA (21 U.S.C. 342(a)(4) and 371(a)). 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). This authority has been delegated to the Commissioner of Food and Drugs. Under section 402(a)(4) of the FFDCA, a food is adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. Under section 701(a) of the FFDCA, FDA is authorized to issue regulations for the efficient enforcement of the FFDCA. These authorities, as well as others specified in the following paragraphs, support the new requirements in the final rule.

Section 118.4(e) requires that persons who transport or hold shell eggs for shell egg processing or egg products facilities must comply with refrigeration requirements. It is well documented that shell eggs may contain *Salmonella,* including transovarian transmitted SE, which can result in serious, life-threatening illness. Temperature abuse of shell eggs, such as by failing to refrigerate eggs as required by the rule, can lead to the multiplication of SE in shell eggs, and thus, increase the likelihood of illness if the eggs are not thoroughly cooked. The refrigeration requirement in § 118.4(e) prohibits food from being held under insanitary conditions and allows for the efficient enforcement of the FFDCA (21 U.S.C. 342(a)(4) and 371(a)). Further, this requirement is necessary to prevent the spread of communicable disease from one state into another state. (42 U.S.C. 264).

Section 118.10 requires that egg producers have written SE prevention plans and maintain records documenting compliance, as well as records of review and modification to the plan and any corrective actions taken. Through records maintenance and review, an egg producer can, over time, develop a comprehensive picture of its prevention measures and identify shortcomings or potential shortcomings. A written plan and records documenting implementation of that plan are necessary for producers to ensure that they have effectively and consistently implemented the plan. For example, without records documenting environmental sampling procedures, a producer cannot ensure that the environment was sampled using a plan appropriate to the poultry house layout.

Similarly, records maintenance and access provide FDA with the opportunity to oversee, in a comprehensive way, the implementation of the producer's SE prevention plan, thereby preventing SE contamination of eggs. SE prevention measures may be quite different among farms, given different facility design and size, and yet be equally effective in preventing SE contamination. Knowledge of the specific prevention measures taken on a farm, as specified in an SE prevention plan, will assist FDA to assess compliance with the prevention measures. In addition, reviewing records is the best mechanism for FDA to use to determine whether preventive measures have been implemented over a period of time. Because the preventive measures are essential to the production of safe eggs as a matter of design, the statutory scheme is benefited by agency access to records that demonstrate that these measures are being systematically applied.

By requiring records, we will be able to ensure that producers follow the SE prevention measures so that eggs are prepared, packed and held under sanitary conditions (21 U.S.C. 342(a)(4) and 371(a)) and in a manner designed to prevent the spread of communicable disease via SE-contaminated eggs (42 U.S.C. 264).

Section 118.11 requires registration by egg producers who must comply with either all of the SE prevention measures or only with the refrigeration requirements. It is essential that we know, via registration, certain information about egg producers, such as whether a producer has 3,000 or more laying hens at a particular farm, so that we can identify and inspect those farms subject to the rule. Inspection is necessary to ensure that shell eggs are being produced in compliance with SE prevention measures, thereby reducing the likelihood of foodborne illness. Therefore, the registration requirement is necessary to prevent the spread of communicable disease from one state into another state. (42 U.S.C. 264).

Section 118.6(f) requires that for diverted eggs, the pallet, case, or other shipping container must be labeled and all documents accompanying the shipment must contain the specified statement to indicate that the eggs must be treated to destroy SE. This requirement is supported by sections 201(n), 403(a)(1), and 701(a) of the FFDCA (21 U.S.C. 321(n), 343(a)(1), and 371(a)) and sections 311, 361, and 361 of the PHS Act. Under section 403(a)(1) of the FFDCA, a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the FFDCA provides that in determining whether labeling is misleading, the agency shall take into account not only representations made about the product, but also the extent to which the labeling fails to reveal facts that are material in light of such representations made or suggested in the labeling or material with respect to consequences that may result from use of the product under conditions of use prescribed in the labeling or under customary or usual conditions of use. FDA previously has relied on these authorities when it required label statements on shell eggs not processed to destroy all viable *Salmonella* (65 FR 76092, December 5, 2000).

The rule requires eggs to be diverted in certain circumstances, including after a positive egg test, to ensure that SE will

be destroyed before the eggs are consumed. Without treatment, these eggs would present the greatest risk of causing SE illnesses. As discussed in section V of this document, the eggs that must be diverted to a treatment are worth less than eggs that may be used for the table egg market. This creates an economic incentive to send the eggs to the table egg market. Further, without labeling, a purchaser might not know that particular eggs are subject to the diversion requirement. Therefore, the agency concludes that information that the eggs must be treated to destroy SE is material information that must be provided on the shipping container and accompanying documentation and that the requirement is necessary to prevent the spread of communicable disease from one state into another state. (42 U.S.C. 264).

As explained in the proposal, activities that are intrastate in character, such as the production and final sale of shell eggs to an institution for ultimate consumption by a consumer within one State, are subject to regulation under section 361 of the PHS Act (*State of Louisiana* v. *Mathews,* 427 F. Supp. 174, 176 (E.D.La. 1977)). The proposed rule explained FDA's reasoning for tentatively determining that the SE prevention measures in this rule must apply to producers of shell eggs who sell their eggs intrastate, other than directly to consumers. For the reasons discussed therein, we are making that determination final.

V. Analysis of Economic Impacts—Final Regulatory Impact Analysis

A. Introduction

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 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). The agency believes that this final rule is an ''economically significant'' regulatory action as defined by Section 3(f)(1) of the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Using the Small Business Administration (SBA) definitions of small for chicken and egg producers, FDA estimates that more than 99 percent of all egg farms are small. Though more than 45,000 farms with less than 3,000 layers are exempt from all provisions of the rule, the agency certifies that the rule will have a significant economic impact on a substantial number of small entities. This is discussed further in section VI of this document.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before finalizing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. FDA expects this final rule to result in 1-year expenditures that would meet or exceed this amount. This is discussed further in section VII of this document.

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 sufficient 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, although farmers and producers do have an incentive to put safety programs into place, the lack of awareness and information about the risk suggests that an inefficiently high demand exists for eggs that are produced without using adequate measures to prevent SE.[2] Because the demand for specific 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, since the particular source of the SE contamination of the eggs is not known in many circumstances.

In sum, the imperfect information about the risk associated with SE from particular shell eggs means that neither the legal system nor the marketplace may be able to provide adequate economic incentives for the production of eggs sufficiently free of SE contamination. 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 rule and comments addressing the benefits and costs of options presented 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 this final rule.

C. Comments on the Preliminary Regulatory Impact Analysis in the Proposed Rule and Responses

(Comment 51) One comment agreed that FDA should exempt small producers generally from the final rule, but suggested that the proposed testing and diversion requirements should apply to all egg producers, regardless of size. The comment argued that testing of the environment and shell eggs provides verification that on-farm sanitation programs are effective in controlling SE and allows for preventive measures including diversion if a positive test occurs, which could prevent illnesses and outbreaks. The comment suggested that imposing testing and diversion requirements on small producers would limit the burden on these small businesses without reducing the public health benefit from the final regulation.

(Response) Some benefits would be derived by requiring farms with less than 3,000 layers to divert potentially positive eggs upon both a positive environmental and a positive egg test.

[2] For example, although many consumers may be generally aware of the association between shell eggs and SE, they may not know that a few common methods of preparing eggs for consumption will not eliminate SE in a contaminated egg.

However, the cost per case averted on farms with less than 3,000 layers, producing less than 1 percent of the shell eggs on the market (accounting for 300 to 1,000 SE-related illnesses per year and less than 1 death per year), is approximately $205,000 per case averted, which would not be a cost-effective public health intervention on over 45,000 very small egg farms.

(Comment 52) One comment noted that, over the last several years, numerous shell egg production facilities in the United States were built to produce eggs only for processing into egg products; these facilities may divert eggs for sale as table eggs when market conditions or seasonal production patterns warrant. The comment stated that this diversion is done when demand for egg products is weak and the producer can avoid or minimize potential economic loss by moving temporary surpluses to the table egg market. The comment stated that, although under the proposed rule producers whose entire production will be processed into egg products need comply only with the refrigeration requirements for on-farm storage, these producers who may divert their eggs to the table egg market must comply with all of the egg production requirements when any part of their production is not processed into egg products or does not receive a treatment that achieves at least a 5-log destruction of SE. The comment stated that, while many firms that produce shell eggs for use primarily in the manufacture of egg products now have extensive on-farm programs to ensure the safety of eggs and egg products, some of these producers will need to impose additional food safety measures at the production site in order to be able to continue to occasionally divert eggs to the table egg market. The comment questions whether the agency considered these expenditures in determining total costs of the proposed rule on the egg industry.

(Response) Those farms that produce only a portion of their eggs for sale on the table egg market have been covered within the scope of this rule and their costs are included in the costs and the benefits analysis of the final rule.

(Comment 53) One comment states that the requirement that eggs be refrigerated at a temperature of no greater than 45 °F within 36 hours of laying is not realistic. The comment recommended instead that the rule require that eggs held at the farm be refrigerated at a temperature no greater than 55 degrees, provided the eggs are not to be stored on the farm for more than 4 days. The comment states that eggs are generally held in on-farm coolers for a relatively short period of time; that there is evidence that any low level of SE within a naturally infected egg will not undergo significant multiplication until the albumen begins to degrade; and that, even at room temperature, significant growth may take several weeks. The comment stated that the cost involved in remodeling and operating on-farm coolers to maintain a 45-degree ambient temperature, rather than a 55-degree ambient temperature, would not show a reasonable cost/benefit ratio.

(Response) Not all farms will need to remodel their on farm coolers to maintain a 45-degree ambient temperature. However, many will, and the costs associated with that remodeling are significant. In the analysis detailed in section V.F of this document, FDA estimates annualized costs for farms that build cooling facilities from scratch, remodel existing cooling facilities, use extra power to reduce temperature, use refrigerated shipping, and use refrigerated preproduction storage, to be $20.1 million using a 7 percent discount rate and $16.4 million using a 3 percent discount rate. Using the 2005 FSIS risk assessment (Ref. 22), FDA estimated that the refrigeration at 45 degrees within 36 hours of lay through the preproduction stage, in the absence of the other provisions in the final rule, would reduce the number of annual SE related illnesses by nearly 45,000. With all provisions in the final rule fully implemented, refrigeration would reduce the number of SE related illnesses by nearly 29,000. Including all costs of egg-related SE illnesses (i.e., both mild cases and the less frequent though more severe ones including hospitalization, chronic arthritis, or even death), FDA estimated the average cost of an SE illness to be $17,900. This provision, when implemented with the rest of the final rule, is estimated to provide nearly $520 million in benefits annually and nearly $500 million in annual net benefits.

(Comment 54) One comment stated that, for environmental testing, consideration should be given to the sampling of a given proportion of available sites as opposed to a given number of samples regardless of the size of the flock or the number of houses. The comment stated that a farm may have a single age group in more than one house.

(Response) This comment reflects a misunderstanding of the proposal. Sampling is performed on a per house basis. Section 118.7(a) requires that 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 sampling plan appropriate to the poultry house layout. We agree that sites/houses are the appropriate sampling location. Costs and benefits of environmental sampling are calculated on a per house basis.

(Comment 55) Several comments stated that breaker eggs will sell for a lower price than table eggs, that diversion costs will vary by region, and that breaker eggs from SE-positive flocks will sell for even less than normal breaker eggs. One comment stated that the cost estimated for normal breaker eggs is underestimated in the analysis of the proposed rule. Data were provided to support the comment. One comment stated that processors are likely to refuse eggs from SE-positive flocks.

(Response) We agree with the comments and recognize differences exist regionally in the price received for eggs, in the price of breaker eggs, and in the price of eggs from SE-positive flocks. All of these costs, including regional differences in diversion costs, and the adverse effects of bad publicity, are discussed in the analysis. The additional data the comment provides are considered in the final rule. The expected cost of a diverted egg has increased in the new analysis to $0.23 per dozen eggs (drawn from a uniform range of $0.13 to $0.33 per dozen eggs) from the proposed rule's estimate of $0.17 per dozen (drawn from a uniform range of $0.13 to $0.21 per dozen). The analysis and new results are detailed in table 22 and section V.F of this document.

FDA does not agree with the comment that processors will refuse eggs from positive flocks. FDA is aware of at least one processor that will purchase eggs from SE-positive flocks, and FDA believes others will as well because the pasteurization process for breaker eggs is designed to achieve at least a 5-log reduction in any SE that may be in eggs. However, because of the restrictions placed on eggs from SE-positive flocks, these eggs are intrinsically less valuable than normal shell eggs. This decrease in value, and cost burden likely to be transferred from egg processor to producer through a discount on eggs purchased from SE-positive flocks, is considered a cost of this rulemaking and is accounted for in the analysis and detailed in section V.F of this document.

(Comment 56) One comment stated that, to replace diverted eggs for a farm's existing markets, other eggs would need to be purchased, probably at an inflated price.

(Response) Although FDA recognizes this effect is possible in the rulemaking, it is a within-industry transfer of burden and is not counted as a cost in the analysis (the costs net out between producers).

(Comment 57) One comment questioned the presumed number of houses on the ''larger than 3,000 hens'' farms, although the comment recognized that the number was estimated using the National Animal Health Monitoring System (NAHMS) study.

(Response) The number of houses was estimated using the best data available, which the comment correctly identified as the NAHMS study.

(Comment 58) One comment stated that all cost calculations are broken down by house capacities. Results are applied to each size category with no acknowledgement that within each category, considerable variation still exists.

(Response) FDA agrees. There will be considerable variation of costs within groups. Costs in most cases will be smaller than average for the smaller than average farms within a size category and larger than average for larger than average farms. For rodent and other pest control, within group variation from the mean estimation is due to uncertainty about the extent to which current farm practices are adequate to meet the rule's requirements and costs of inputs, and due to variation in the number of houses. The variation is driven by the number of houses on a farm, so larger farms within a given size category will incur higher costs. The same is true for the biosecurity and cleaning and disinfecting provisions. Within group variation for the refrigeration provision is driven primarily by the variance in egg production and compliance. Farms that produce more eggs will require the construction of larger and more costly egg rooms than average. For testing and diversion, the within group variation is driven by the number of houses and egg production. Farms with more houses will have higher environmental testing costs, and farms with higher egg production per house will have a higher cost of diversion.

(Comment 59) Several comments stated that the cost of testing eggs is underestimated in the proposed rule analysis. One comment noted that, although in the proposal FDA estimated lab costs at $30, the pilot project lab cost relied on in developing that estimate were for direct plating from the egg pool onto two plates, not for the testing proposed of one pre-enrichment followed by two enrichments followed by five plates for each enrichment broth and then inoculation onto two differential media.

One comment stated that there would be start up costs for new labs entering the market due to increased demand for testing as a result of the rule.

(Response) FDA agrees that the costs estimated in the proposed rule analysis refer to the costs of the testing regime outlined in the pilot project, a less intensive regime than the one required in the proposed and final rules. These cost estimates have been corrected in the analysis of the final rule. A detailed description of the analysis is located in section V.F of this document.

We do not include start up costs for labs that enter the market or increase capacity due to increased testing demand as a result of the rule. The lab fees are set up by these firms to cover both the initial set up costs and the costs of each test. Counting these costs in addition to lab fees charged to egg producers would be double counting.

D. 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 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.F of this document, we summarize the benefits and costs of the rule and regulatory options. In section V.G of this document, we present the detailed analysis of SE prevention measures we considered (including both those included and not included in the final rule).

1. Measuring Benefits

a. *Modeling benefits.* The primary benefit of the provisions in this 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 × % risk reduced (C1, C2, C3, * * *) × value of risk reduced*

Where:

- Benefits = annual health benefits realized due to this rule.
- Base line risk = the base line level of risk facing consumers today, expressed as the number of SE cases attributable to shell eggs consumption
- Risk reduced (C1, C2, C3, * * *) = the % of risk reduced from the baseline due to changes in production (C1, C2, C3, * * *)
- Value of risk reduced = 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 risk reduced component of the benefits equation in a general functional form rather than an additive form because combinations of the rule's components (C1, C2, C3, * * *) 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.[3] 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 Centers for Disease Control and Prevention (CDC) passive surveillance system recorded 6,740 illnesses due to SE in 2006. Using the CDC multiplier (used to estimate total cases based on ratio of total to reported cases) derived by Voetsch, et al. (Ref. 5) of 38 (with a 90 percent confidence interval of 23 to 61), we estimated the number of illnesses due to SE to have been 256,120 in 2006 (ranging between 155,020 and 411,140).[4] Because SE is not unique to eggs, not all of the 256,120 illnesses due to SE in 2006 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 215,140 (ranging between 130,220 and 345,360). Between 1985 and 2002, a total of 53 percent of all SE illnesses identified through CDC 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 (Ref. 17). The midpoint between the lower bound (53 percent) and upper

[3] 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.

[4] All data for the calculations in this paragraph and the following paragraph are from Meade (Ref. 6) and CDC (Refs. 8, 11, 15, and 56).

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 69,020 (53 percent × 130,220) and an upper bound estimate of 218,260 (79 percent × 345,360) cases due to SE in eggs. The CDC method generates a mean point estimate of 141,990 (66 percent × 215,140) cases for 2006.[5] Table 1 of this document illustrates how we arrived at our base line.

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

	Low estimate	Mean	High estimate
2006 Passive Surveillance Cases		6,740	
Multiplier	23	38	61
Estimated SE Cases in 2006	155,020	256,120	411,140
Cases from Outside the United States		−16%	
	130,220	215,140	345,360
Percent of SE cases from eggs	53%	66%	79%
Egg Related SE cases in 2006	69,020	141,990	272,830

c. *Measuring the health benefits from preventing salmonellosis.*

i. *The economic impact of illness from SE in eggs.* In measuring the economic impact of illness due to the consumption of SE-contaminated eggs, it is important that we include all of the effects of SE on human health. These effects include both monetary and nonmonetary losses and are both acute and chronic in nature.

ii. *The consequences of SE illness.* We outline the consequences of SE illnesses in table 2 of this document. Table 2 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]

The acute illness that accompanies SE generally causes gastrointestinal symptoms, which might be mild. However, SE infections can be severe and result in death, especially for the elderly, immunocompromised, and children (Ref. 58). Finally, a small percentage of all SE infections result in chronic reactive arthritis (Ref. 4).

TABLE 2—CONSEQUENCES OF SE 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	1.3
Long-term	Chronic arthritis	365	2.4
Death	Death		0.04

We classify the gastrointestinal illness caused by SE illness as 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.

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. 15). 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. 6). Based on this we can calculate that the remaining 90.7 percent of gastrointestinal illness cases occur without a visit to the doctor; that is, they 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.

[5] In the proposed rule, we adjusted the estimated number of cases downward to account for the projected effects of the refrigeration and labeling rule. After that rule took effect in 2001, the estimated number of SE illnesses in the United States in 2002 decreased by nearly 9 percent. However, since then the rate has remained relatively steady, implying that at least the short term effects of the refrigeration and labeling rule have been realized. We therefore do not adjust for the effects of the refrigeration and labeling rule in this final rule.

[6] We use recent data from CDC to estimate the relative prevalence of illnesses of different severities (Ref. 57). The expected duration of illness for each category of severity is taken from Zorn and Klontz (Ref. 4).

Studies of outbreaks imply that short-term reactive arthritis may last from 1 day to a total of 121 days. Chronic reactive arthritis can last from the time of onset until death. Overall, we estimate that 1 to 10 percent of SE infections lead to some form of reactive arthritis. We expect two-thirds of these to be long-term and one-third to be short-term (Ref. 4).

The most severe potential result of SE infection is death. CDC estimated in 1999 that 553 deaths occur annually due to foodborne *Salmonella* (Ref. 6). The estimate suggests that about 0.04 percent (553 ÷ 1,340,000) of foodborne cases of *Salmonella* result in death.[7]

iii. *Quality adjusted life years (QALYs).* The benefits from this regulation will be presented in both monetary and nonmonetary terms. In section V.G 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.[8] QALYs range from 0 to 1 where 0 is equivalent to death and 1 is equivalent to perfect health for 1 year.

A number of methods have been constructed to measure QALYs. One class of methods uses surveys to ask doctors and the general population 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 published (Ref. 4). An alternative method used by Cutler and Richardson uses regression analysis to estimate the effect of particular conditions on overall health status (Ref. 59). In our analysis, we use both methods where appropriate.[9]

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 dividing the estimated number of QALYs lost by 365. Then, to calculate the disutility per day, or 1 QALD, we multiply 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 for 1 day. We report the loss in QALDs because most of the illnesses associated with SE 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. 4). 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 to 10.

TABLE 3—LOST QUALITY ADJUSTED LIFE DAYS DUE TO SE

Severity	Disutility per day (QALDs lost)				Total QALDs lost per illness
	Functional	Symptom	Total	Average days Ill	
Illness:					
Mild	0.44	0.08	0.053	2	1
Moderate	0.44	0.08	0.053	7	4
Severe	0.53	0.09	0.062	16	10
Reactive Arthritis:					
Short-term	.....	.....	0.22	25	5
Long-term	.....	.....	0.14	18,250	2,613

For reactive arthritis, we used the regression approach of Cutler and Richardson (Ref. 59). The regression approach yields estimates of losses per day of 0.22 for short-term reactive arthritis and 0.14 for long-term reactive arthritis. We estimate that short-term reactive arthritis results in a loss of 5.4 to 10.8 QALDs while long-term reactive 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. Because 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 reactive arthritis without using QALYs or some other measure of morbidity effects. Benefit 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.F 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. The first column of table 4 lists the type of ailment. The second and third columns of table 4 are taken from tables 2 and 3 of this document. The health loss per case is calculated by multiplying the value of a QALD by the

[7] CDC updated the estimate of the overall burden of salmonellosis in 2004. The rates of death for both salmonellosis and SE were estimated to be 0.03 percent, a decrease of one one-hundredth of a percent from the 1999 estimate. The rate of death may vary slightly from year to year. A decrease in the rate of death from SE by 0.01 percent would decrease the baseline mean estimated number of deaths related to consumption of eggs containing SE from 44 to 32. Mean estimated annual benefits would decrease by roughly $35 million.

[8] 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.

[9] 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. 60).

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 estimates of the value of a statistical life (VSL), the value of a QALY, and the discount rate. The fifth column of table 4 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 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. 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.

TABLE 4—VALUING OF A TYPICAL CASE OF SE[1, 2]

Type and severity	Case breakdown (percent)	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	$780
Moderate	8.1	3.68	3,025	92	250
Severe	1.2	9.99	8,208	9,257	210
Arthritis:					
Short-Term	1.26	5.41	4,442	139	60
Long-Term	2.40	2,613.12	592,411	9,536	14,460
Death	0.04	18,250.00	5,000,000	.....	2,140
Total expected loss per case	.....	.....	.....	.....	17,900

[1] The value of a typical case will actually vary widely depending on the values used for the VSL, QALY, and the discount rate. The figures presented here are based on VSL = $5 million, QALY = $300,000, 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 decedent 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. 58).[10] The figures they estimated include the lost productivity of workers due to salmonellosis. Because we account for 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. 58).

For medical costs for those who contract moderate illnesses, we use figures from Williams (Ref. 61) updated with medical cost indices. In 1996, the average total cost of treatment for a non-urgent 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 228.2 in 1996 to 323.8 in 2005 (Ref. 62).

The data for the medical cost of a severe case of SE was obtained from the Health Cost and Utilization Project's Nationwide Inpatient Sample (Ref. 63) and updated to 2005 constant dollars using the CPI. Medical costs due to reactive arthritis are based on Zorn and Klontz (Ref. 4). Zorn and Klontz estimated that short-term reactive arthritis medical costs were approximately $100 per case in 1998. We adjust these numbers to account for the increased cost of medical care since 1998. We estimate that long-term reactive arthritis costs had a present value of $5,370 in 1992.[11] We use the CPI for medical care in general to update this cost to current dollars. Between 1992 and 2005, the CPI for medical services rose from 190.1 to 323.8.

FDA uses a range to estimate the value of an additional year of life to reflect the uncertainty in the literature. As a low estimate, FDA uses $100,000 per QALY. Cutler and Richardson (Ref. 59) use a similar estimate, and Garber and Phelps (Ref. 64) 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. 65). 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. 66) 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 uses values of a statistical life of $5 million and $6.5 million. This range of VSL estimates is consistent with a reasonable interpretation of studies of willingness to pay to reduce mortality risks (Refs. 66 and 67). 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.

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

[11] 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.

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

TABLE 5—VALUE OF A TYPICAL CASE OF SALMONELLA ENTERITIDIS UNDER DIFFERENT ECONOMIC ASSUMPTIONS[1, 2, 3]

	Discount rate = 3 percent		Discount rate = 7 percent	
	VSL = $5 million	VSL = $6.5 million	VSL = $5 million	VSL = $6.5 million
VSLY = $100 thousand	$11,900	.....	$7,600	.....
VSLY = $300 thousand	30,400	31,000	17,900	18,500
VSLY = $500 thousand	.....	49,500	.....	28,800

[1] VSL means value of a statistical life.
[2] VSLY means value of a statistical life year.
[3] Values are only reported for most likely combinations. A VSLY of $100,000 is not consistent with a VSL of $6.5 million, and likewise, a VSLY of $500,000 is not consistent with a VSL of $5 million.

The expected value of a typical case of SE varies greatly depending on the estimates used. The lowest expected value for a case of SE, $7,600, occurs when we use a VSL of $5 million, QALY of $100,000, and a discount rate of 7 percent. The highest expected value for a case of SE, $49,500, occurs when we use a VSL of $6.5 million, a QALY of $500,000, and a discount rate of 3 percent. For purpose of this analysis, we have chosen to use $17,900 per case as a central estimate. This value corresponds to where the VSL is $5.0 million, a QALY is valued at $300,000, and the discount rate is 7 percent.

d. *Other benefits.* Pathogens other than SE have been associated with eggs. In particular, *Campylobacter* (Ref. 68) and non-SE *Salmonella* (Ref. 20) 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. 69). 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. 69).[12] Pathogen migration is unlikely given current USDA standards and industry practices.[13] Regarding egg breaking, current USDA washing and sanitizing standards are designed to reduce pathogens on the exterior of the egg. Consequently, we do not expect benefits from the reduction of illnesses due to pathogens other than SE to be large.

2. Measuring Costs

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[14] with respect to SE mitigation exist, we adjust the costs downward to account for the economies.[15]

3. Coverage of the Analysis

Two major sectors are affected by this rule: Farms that produce eggs for the retail markets and farms that raise pullets that become layers. We estimate costs and benefits of changing practices in each of these sectors separately.

We estimate costs and benefits of potential prevention measures for all farms that produce eggs for distribution in retail markets. Because the 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 measure the regulatory relief provided by the exemption for very small farms.[16] 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. Farmers 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 3,300 farm sites with roughly 7,400 poultry houses will be covered by some or all parts of the rule. These figures are calculated as follows:

- We use the National Agricultural Statistics Service (NASS) 2002 Census of Agriculture to determine the number of farm sites with layers on hand. NASS estimated that there are 98,315 farms with layers over 20 weeks old in their inventory (Ref. 71).
- Next, we adjust for the fact that a large portion of farms with fewer than 3,000 layers either sell their eggs directly to consumers or do not sell their eggs at all. We estimate that, of the approximately 94,300 farms with fewer than 3,000 layers,[17] over 48,600 of these farms sell their eggs, but not directly to consumers.[18]
- NASS data suggested that 83 percent of layers are table egg layers

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

[13] 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. 70).

[14] Economies of scope occur when more than one activity can be more efficiently performed at the same time, rather than one at a time.

[15] Where economies of scope with regard 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.

[16] A detailed breakdown of the estimated impact of each provision were they required for farms with less than 3,000 birds can be found in section VII of this document.

[17] 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.

[18] Based on assumptions that industry experts (Refs. 72, 73, and 74) validated as plausible, we have calculated that approximately 2,860 farms sell eggs via retail channels other than farmers markets, roadside stands, and neighborhood sales. Many of the remaining 91,400 very small farms sell their eggs to consumers indirectly at roadside stands or farmers markets (Ref. 71). In the absence of better information, we assume that half of those remaining 91,400 very small farms sell eggs indirectly to consumers.

(Ref. 75). For those farms with more than 3,000 layers, we adjust 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 category in table 6 of this document. We use data from the 1999 Table Egg Layer Management in the U.S. Survey (Refs. 27 and 28) to estimate the number of houses per farm site for those farms with more than 3,000 layers.[19] For those farms with fewer than 3,000 layers, we assume 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 RULE

Farm size (number of layers)	Adjusted number of farm sites	Number of houses per site	Total number of houses	Total number of eggs produced (in millions)
3,000 to 19,999	1,746	1.4	2,445	5,607
20,000 to 49,999	925	1.4	1,295	6,886
50,000 to 99,999	248	2.4	595	4,662
100,000 or more	409	7.4	3,024	54,958
Total potential coverage	3,328	2.2	7,359	72,113

We also estimate the costs and benefits of prevention measures on farms that raise pullets. Comments to the proposed rule stated that there are roughly one third as many pullets as there are layers at any given time. Further, there are roughly one third as many pullet houses as there are layer houses. FDA therefore estimates that 2,453 pullet houses (7,359 layer houses/3) will be covered under this provision.[20] Some of the pullet houses are located onsite at layer farms and others are located on pullet growing facilities.

E. Summary of Costs and Benefits of Regulatory Options and the Rule

In this section we summarize the costs and benefits of the rule and the regulatory options. In section V.F 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 final rule.

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 final rule, more extensive on-farm prevention measures, less extensive on-farm prevention measures, and the inclusion of mandatory food establishment prevention measures.

1. No New Regulatory Action

One possible alternative to the 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 by 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, to inform consumers, required safe handling instructions on all cases and cartons of shell eggs. 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. This program, although 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 preventing SE in their flocks. One of the first States to implement a structured quality assurance program was Pennsylvania. Though voluntary, the implementation of the PEQAP 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 rule (Ref. 76). 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 (Ref. 56). 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.

[19] 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, Veterinary Services, APHIS, USDA.

[20] Comments received on the number of pullet houses came primarily from large farm representatives. Farms with less than 3,000 layers are not covered by this provision, so the pullet houses from which they procure their layers will either not be covered (if they sell only to farms with less than 3,000 layers) or will be covered by virtue of selling to larger farms. Therefore, FDA uses the number of houses located on farms with 3,000 layers or more to calculate the number of pullet houses affected by the provision.

2. HACCP

We could, in theory, require that a HACCP system be implemented on layer farms. Although the general sanitation and hazard control measures in the rule are similar to aspects of existing HACCP programs in other areas, the agency has decided not to mandate HACCP on layer farms. To be effective, a HACCP system must be based on a foundation of prerequisite programs that provide basic environmental and operating conditions. Thus, to be technically and scientifically feasible for egg production, a HACCP system would require adoption of basic measures such as those required in this final rule, as well as several additional measures. Even if FDA were to provide less detail as to its expectations for compliance in the regulation and to require a HACCP plan rather than an SE prevention plan, these measures would certainly be required for producers to effectively prevent SE contamination of eggs.

Furthermore, we are not aware of any precedent for use of a HACCP approach on egg farms, either voluntarily developed by individual businesses or required by states, and we note that FDA did not receive any comment suggesting that it attempt to apply a HACCP approach to egg farms.

FDA considers that the level of scientific and technical knowledge needed to identify the range of possible hazards reasonably likely to occur and the critical control points needed for eliminating those hazards from shell eggs may not always be readily available on layer farms. Moreover, we believe that the HACCP plans that most layer farms would develop, if required to do so, would contain many if not all of the measures in this rule. We believe the targeted SE-prevention measures required by this final rule are as effective as any conceivable HACCP system, and avoid imposing on each layer farm the burden of developing scientific and technical knowledge required to develop an individualized HACCP system.

3. The Final Rule

The rule includes the following requirements for farms with 3,000 or more layers that do not have all of their eggs treated or do not sell all of their eggs directly to consumers: Rodent and other pest control, biosecurity, cleaning and disinfecting, use of SE-monitored chicks and pullets, testing and diversion, refrigeration during holding and transport, registration, and records with respect to compliance with each provision. Farms where all eggs are treated need only comply with the refrigeration requirements.

The benefits from the SE prevention measures in the rule would take time to be fully realized, but the costs would be more immediately incurred. Table 7 of this document shows the initial costs and benefits and the eventual costs and benefits following implementation of the rule.[21] Following are the detailed calculations underlying table 7, in section V.F. of this document.

TABLE 7—FINAL RULE ANNUAL COSTS AND BENEFITS

	Total costs (in millions)	Illnesses averted	Cost per illness averted	Total benefits (in millions)
Initially (first four years):[1]				
Discount Rate = 3%	$83	68,790	$1,200	$1,231
Discount Rate = 7%	88	68,790	1,300	1,231
Eventually (after four years):[1]				
Discount Rate = 3%	76	79,170	1,000	1,417
Discount Rate = 7%	81	79,170	1,000	1,417

[1] As explained in the detailed analysis in section V.F., some of the provisions, particularly rodent and pest control, will take up to 4 years to become fully effective. The effectiveness of the provisions affects the prevalence rate and thus affects both benefits and costs of each provision. Therefore, the costs and benefits are presented over two time frames: ''initially'' assuming an average effectiveness over the first 4 years, and ''eventually'' assuming full effectiveness after 4 years.

4. More Extensive On-Farm SE Prevention Measures

FDA could issue a rule that is broader in scope and has more extensive provisions including: (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 rule. Additional on-farm provisions include requiring the use of SE-negative feed and vaccinating flocks against SE.

Such extensive controls would lead to total eventual costs of $274.0 million per year and eventual expected number of illnesses averted of 80,777, per year. This approach increases costs by more than $175 million, while only increasing the number of illnesses averted by 556 cases (valued at a total of $10.0 million). These more extensive controls would result in a marginal cost-effectiveness of more than $315,000 per additional illness averted and a decrease in net benefits of over $100 million. 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 45,000) means that requiring them to comply with all provisions of the rule would greatly increase costs. These farms, however, account for less than 1 percent of egg production. 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 these farms. For these reasons, FDA has decided not to pursue this option.

5. Less Extensive On-Farm SE Prevention Measures

We could also require fewer controls than are in the rule. Several provisions could be combined to provide a less extensive set of controls than in the 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 of this document. As documented in table 28, the various individual measures would, by themselves, generate lower

[21] The discount 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 discount rate of 7 percent. Those interested in the total cost number reflecting a 3-percent discount rate should subtract roughly $5 million from the calculations performed with a 7-percent discount rate. The exact difference is shown in section F of this document.

net benefits than the integrated program outlined in the rule.

6. Include Mandatory Provisions Applicable to Food Service Establishment Serving Highly Susceptible Populations

We could require certain safe egg handling and preparation practices for food establishments that serve highly susceptible populations as part of custodial care, health care, assisted living, or nutritional or socialization services. These provisions would affect nearly 40,000 such establishments. In place with the other provisions of the final rule, the provisions pertaining to food service establishments serving a highly susceptible population would prevent 1,052 illnesses annually at a cost of $16,700 per illness and $1.2 million in annual net benefits (Ref. 77).

As we discussed in section I.G., a majority of states and territories have adopted into their own retail food codes the relevant egg-associated provisions of the FDA Food Code. With most states adopting as mandatory the relevant sections of the FDA Food Code (or similar safety standards), FDA believes it would be an unnecessary exercise of authority to codify the FDA Food Code. We will continue education efforts at the retail and consumer levels. Further, we will continue to encourage states to adopt the relevant provisions of the FDA Food Code.

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

In this section, we describe the SE prevention measures that we considered, including provisions that were not included as requirements or that were only required for certain producers in the rule.

For the costs and benefits of the provisions of the rule, we examine a number of on-farm measures including the following:

- Rodent and other pest control,
- Biosecurity measures,
- Cleaning and disinfecting of layer houses between flocks,
- Refrigeration of eggs,
- Layer house environmental testing,
- Follow-up egg testing,
- The diversion of SE-positive eggs,
- The use of SE monitored chicks or pullets, and
- Other provisions, including the use of SE negative feed, and vaccinating flocks against SE.

For each of these on-farm measures we estimate the costs of the following administrative measures: Registration, training, plan design, and recordkeeping.

1. On-Farm SE Prevention Measures

a. *Interdependence of on-farm measures.* Rodent and other 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 remove not only SE, but also rodents and pests.

This interdependence means that the total 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, when two practices substitute or complement one another, the efficacy of the first practice is affected by the introduction of a second. Throughout the analysis, results for benefits calculations are presented for each provision standing alone as well as in the presence of all other provisions. Therefore, a provision that occurs later in the production chain than a provision that has already reduced the prevalence of SE will have less of an impact on total illnesses averted than if that provision stood alone. The hierarchy of provisions (first in production chain to last) is as follows:

(1) Chicks and pullets procurement.

(2) Testing, cleaning, disinfection of chicks and pullets.

(3) Rodent control, biosecurity, cleaning and disinfection in layer houses.

(4) Testing and diversion in layers.

(5) Refrigeration.

Second, a simple comparison of farms that use one given practice with farms that do not use that practice is insufficient in measuring the effectiveness of that individual practice. 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 any one 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 lower prevalence of SE 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 prevention plan, which may have been put in place in areas because they had higher than average prevalence of SE. 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, administrative, and institutional SE prevention measures. The provisions that we considered are examined below. We have included some, but not all, of these provisions in the rule.

Marginal costs and benefits are calculated for farms with less than 3,000 layers, although these farms are exempt from the final rule. These results are presented in section VI of this document, where relief for small businesses is discussed.

The costs and benefits of the provisions of the final rule as written are summarized in table 34 in section V.G of this document.

c. *Control of rodents and other pests, biosecurity, and cleaning and disinfection.*—i. *Rodent and other pest control provisions.* One requirement of this final rule is that each layer house be under a pest control program. Such a program could include the use of traps or poisons to reduce rodents and other pests. Each farm must have a written control plan for rodents and other pests, and pest control records must be kept to verify that the program is accomplishing its goals.

ii. *Current industry practices—rodent and other 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 in order to achieve a higher level of rodent and other pest control.

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.[22] In

[22] Only operations with 30,000 or more layers are included in the Layers study (Refs. 27 and 28).

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 8 of this document illustrates, by farm size, the number of programs that would satisfy the rodent control provisions in the 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. 27 and 28), we estimate that the number of farms with unacceptable 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.[23] 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 provision to increase their rodent control efforts. 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 8—RODENT CONTROL

Farm size (number of layers)	Unacceptable rodent control (in %)	Number of farms with unacceptable rodent control	Number of farms increasing effort
3,000 to 19,999	19	328	709
20,000 to 49,999	21	194	365
50,000 to 99,999	4	9	119
100,000 or more	2	7	201
All farms with 3,000 layers or more	.....	539	1,394

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. 78). However, we chiefly are interested in the presence of flies and fly control because they have been implicated in the transmission of *Salmonella* (Ref. 79).[24]

The survey used to develop the Layers study asked questions about on-farm fly control practices (Refs. 27 and 28). 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, are not permitted by the final rule. In particular, the rule does not allow the use of biological predators, such as wild birds, for fly control because these predators may themselves be vectors for SE transmission (Ref. 79).

TABLE 9—FLY CONTROL

Farm size (number of layers)	Unacceptable fly control (in %)	Number of farms with unacceptable fly control	Number of farms increasing effort
3,000 to 19,999	27	470	638
20,000 to 49,999	18	162	382
50,000 to 99,999	12	29	109
100,000 or more	22	89	160
All farms	.....	750	1,289
All farms with 3,000 or more layers	.....	750	1,289

Table 9 of this document shows the number of farms with unacceptable (not sufficient to satisfy the rule) fly control programs. Farms that do 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 750 farms with 3,000 or more layers 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 9 of this document would suggest. The 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 provision would be likely to increase their use of fly controls. In order to estimate the costs, we assume that the number of farms using acceptable fly control methods but will increase their fly control efforts is uniformly distributed between 0 and 100 percent. Consequently, at the mean estimate of 50 percent, an additional 1,289 farms will increase their fly control efforts.

iii. *Costs of rodent and other pest control.*[25] We estimate the cost of rodent

[23] Our primary source for on-farm practices related to SE prevention measures is the Layers study (Refs. 27 and 28). 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 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.

[24] Beetles have also been shown to be a reservoir for SE (Refs. 80 and 81). Beetle populations can be controlled primarily by the removal of all visible manure upon a house cleaning, the costs and benefits of which are discussed later in this document. Other costs of control, as well as benefits, are assumed to be accounted for in the analysis of fly control.

[25] 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

and other pest control to farms in table 10 of this document. We assume that a farm with an adequate control program for rodents and other pests will be using a combination of control measures.

Included in the cost of rodent control are the costs of setting up and maintaining bait stations and of rodent indexing. The annual cost of rodent control ranges from $680 for the average farm with between 3,000 and 20,000 layers to $5,860 for the typical farm with over 100,000 layers. The costs of limiting rodent 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 $4,600 for farms with between 3,000 and 20,000 layers to $77,660 for farms with more than 100,000 layers.

TABLE 10—COST OF RODENT AND OTHER PEST CONTROL

[In thousands]

Farm size (number of layers)	Rodent control		Pest control		Total
	Unacceptable controls	Increased effort	Unacceptable controls	Increased effort	
3,000 to 19,999	$222	$240	$2,160	$1,467	$4,089
20,000 to 49,999	157	148	1,355	1,597	3,256
50,000 to 99,999	12	76	460	859	1,408
100,000 or more	43	588	6,887	6,212	13,730
All farms with 3,000 or more layers	434	1,052	10,861	10,136	22,483

The total cost of rodent and other pest control shown in table 10 of this document, is found by multiplying the cost per farm by the number of farms affected. Some farms are already using acceptable rodent and other pest control methods, but they will increase their rodent and other pest control efforts in order to reduce the subsequent expected costs of testing and diversion. We estimate that their cost of rodent and other pest control enhancements will be approximately half of the cost of farms with unacceptable controls. This provision results in costs of $22.5 million for the effected farms.

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 the document, we merge field 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. 27 and 28) to determine the magnitude of the rodent problem on farms. The first four rows of table 11 of this document show the percentages of farms in four size categories with four severities of mouse or rat infestation.[26] Table 11 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.[27]

TABLE 11—SEVERITY OF RODENT PROBLEM

	Severity in %				Number of houses in category
	Severe	Moderate	Slight	None	
Farm Size (Number of Layers):					
< 20,000	0	14.8	81.7	3.5	48,145
20,000 to 49,999	9.1	13.2	70.1	7.6	1,295
50,000 to 99,999	1.2	28.4	52.3	18.1	595
100,000 or more	1.5	32.1	60.1	6.3	3,024
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	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	25.8	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%.

record (Ref. 82). Where applicable, costs are changed to year 2005 constant dollars using the Gross Domestic Product (GDP) deflator.

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

[27] 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.

Henzler (Ref. 83) 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.[28] 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 study (Ref. 29)[29] 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.[30] This difference is statistically significant.

Using data from the Henzler study, we estimate 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:

$$\text{Base} = \text{Overall} \div [(\text{prevention}_{SEV} \times \text{Birds}_{SEV}) + (\text{prevention}_{MOD} \times \text{Birds}_{MOD}) + (\text{prevention}_{SLT} \times \text{Birds}_{SLT}) + (\text{prevention}_{NON} \times \text{Birds}_{NON})];$$

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, respectively.

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. 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 11 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. Severe rodent infestations are probably caused by more than just the failure to have a rodent control program. House design (open walls, dirt floors, and other features), unfavorable location (near other rodent-infested entities, climate, and so on), and lack of knowledge regarding proper rodent control techniques are additional factors 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 11.

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 baseline number of SE cases due to eggs and the value of a typical case of salmonellosis to estimate the value of rodent and other pest control benefits. On the affected farms, rodent and other pest control results in expected annual benefits of 19,433 illnesses averted initially to 38,954 illnesses averted eventually.

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 other 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. 84).[31] Beetles and wild birds have also been implicated in the transmission of SE (Ref. 79). Wild birds currently have access to layer feed troughs on 23.5 percent, and flies have access to layer feed troughs on 91.3 percent, of farms (Refs. 27 and 28).

Despite the high prevalence of pests other than rodents on farms, most farms attempt to limit their presence. For example, approximately 82 percent of farms currently use fly control methods other than the use of biological predators (Refs. 27 and 28).[32]

The third section of the Layers study (Ref. 29) illustrates the effect of other pest control. On those farms in which pests have access to feed storage sites, the prevalence of SE is estimated to be higher than on farms where pests do not have access to feed in storage. Because the practices and effects of other pest control are highly correlated with rodent control we do not estimate the benefits separately.

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

The Cooperative Extension Service of Oklahoma State University estimated that each rat in a poultry house consumed $2.18 worth of feed annually (Ref. 86) in 1987. This amount is equivalent to $3.75 in the year 2005 constant dollars.[33] Because mice eat 5 to 10 percent as much as rats (Ref. 78), the expected annual loss of feed for each mouse in a house is estimated to cost $0.19 to $0.38.

We estimate that an infested house may have over 1,000 mice (Ref. 83). This infestation will cost a farmer approximately $285 for that house (1,000 × $.285). A house infested with rats may have as many as 700 rats (Ref.

[28] A total of 84 flocks were examined in Pennsylvania (Ref. 83).

[29] The third part of the Layers study (Ref. 29) 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.

[30] The standardized rodent index is calculated as (number of rodents trapped) × (7 ÷ number of days) × (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. 29).

[31] *See* also Olsen (2000) (Ref. 85).

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

[33] Nominal 1987 dollars are converted to 2005 constant dollars by multiplying the amount as estimated in 1987 by the ratio of the GDP deflator in 2005 to the GDP deflator in 1987 ($2.18 × 113.386/65.958).

87). In this case, the infestation costs the farmer $2,625 (700 × $3.75).

TABLE 12—FEED SAVINGS FROM RODENT CONTROL

Problem	Rodents in a house	Feed savings per house	% of houses [1]	Houses in classifiction [2]	Cost to houses in classification
Mice:					
Severe	1,000	$285	2.4	105	$30,000
Moderate	500	143	25.5	1,118	159,800
Slight	250	71	62.4	2,735	194,200
None	0	0	9.7	425	0
Rats:					
Severe	700	2,625	1.6	70	184,100
Moderate	350	1,313	6.9	302	397,100
Slight	175	656	43.7	1,915	1,256,500
None	0	0	47.8	2,095	0
Total cost of rodents					2,221,700
Expected savings from control (assumes 50% reduction)					1,110,850

[1] The percentages are from the Layers study (Refs. 27 and 28).
[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 12 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 more than $1.1 million annually.

vii. *Biosecurity provisions.* We have examined the effects of several 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 from entering poultry houses; and (5) prohibiting employees from keeping birds 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. Although it is impossible to predict what measures each farm will take to guarantee the hygiene of persons moving between houses, for the purposes of calculating the costs of this provision, discussed in detail in the following paragraphs, we assume that farms will use footbaths and have visitors wear protective clothing.

Stray poultry, wild birds, cats, and other animals must also be prevented from entering the farm's poultry houses. This may be done by keeping grass and weeds cut, minimizing the existence of standing pools of water near poultry houses, repairing holes on poultry houses, and keeping doors closed on poultry houses.

Finally, biosecurity precludes employees of the farm from keeping any birds as domestic animals at home.

viii. *Current industry practices; biosecurity.* Most farms already practice some form of biosecurity.[34] Roughly 68.1 percent of farms do not allow nonbusiness visitors and 22.1 percent do not allow business visitors into poultry houses. Of those that do allow visitors to enter, 65.6 percent have biosecurity rules for nonbusiness 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 poultry 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.

ix. *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 restricting 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. One estimate of protective clothing found costs of $102.75 for a box of 25 disposable coveralls and $112.97 for a box of 200 plastic shoe covers (Ref. 88). 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

[34] All data in this section are from the Layers study (Refs. 27 and 28).

choose to do this. 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 will devote 69 labor hours annually to cleaning equipment. At a labor rate of $9.56 per hour (Ref. 89), plus 50 percent to include overhead costs, the total expected labor cost of this provision is $990 per farm, or $3.3 million for all affected farms.

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 to be $360 per year.[35] Because only 24.6 percent of houses currently use footbaths, the total annual cost of footbaths is estimated to be (100 − 24.6 percent) × 7,359 houses × $360 per house = $2.0 million.

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

The total measured costs of biosecurity provisions are $5.3 million for affected farms.

x. *Benefits of biosecurity.* The importance of biosecurity in the reduction of disease transmission is well established.[36] For example, the Layers study (Ref. 29) estimates that farms allowing nonbusiness visitors onsite are five times more likely to test positive for SE than farms that ban such visitors. Farms allowing nonbusiness 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 practices and effects are highly correlated and cannot be estimated separately.

xi. *Cleaning and disinfecting provisions.* Specific cleaning and disinfecting provisions include the removal of all visible manure, and a dry clean and disinfection of the house.

xii. *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. 27 and 28) estimates that, every year or two, manure is removed from 100 percent of houses, 80.5 percent of houses are dry cleaned annually, 53.6 percent of houses are wet cleaned annually, and 65.1 percent of houses are disinfected. The prevalence of these practices on affected farms is illustrated in table 13 of this document.

TABLE 13—CURRENT CLEANING AND DISINFECTING PRACTICES

	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	20.6
Never	0	19.5	46.4	34.9

xiii. *Costs of cleaning and disinfecting.* The cost of cleaning and disinfecting houses is illustrated in table 14 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 14 of this document), the probability of a positive flock, and the number of affected houses (7,359, calculated from data in table 6 of this document).

TABLE 14—COST OF CLEANING AND DISINFECTING HOUSES ON AFFECTED FARMS

	Houses using practice (%)	Probability of a positive environmental test (%)	Number of houses affected	Cost per house	Cost to industry
Dry clean	79.8	8.4	125	$1,200	$130,300
Disinfect	51.4	8.4	300	600	152,300
Total cost	.....	.....	.....	.....	282,600

The percentages of houses engaged in the different cleaning and disinfecting practices (the first column of numbers in table 14 of this document) is based on the first two rows of table 13 of this document. In table 14 we calculate the percent as follows:

CA + (CO × PC), where

CA is the percent of farms that are cleaned and disinfected annually, (see table 13 of this document)

CO is the percent of farms that are cleaned and disinfected occasionally, (see table 13), 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.

The per-house cost for each component is taken from Morales and McDowell (Ref. 91) and is converted to year 2005 constant dollars using the GDP deflator. We assume that the true

[35] 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 $9.56 an hour (Ref. 89) plus 50 percent to include overhead; and (5) changing the bleach-water mixture takes 10 minutes. The estimate in the text is calculated as 2 × [($5 × 1) + ($1 × 52) + ($14.34 × 0.167 × 52)] = $360 per year.

[36] A number of State extension services have written extensively about the importance of biosecurity (Refs. 79, 80, and 90).

cost of each component is distributed uniformly between the low and the high estimates given.

xiv. *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. 92). Because they do not address cross-contamination, 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 study (Ref. 29) finds that farms that are cleaned and disinfected are less likely to be contaminated with SE. No surveyed farms that performed 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. However, because the practices and effects of cleaning and disinfecting are highly correlated with rodent control we do not estimate the benefits separately.

xv. *Total and net benefits of rodent and other pest control programs, biosecurity, and cleaning and disinfecting.* The total annual cost for all three provisions is $28.1 million.

As discussed in detail under rodent control, the benefits of these provisions are highly correlated. The data attributing a correlation between any one practice and a decrease in SE prevalence is probably overstating the effect because, for instance, farms with a good biosecurity system tend to have good rodent and other pest control programs. In order to avoid the double counting of benefits, we use only the benefits estimated for rodent control as a proxy for the benefits of all three provisions implemented correctly. Therefore all three provisions implemented together are estimated to reduce the number of SE related illnesses every year by nearly 39,000 for total estimated annual benefits of more than $697.3 million. The provisions would cost about $690 per illness averted and have net benefits of about $675.9 million.

If we account for estimated reductions in SE prevalence due to the chick and pullet provisions (an estimated decrease of 0.23 percent, discussed in detail in section V.F.1.i), occurring earlier in the production cycle, these three provisions would prevent about 90 less illnesses than they would standing alone ((1–0.0023) × 39,000 illnesses). Costs would only decrease slightly, as cleaning and disinfecting costs are the only ones that are a function of SE prevalence. In place with the other provisions of the final rule, these three provisions will cost about $700 per illness averted and have net benefits of about $674.3 million.

d. *Refrigeration.*—i. *Refrigeration provisions.* This rule requires that shell eggs being held or transported must be refrigerated at or below 45 °F ambient temperature beginning 36 hours after time of lay.

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, either on-farm, during shipment, or during holding before shell egg processing or entering egg products facilities. We use data from the Layers study (Refs. 27 and 28), shown in table 15 of this document, to determine the percentage of farms affected by the on-farm storage temperature requirements.

TABLE 15—FARMS AFFECTED BY ON-FARM EGG STORAGE TEMPERATURE REQUIREMENTS

Farm size (number of layers)	Packed off-farm (%)	Stored longer than 36 hours (%)	Temp > 45 °F (%)	Percent of farms affected	Number of farms affected
3,000 to 19,999	98.3	98.2	78.1	75.4	1,317
20,000 to 49,999	96.3	100	75.8	73.0	675
50,000 to 99,999	83.1	83.4	92.1	63.8	158
100,000 or more	65.6	75	72.6	35.7	146
Total	81.2	87.3	81.2	57.6	2,296

The first three columns of table 15 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.

Due to current rules on refrigeration, most farms currently ship eggs from the farm in refrigerated freight at 45 °F, even though they are not required to do so until the eggs have been packaged or further processed.[37] Farms with more than 10,000 layers are likely to be currently in compliance with this provision. Some smaller farms, those with 10,000 layers or less, which account for roughly 5 percent of current egg production, may be out of compliance. It is unlikely that even the smallest farms that are currently refrigerating eggs onsite would ship eggs on unrefrigerated trucks. As a high estimate of the costs of this provision, FDA assumes that producers with 10,000 layers or less, who are currently not in compliance with the on-farm refrigeration part of this provision (all farms with less than 3,000 layers and 75.4 percent of farms with between 3,000 and 20,000 layers)[38] are not in compliance with the refrigerated shipping requirement.

There are 514 producers, packers, and grading stations that will be affected by this provision (Ref. 93). While the majority of eggs in the United States are processed within 2 to 3 days, some cases arise where eggs are held longer. Seasonal fluctuations in demand or within industry egg trading, at times causes eggs to be held for more than 36

[37] Current industry practices and the costs of egg transportation are based on information gained from telephone conversations between FDA, an egg processor, and a shipper.

[38] *See* table 16 of this document.

hours between lay and processing [39] (Ref. 94).

There is currently no regulation requiring a specific temperature for preprocessed eggs. Eggs are typically held between 55 and 60 °F (Ref. 94). FDA believes most producers will have to decrease the holding temperature for their eggs.

iii. *Cost of on-farm refrigeration.*[40] The refrigeration provision will cause producers to choose to perform one of 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 addition, producers that do not currently ship in refrigerated freight will need to do so. Furthermore, producers, packers, and egg grading stations will have to refrigerate eggs at no more than 45 °F if they hold the eggs for more than 36 hours prior to processing.

In table 15 of this document, we estimate that almost 2,300 farms do not meet the on-farm standards set by the refrigeration provision. Of these farms, some are currently using refrigeration, albeit at higher temperatures than the 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 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 16 of this document, we use data from the Layers study to determine how many 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.[41] If temperatures in egg rooms on these farms are uniformly distributed between 45 and 60 °F, the average reduction in temperature is 7.5 °F. If the electricity rate is $0.057 per kilowatt-hour (Ref. 96), farms will spend between about $130 for farms with between 3,000 and 20,000 layers to a little over $1,400 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 about $168 per month, or about $2,020 per year.[42] The cost of cooling to 45 °F is about $202 per month, or about $2,420 per year.[43] The resulting cost of decreasing the ambient temperature in the egg cooler by 15 °F is approximately $400. Using a linear relationship between refrigeration and cost gives us an estimate of approximately $200 for a 7.5 °F reduction.[44]

TABLE 16—ANNUAL COST OF ON-FARM REFRIGERATING AFFECTED FARMS

Farm size (number 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% discount rate)	(3% discount rate)
3,000 to 19,999	720	$6,979	$5,074	597	$128	$5,102	$3,730
20,000 to 49,999	201	13,793	9,779	474	203	2,868	2,062
50,000 to 99,999	65	26,359	18,500	93	352	1,746	1,235
100,000 or more	32	112,681	78,595	114	1,413	3,767	2,676

The fixed cost of new refrigeration 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 discount rate, we estimate that the annualized cost of installing new refrigeration would be about $1,300 for a farm with 20,000 to 50,000 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 (294 square feet) times the number of eggs produced in a 24-hour period (1,700 dozen eggs) times the number of days the eggs are expected to be stored (about 4 days). The average 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 $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 $13.38 for a 32 square foot sheet. For a farm with 20,000 to 50,000 layers requiring 3,670

[39] Within industry egg trading refers to trading between firms to meet unexpected demand or get rid of excess supply.

[40] All cost estimates regarding on farm storage 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. 95).

[41] 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. As such, actual refrigeration costs will be higher than estimated. As most farms currently using refrigeration will simply have to increase their energy usage, we believe the difference between actual costs and costs estimated using energy usage as a proxy is small. Furthermore the underestimate will be at least somewhat offset by the use of newer, more efficient equipment, and overestimates in other parts of this calculation (*see* footnote 44 of this document).

[42] (4.83 + 1.73) kilowatt hours used per hour × 15 hours of operation × $0.057 per kilowatt hour used × 30 days.

[43] (4.83 + 1.73) kilowatt hours used per hour × 18 hours of operation per day × $0.057 per kilowatt hour × 30 days.

[44] In actuality, the relationship between refrigeration and cost is increasing at an increasing rate, so that our use of a linear relationship somewhat overstates the cost of lowering refrigeration temperatures.

square feet of insulation, the expected cost of insulation is therefore $1,540. The annualized cost of insulation (amortized over 30 years at 7 percent) is $125.

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 ($10,300) plus the cost of installation ($10,300 × 5 percent) for a total of $10,816. Amortizing this cost over 15 years at 7 percent yields an annual cost of $1,190.

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 $11,350. Including the cost of energy increases the total cost to $13,800.

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 $0.057 per kilowatt-hour, we estimate that farms not currently using refrigeration will spend an additional $1,500 to $17,000 annually for power.[45] Farms that currently use refrigeration, but at higher temperatures than 45 °F, will spend an additional $130 to $1,400 annually for power.[46]

The cost of this provision to a farm without any refrigeration in place is estimated to range from about $7,000 for farms with between 3,000 and 20,000 layers to over $112,600 for farms with more than 100,000 layers. The cost of this provision to a farm with adequate refrigeration is simply the cost of the additional energy, ranging from about $130 for farms with between 3,000 and 20,000 layers to over $1,400 for farms with more than 100,000 layers.

iv. *Cost of refrigerated shipping.* The average cost of refrigerated shipment at 45 °F is $0.12 per dozen eggs. Unrefrigerated shipments cost 20 percent less than refrigerated shipments. Therefore, the difference in cost between refrigerated and unrefrigerated shipments is $0.024 per dozen eggs. Since farms with 10,000 layers or less produce roughly 1.5 percent of the eggs sold annually (93 million dozen eggs), the additional cost of refrigerated shipping on these farms is $1.7 million (93 million dozen eggs × $0.024 × 0.754 not in compliance).

v. *Cost of preprocessing storage.* The cost of this provision to facilities holding eggs at above 45 °F for shell egg processing or before entering egg products facilities is assumed to be the cost of increased energy usage. If temperatures in egg rooms at these facilities are uniformly distributed between 55 and 60 °F, the average reduction in temperature is 7.5 °F. If the electricity rate is $0.057 per kilowatt-hour, facilities holding 100 dozen eggs at a time will spend $35 annually while facilities holding 1,000 dozen eggs at a time will spend nearly $20,000 annually. Using calculations similar to those described previously for on-farm holding, it is estimated that the average annual cost of additional refrigeration is about $9,700 per facility. The total annual cost for the 514 facilities holding eggs at above 45 °F is expected to be $5 million.

vi. *Total cost of refrigeration provisions.* The total cost of the refrigeration provision, using a 7 percent discount rate, is approximately $20.2 million.[47] Using a 3 percent discount rate, the cost is approximately $16.4 million. 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 pickups are a lower cost alternative to refrigeration installation, the previously mentioned figures may overstate the actual cost of increased refrigeration.

vii. *Benefits of refrigeration.* The probability that an individual will become ill from an SE-contaminated egg 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. 22). This provision would require that eggs that are stored for more than 36 hours after laying be refrigerated at 45 °F through the preproduction stage. We use the USDA SE risk assessment model (Ref. 22), a model designed, in part, to estimate the effects of refrigeration on the number of SE illnesses. The FSIS risk assessment estimates that if all eggs on farms affected by the final rule are refrigerated at 45 °F within 36 hours of lay to the time they were processed, we would see a 31 percent decline in annual SE illnesses. This translates to nearly 45,000 illnesses avoided annually, or about $800.6 million in annual benefits. Standing alone, the refrigeration provisions would cost about $450 per illness avoided and provide $780.4 million in net benefits.

If we account for estimated reductions in SE prevalence due to the provisions pertaining to chicks and pullets, rodent and pest control, biosecurity, cleaning and disinfecting, and testing and diversion (a 35 percent reduction in prevalence when all provisions are in place and fully effective), all occurring earlier in the production cycle, the refrigeration provisions would provide a 20 percent decline in SE illness, preventing about 29,000 illnesses annually ((1–0.35) × 45,000 illnesses). Costs of refrigeration are not a function of SE prevalence and remain constant. In place with the other provisions of the final rule, the cost per illness averted on farms with more than 3,000 layers is estimated to be roughly $700.[48] The annual net benefit of the provision is $496.9 million.

e. *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 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 4 to 6 weeks after molting for each group is completed.[49]

Environmental sampling would be accomplished by a method such as swabbing manure piles in the poultry

[45] 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 × 18 hours of operation per day × $0.057 per kilowatt hour × 30 days ≈ $202 per month, or about $2,420 per year. Using similar calculations, average annual energy costs for refrigeration on farms that previously did not use refrigeration are estimated to be $1,540 on farms with 3,000 to 19,999 layers, $4,230 on farms with 50,000 to 99,999 layers, and $16,950 on farms with 100,000 layers or more.

[46] Using a calculation similar to the one illustrated in the discussion of the costs of inadequate refrigeration for farms with 20,000 to 50,000 layers, average annual energy costs for farms with inadequate refrigeration are estimated to be $130 on farms with 3,000 to 19,999 layers, $350 on farms with 50,000 to 99,999 layers, and $1,400 on farms with $100,000 layers or more.

[47] For ease of explanation, the total new burden of the refrigeration requirement is assumed to be carried by the farmers. In reality, this burden, although equal in total, might be spread among the farmer, shipper, producer, retailer, and consumer.

[48] This estimate assumes a 7-percent discount rate.

[49] In the proposed rule, molted flocks were to undergo environmental testing at 20 weeks post molt. Changing the time from 20 weeks to 4 to 6 weeks post molt increases the costs to farms that test environmentally positive, egg positive, and continue to test egg positive. For these farms, earlier testing means more eggs diverted over the life of the flock and more egg tests. However, the benefit of diverting more potentially positive eggs is greater than the additional costs.

house and then culturing those swabs using a primary enrichment testing method. We consider variants of sampling protocols that are currently in use. The California Quality Assurance program currently requires a sampling plan that relies on randomly swabbing 30-foot sections of the poultry house (Ref. 97). To obtain a 95 percent probability of finding a house that is 10 percent infected, we estimate that 32 samples would have to be taken. Many other State quality assurance plans, including Pennsylvania's, require the span of each row of the layer house to be swabbed with one swab, regardless of row length (Ref. 92).

ii. *Current industry molting practices.* Molted flocks face additional testing under this provision. Overall, 62 percent of all large flocks are molted once and 12 percent are molted twice before depopulation (Refs. 27 and 28). 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 17 of this document.

TABLE 17—REGIONAL MOLTING PRACTICES [1]

Region	Times molted		
	0	1	2
Great Lakes	30%	65%	5%
Southeast	7%	80%	13%
Central	49%	51%	0%
West	18%	50%	32%

[1] Layers study data provided by APHIS.

Molting practices also vary by farm size. As table 18 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 28 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 18—MOLTING PRACTICES BY FARM SIZE [1]

Farm size (number of layers)	Times molted		
	0	1	2
Fewer than 20,000	72%	28%	0%
20,000 to 49,999	35%	54%	11%
50,000 to 99,999	14%	68%	18%
100,000 or more	16%	72%	12%

[1] Layers Study data provided by APHIS.

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. 27 and 28). The vast majority of these producers are also members of formal quality assurance programs.

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 estimate that it will take approximately 15 minutes to collect and pack each sample. Because the wage for a typical livestock and poultry worker is approximately $9.56 per hour (Ref. 89), after adding 50 percent to reflect overhead costs, we assume that the cost of labor is $3.59 per sample collected.[50]

The cost of shipping samples will vary by the weight of the shipment. We assume that a swab, with its packing material, weighs approximately 1 pound. To calculate the cost of shipping, we estimate the average number of swabs sent per shipment and use rate tables (Ref. 98) 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 $36.00 per sample (Ref. 99).

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

$$\text{Cost} = \text{SWABS} \times (\text{LABOR} + \text{MAIL} + \text{LAB})$$

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. 27 and 28) are using a row-based plan.

The number of rows that will have to be swabbed in larger houses is estimated in table 19 of this document. Information for the first three columns is drawn from the Layers study (Refs. 27 and 28). We estimate the number of houses affected by the provision (the fourth column) by multiplying the number of large houses (7,315) 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. We estimate

[50] $(15 \div 60) \times \$14.34$.

that a total of 21,325 rows would have to be swabbed due to this provision.

TABLE 19—NUMBER OF ROWS TO BE SWABBED

[Houses with 3,000 or more layers]

Number of rows or batteries of cages	Average number of rows [1]	Percent of houses	Number of houses affected	Number of rows affected
1	1.0	1.9	67	67
2 to 3	2.5	12.5	442	1,105
4 to 5	4.5	50.8	1,794	8,073
6 or more	10.0	34.2	1,208	12,080
Total	6.1		3,511	21,325

[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.

Because each row has two sides, each of which we assume will have to be swabbed, the total number of swabs required is estimated to be approximately 42,650. On average, 12.2 swabs will be used for each house with more than 3,000 layers. The total cost of testing the average large house is $532 (12.2 swabs × ($3.59 labor + $3.98 shipping + $36.00 lab culture)) when two swabs are used per row.[51]

The random swabbing plan requires that 32 samples be taken per house. Although 52 percent of houses conduct some routine environmental testing, far fewer are likely to follow 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. The cost per swab under the random swabbing sampling plan is about $42 ($3.59 labor + $2.42 shipping[52] + $36.00 lab culture). The total cost of one round of testing under the random swabbing plan is calculated to be $1,344 per house, regardless of size (32 swabs per house × $42 cost per swab).

f. *Follow-up egg testing.*—i. *Egg testing provisions.* Follow-up 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 lab both initially and subsequently every 2 weeks for a total of 4,000 eggs. Consistent with the method described in chapter 5 of FDA's Bacteriological Analytical Manual (BAM) the eggs that are submitted for testing may be pooled in samples of 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.[53]

ii. *Current industry practices; Follow-up 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 follow-up testing provisions that are largely the same as this provision (Ref. 76). According to ''Chicken and Eggs'' (Ref. 75), 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 × 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 follow-up egg tests.

Farms using the number of eggs for sampling required by the Pennsylvania and Maryland plans are sampling fewer eggs than are required by this rule. Specifically, this provision would require that batches of 1,000 eggs be tested if egg testing is required, 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. Furthermore, the testing protocol used in Pennsylvania and Maryland is less rigorous than the one prescribed by FDA. Therefore, farms currently testing under the Pennsylvania and Maryland plans will also have to change their testing protocol. Because these farms are already paying for egg testing, however, not all costs of the new testing plan will be new costs. The tests under the Pennsylvania plan cost about 71 percent as much as the test required under the FDA plan.

These numbers suggest that the current net level of compliance with the provision is 2.8 percent (8.2 percent under state quality control plans × 48 percent as many eggs tested as required by this rule × 71 percent the cost of FDA test) for farms with more than 3,000 layers.

iii. *Egg testing costs.* The cost of follow-up 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 estimate that it will take the typical farmhand approximately one-half minute per egg to select eggs for testing, so the labor cost of egg testing is $119.50 per 1,000 eggs tested (50 samples × 20 eggs per sample × 0.0083 hours per egg × $14.34 dollars per hour) (Ref. 89).

The lost value of the eggs used for testing is the number of eggs tested

[51] The cost of shipping 12 swabs (12 pounds) overnight is estimated to be between $25.58 and $70.73, including pickup charges (Ref. 98). We divide the average cost of shipping by 12 to obtain the cost per swab ($3.98).

[52] The cost of shipping 32 swabs (32 pounds) overnight is estimated to be between $42.10 and $114.65, including pickup charges (Ref. 98). We divide the average cost of shipping ($77.44) by 32 to obtain the cost per swab ($2.42).

[53] Under the provision on diversion, farms that test positive for SE in their eggs would be required to divert their eggs for treatment until they are able to show via testing that SE is not present in the eggs produced in the infected house. This is discussed in detail in the following section on diversion costs.

times the producer price of an egg.[54] To avoid 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 required to be diverted 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 21 of this document). The expected value of a tested egg is the weighted average of the value of a table egg and a diverted egg, or about $0.03 per egg.[55] 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 $32.15.

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 $260.[56]

The largest cost of egg testing is the laboratory; we estimate the average lab cost for 1 batch of 20 eggs to be $35.16.[57] Hence, for 50 tests the laboratory cost of eggs testing is $1,758 per 1,000 eggs tested (50 batches × $35.16 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 $2,169 per 1,000 eggs tested ($119.50 collection costs + $32.37 lost income from egg sales + $259.05 shipping costs + $1,758 lab costs).

g. *Diversion.*—i. *Diversion provisions.* Under this provision, farms that test positive for SE in their eggs would be required to divert their eggs for treatment until they are able to determine 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 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 20 of this document shows, these regions are responsible for only 52 percent of overall egg production, but over 86 percent of breaker eggs.[58] The centralization of the breaker industry is even more clearly illustrated in the fourth column of table 20. 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 20—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	12.3	300,406	17.1	35.7
North Central	32,869	40.0	1,212,758	69.1	44.3
South Atlantic	13,979	17.0	69,774	4.0	6.0
South Central	14,512	17.7	84,071	4.8	7.0
West	10,636	13.0	87,662	5.0	9.9
Total	82,102	100.0	1,754,671	100.0	25.7

[1] National Agricultural Statistical Services (NASS) (Ref. 75).
[2] NASS (Ref. 101).

To predict how the industry will respond to a provision mandating diversion, it is important to consider the following information: (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 several 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. Because processed foods are less costly to transport than are their ingredients, it makes sense to locate processed food 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.[59] 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

[54] Using the producer price of the egg may slightly underestimate the value of the lost egg. Although much of the price increase between producer and consumer includes transfers, there is real value added during some processing.

[55] The following calculation is used to reach this figure. [(74 percent of eggs not diverted × $0.43 per dozen table eggs) + (26 percent of eggs diverted × $0.26 per dozen diverted eggs)] ÷ 12 eggs in a dozen = $0.03215 per egg.

[56] The cost of shipping a 60-pound package overnight is between $67.35 and $191.70, including pickup charges (Ref. 98). We multiply the average cost of shipping ($129.52) by 2 to obtain the total cost of $259.05.

[57] For the testing method FDA prescribes, the lab cost per 20 egg pool is $35 initially and an additional $30 for confirmation if the pool tests positive (Ref. 100). Upon an environmental positive, eggs will test positive at a rate of 2.75 per 10,000 (Ref. 92). Therefore the probability of a pool of 20 eggs testing negative is 99.45 percent ((1 − (2.75/10,000)) − 20). Conversely the probability of a pool testing positive is 0.55 percent. So the expected cost of a test is $35.16 (($35 × 0.9945) + ($65 × 0.0055)).

[58] In table 20 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.

[59] Shipping grains from the Midwest to the West Coast by rail car cost over $1 per bushel (Ref. 102).

cheaply. Furthermore, because 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 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 and freight for diverted eggs is relatively high (such as in California), the cost of diversion is likely to be high. Similarly, where the price of egg production and freight 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 impossible. 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 previously mentioned regions and was given estimates of diversion costs that are consistent with the above reasoning. The diversion cost per dozen eggs in Pennsylvania was estimated to be insignificant while the diversion cost in California 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 cost 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 [60] because they can 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 cause a small farm with one house to incur significant losses for that farm.

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. The pasteurization process for breaker eggs is designed to achieve at least a 5-log reduction in any SE that may be in eggs. Further, the actual cost of marking the shipments and stamping documents accompanying diverted eggs as ''these eggs must be treated to achieve at least a 5-log destruction of *Salmonella* Enteritidis or processed as egg products in accordance with the Egg Products Inspection Act'' will be insubstantial.[61] However, because these eggs are limited in how they may be used, SE-positive eggs are intrinsically less valuable than SE-negative eggs.

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 21 of this document 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 between $0.13 and $0.23 per dozen eggs. If there is an additional discount for those eggs with SE, the total cost could rise as high as $0.33 per dozen eggs.

TABLE 21—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	0.39	0.30	0.09
South-Atlantic	17	0.43	0.31	0.12
South-Central	17.7	0.47	0.30	0.17
West	13	0.53	0.31	0.22
Average Cost of Diverting Eggs [3]				0.13–0.23
Additional Discount for SE+ Eggs [4]				0.00–0.10
Total Cost of Diverting Eggs				0.13–0.33

[1] The shell egg price paid to producers for the north-central region was estimated as equivalent to the prices 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. 103).

[2] All figures are from AMS data accessed through the North Carolina Department of Agriculture (Ref. 104).

[3] The lower bound of this range is the average cost of diverting eggs calculated as described above, and is weighted by regional production (Ref. 75). The upper bound of this range is calculated using data from comments to the analysis of the proposed rule, suggesting that the difference between the value of shell eggs and breakers has been greater recently. Because prices tend to fluctuate, and therefore differences in the price between shell eggs and breaker eggs fluctuate, the full range of estimated price differences is used in the calculation of the total cost of diverting eggs.

[4] Ref. 91 and comment to analysis of the proposed rule.

[60] Filling orders for table eggs when eggs from one house must be diverted.

[61] Eggs are typically shipped on palates holding 900 dozen eggs. The palates are shrink-wrapped. Diverted eggs will need to be marked somewhere on the shrink wrapping. Based on FDA's estimate of 474 million eggs diverted annually (discussed in detail in section F.1.h of this document), between 45,000 and 60,000 labels would have to be affixed to palates each year. This estimate accounts for the fact that some shipments may use partially full palates. The labels themselves will cost about $0.025 each and require less than 30 seconds to apply. Thus, a conservative estimate puts the cost at less than $8,000 annually across the entire industry, or less than two one-thousandths of a cent additional cost per egg. Each farm will need to buy a label gun for a one time cost of approximately $100. Amortized over 10 years, this cost is less than $15 per year, per farm. The cost of stamping the accompanying documents is discussed in the recordkeeping section F.2.a of this document.

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.

h. *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 follow-up egg tests and diverting until depopulation of the contaminated house.

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 7.0 percent eventually to account for the expected reduction of SE on the farm due to the adoption of other provisions of the rulemaking 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. 105). We do not know if the experience of Pennsylvania is representative of the nation as a whole. In the absence of better information, we use 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 make 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.[62]

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.[63]

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 22 and 23 of this document illustrate, the expected costs of testing and diversion for a poultry house range from $160 to over $5,500, depending on house size, environmental testing protocol, and molting practices.[64] 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 22—COST PER HOUSE

[Non-molted flocks]

Farm size (number of layers)	Environmental testing	Egg testing	Diversion	Dynamic total cost	Static total cost
Fewer than 3,000	$150 to $1,340 ...	$0	$6	$156 to $1,346 ...	$1,313 to $2,503.
3,000 to 19,999	$530 to $1,340 ...	843	311	$1,684 to $2,494	$1,885 to $2,695.
20,000 to 49,999	$530 to $1,340 ...	843	722	$2,095 to $2,905	$2,140 to $2,950.
50,000 to 99,999	$530 to $1,340 ...	1,124	556	$2,210 to $3,020	$2,352 to $3,162.
Over 100,000	$530 to $1,340 ...	1,124	1,288	$2,942 to $3,752	$3,223 to $4,033

TABLE 23—COST PER HOUSE

[Molted flocks]

Farm size (number of layers)	Environmental testing	Egg testing	Diversion	Dynamic total cost	Static total cost
3,000 to 19,999	$530 to $1,340 ...	$1,378	$537	$2,454 to $3,314	$2,522 to $3,332.
20,000 to 49,999	$530 to $1,340 ...	1,597	766	$2,893 to $3,703	$2,955 to $3,765.
50,000 to 99,999	$530 to $1,340 ...	1,597	1,129	$3,256 to $4,066	$3,315 to $4,125.
Over 100,000	$530 to $1,340 ...	1,597	2,618	$4,745 to $5,555	$4,793 to $5,603

The inclusion of a choice to opt out of egg testing also results in egg testing costs that increase 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.[65] This difference is apparent in the comparison between dynamic total costs and static total costs. If the option to switch from egg testing into diversion were removed, the costs incurred would be the static total

[62] For a detailed look at the mathematical model for this stage, see Ref. 106.

[63] A further refinement of the model would be to include the option of depopulating the flock and 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. We invited comment on the feasibility of this option in the analysis of the proposed rule but did not receive any responses.

[64] Tables 22 and 23 of this document present the cost estimates for houses based on the current estimated prevalence of SE. In the total cost tables (24 and 25 of this document), we also present an estimate that reflects the expected prevalence following the full implementation of this rule.

[65] 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.

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 22 and 23 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 60 percent.[66] 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 multiply 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 24 and 25 of this document.

TABLE 24—TOTAL COST OF TESTING AND DIVERSION: ROW-BASED SAMPLING

[Thousands of dollars]

Farm size (number of layers)	Number of houses	Percent molted	Environmental testing	Egg testing	Diversion	Total cost
Fewer than 3,000	45,700	0	$6,798	$0	$271	$7,069
3,000 to 19,999	2,445	28	617	2,357	839	3,813
20,000 to 49,999	1,295	65	327	1,675	892	2,894
50,000 to 99,999	595	86	150	886	574	1,610
Over 100,000	3,024	84	763	4,476	6,687	11,926
Farms with ≥ 3,000 layers, Initially			1,857	9,393	8,992	20,242
Farms with ≥ 3,000 layers, Eventually			1,857	6,812	6,512	15,181

TABLE 25—TOTAL COST OF TESTING AND DIVERSION: RANDOM SWAB SAMPLING

[Thousands of dollars]

Farm size (number of layers)	Number of houses	Percent molted	Environmental testing	Egg testing	Diversion	Total cost
Fewer than 3,000	45,700	0	$61,425	$0	$271	$61,696
3,000 to 19,999	2,445	28	2,432	2,357	839	5,627
20,000 to 49,999	1,295	65	1,288	1,675	892	3,855
50,000 to 99,999	595	86	592	886	574	2,051
Over 100,000	3,024	84	3,008	4,476	6,687	14,171
Farms with ≥ 3,000 layers, Initially			7,319	9,393	8,992	25,704
Farms with ≥ 3,000 layers, Eventually			7,319	7,319	7,319	21,958

As shown in table 24 of this document, the estimated eventual total cost of testing and diversion is approximately $15.2 million when row-based sampling is used. When we assume that a random swab method of environmental sampling is used, as in table 25 of this document, the eventual estimated costs increase to $22.0 million.

iii. *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 for treatment, the number of these eggs that reach the consumer in an untreated form will 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 used two sources to estimate the current prevalence of SE-positive houses. Our first source is the Layers study (Ref. 29), 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 (for example, those that chose to participate may be a biased sample who are more likely to have cleaner houses).

Regional quality assurance programs have also collected data on SE prevalence on farms. As an upper bound, Pennsylvania experienced a prevalence of 40 percent in the early 1990's (Ref. 107). As a lower bound, we use 1 to 3 percent, which is the current prevalence of houses with SE-positive environments in Maine (Ref. 108). We believe that Pennsylvania's current prevalence of 7 to 9 percent (Ref. 105) is a mode for the nation as a whole.[67] 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

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

[67] 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. 11).

likely value, we estimate a national prevalence rate of 12.3 percent.

We consider 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 an expected 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. 105).

These figures imply that 469 million eggs from affected farms,[68] or 0.5 percent of all shell eggs,[69] would be diverted initially following the initial effective date of the provision. Of these eggs, we expect eggs to be positive at a rate of 2.75 per 10,000 (Ref. 92). Consequently, we estimate that an average of 129,000 SE-positive eggs would be diverted annually. Given a total estimated number of positive eggs of 1.5 million, we estimate that diversion would initially decrease the number of SE-related illnesses by 10.8 percent. This translates to potentially 15,300 illnesses (valued at $274.1 million) prevented each year. Standing alone, the testing and diversion provisions would cost about $1,300 per illness avoided and provide about $261.6 million in net benefits.

If we account for estimated reductions in SE prevalence due to the provisions pertaining to chicks and pullets, rodent and pest control, biosecurity, and cleaning and disinfecting, (a 28 percent reduction in prevalence when all provisions are in place and fully effective), all occurring earlier in the production cycle, the refrigeration provisions would provide a nearly 8 percent decline in SE illness, preventing about 11,000 illnesses annually ((1–0.28) × 15,300 illnesses). Because the baseline SE prevalence will be reduced by other provisions, FDA expects that over 40 million less eggs will be diverted once the rule is fully effective. Furthermore, less egg tests will be necessary. Therefore we expect annual costs to decrease by $3.5 million once all provisions are fully effective. In place with the other provisions of the final rule, the cost of testing and diversion is about $1,900 per SE case prevented. The eventual net benefits of testing and diversion are about $189.6 million per year.

i. *SE-Monitored chicks and pullets.*—i. *Chick and pullet provisions.* Under the final rule, farms must procure pullets that are SE monitored or raise pullets under SE monitored conditions. Pullets to be used as layer hens must be raised under SE control conditions that prevent SE, including (1) procurement of chicks from SE-monitored breeder flocks,[70] (2) cleaning and disinfection, and (3) environmental testing at 14 to 16 weeks of age. If the environmental test is negative, the farm will not need to perform any additional testing of those birds or their environment until the environmental test at 40 to 45 weeks of age. If the 14 to 16 week environmental test is positive, farms must begin egg testing within 2 weeks of the start of egg laying. A positive egg test triggers diversion.

ii. *SE-Monitored chicks.* Farms must procure pullets that have been raised from chicks from SE-monitored breeder flocks that meet the NPIP's standards for ''U.S. S. Enteritidis Clean'' status (9 CFR 145.23(d)) or equivalent standard.

iii. *Current industry practices—SE-monitored chicks.* According to the Layers study (Refs. 27 and 28), 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. 109).

NASS estimates that a total of 138,292,380 chicks were sold in 1997 (Ref. 26). 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 are not currently monitored for SE.

iv. *Costs of SE-monitored chicks.* We do not have data for the cost of monitoring chicks for SE. However, Morales and McDowell (Ref. 91) 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 about $87,000.[71] This cost would be borne by pullet growers but could be passed on to egg farms depending on market conditions.

v. *Benefits of SE-monitored chicks.* The prevalence of SE in breeder flocks is relatively low.[72] Between 1994 and 1996 only 2 out of 847 breeder flocks (0.2 percent) had layers that tested positive for SE. For our estimate of benefits, we used this figure because breeders under the NPIP program must destroy their flocks when layers test positive.[73]

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,[74] we would expect the probability that a farm obtains SE-positive chicks to be greater than the underlying prevalence of SE in hatchery flocks.[75]

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 × 0.2 percent). This percent translates into an expected benefit of 14 illnesses averted on affected farms (valued at about $0.3 million). 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.

vi. *Cleaning and disinfecting, and environmental testing in pullet houses.* To ensure that pullets about to begin the laying cycle are SE free, egg producers must only use pullets whose environments were tested for SE when the pullets were 14 to 16 weeks old. There are two consequences to a positive environmental test. First, an egg producer who uses those pullets must begin egg testing on the positive flock within 2 weeks of the start of egg laying. Second, the pullet house must have all manure removed, and be cleaned and disinfected before a new flock is added.

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

[69] The percent of shell eggs that are diverted is determined by dividing the number of eggs diverted by the total number of shell eggs produced (90,772 million) as published in the USDA's Chicken and Eggs report (Ref. 75).

[70] NPIP certified or the equivalent.

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

[72] The data for this paragraph is drawn from Rhorer (Ref. 110).

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

[74] The Layers study estimates that 38.2 percent of farms obtain pullets from multiple sites (Refs. 27 and 28).

[75] 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.

vii. *Current industry practices—Cleaning and disinfecting, and environmental testing in pullet houses.* FDA does not have detailed information on SE monitoring practices in pullet houses. However, comments from state run programs and industry stated that pullet houses are typically subject to the same provisions as layer houses under state Egg Quality Assurance Programs (EQAPs) and other programs for egg farmers. Therefore, FDA estimates that pullet houses will be in compliance with these provisions at the same rate as estimated for layer houses in previous sections of this analysis.

FDA does not have specific data on the number of pullets and pullet houses there are in the United States. However, multiple comments stated that there are roughly one-third as many pullets as there are layers at any given time. Further, there are roughly one-third as many pullet houses as there are layer houses. FDA therefore estimates that 2,453 pullet houses (7,359 layer houses covered/3) will be covered under this provision. Some of the pullet houses are located onsite at layer farms and others are located on pullet growing facilities.

viii. *Costs of environmental testing in pullet houses.* Because the requirements for tests will be the same for both pullet and layer houses, per house costs are calculated the same way. As in layer houses, the cost of routine environmental testing in pullet houses 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.[76] The total annual cost of environmental testing in pullet houses is estimated to be $1.3 million.

ix. *Costs of cleaning and disinfecting in pullet houses.* The rule requires a similar cleaning and disinfecting routine for both pullet houses and layer houses. Therefore, the per house costs and the number of houses affected are calculated similarly to the costs for cleaning and disinfecting a layer 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 14 of this document), the probability of a positive flock, and the number of pullet houses.[77] The total annual cost of cleaning and disinfecting pullet houses that test environmentally positive is $226,000.

x. *Follow-up egg testing and diversion.* Upon an environmental positive, farms must begin egg testing on the positive flock within 2 weeks of the start of egg laying. Farms that test positive for SE in their eggs would be required to divert their eggs for treatment until they are able to show via testing that SE is not present in the eggs produced in the infected house.

xi. *Current Industry Practices—Follow-up egg testing and diversion.* Comments to the proposed rule suggest that farms do not typically test eggs when a pullet house tests positive for SE. FDA therefore estimates that all pullet flocks in houses that test environmentally positive will be affected by this provision.

xii. *Cost of egg testing and diversion.* Total costs are estimated once again using the testing and diversion model described in section V.F.1.l of this document. The model takes into account prevalence of SE in the environment and the farmer's decision between egg testing and immediate diversion to minimize costs.[78] The prevalence of SE in pullet flocks is relatively low compared to layer flocks. Data gathered from comments, citing PEQAP and CEQAP databases, show that the environmental prevalence of SE in pullet houses ranges from 0 to 1.5 percent. We use a uniform distribution bound between 0 and 1.5 percent to estimate that 0.75 percent of pullet houses would currently test environmentally positive.

The per test cost of egg testing is discussed in detail in section V.F.1.f of this document. The cost of diverted eggs is discussed in detail in section V.F.1.g of this document. To summarize, we find the weighted average cost of diversion to be between $0.13 and $0.23 per dozen eggs. If there is an additional discount for those eggs with SE, the total cost could rise as high as $0.33 per dozen eggs.

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 IN PULLET HOUSES, FOLLOW-UP EGG TESTING, AND DIVERSION: ROW-BASED SAMPLING

[Thousands of dollars]

Farm size (number of layers)	Number of houses	Environmental testing	Egg testing	Diversion	Total cost
3,000 to 19,999	815	$58	$53	$50	$161
20,000 to 49,999	432	31	47	18	96
50,000 to 99,999	198	14	22	12	48
Over 100,000	1,008	72	111	144	326
Farms with ≥ 3,000 layers		174	233	225	632

[76] For a detailed breakdown of per house environmental testing costs, see section V.F.1.e of this document.

[77] For a detailed discussion of cleaning and disinfecting costs, see previous section on cleaning and disinfecting costs for layer houses.

[78] The choice on whether to destroy the flock or move it to the layer house is also included in the pullet section of the testing and diversion model. However, except for very small flocks not covered by this rule, the cost of flock destruction, including the cost of disposal, bird replacement costs, and lost production, is much greater than the costs of egg testing and diversion. Therefore, FDA believes nearly all farms covered by this rule will choose to test eggs rather than destroying the flock upon and environmental positive in the layer flock.

TABLE 27—TOTAL COST OF TESTING IN PULLET HOUSES, FOLLOW-UP EGG TESTING, AND DIVERSION: RANDOM SWAB SAMPLING

[Thousands of dollars]

Farm size (number of layers)	Number of houses	Environmental testing	Egg testing	Diversion	Total cost
3,000 to 19,999	815	$811	$53	$50	$914
20,000 to 49,999	432	429	47	18	495
50,000 to 99,999	198	197	22	12	231
Over 100,000	1,008	1,003	111	144	1,258
Farms with ≥ 3,000 layers		2,440	233	225	2,897

Table 26 of this document shows that the estimated eventual total cost of testing in the pullet house and diversion is approximately $0.6 million when row-based sampling is used. If a random swab method of environmental sampling is used, as in table 27 of this document, the estimated costs increase to $2.9 million.

xiii. *Benefits of SE-monitored chicks and pullets.* While the primary purpose of an SE monitoring program is to ensure that pullets entering layer houses producing table eggs are SE free, testing and diversion will also directly reduce SE infection by preventing SE-positive eggs from reaching consumers. Furthermore, cleaning and disinfecting a house after an environmental positive will help ensure SE does not spread and infect current and future flocks on the same farm.

As stated in the previous section, FDA estimates that the national prevalence of SE in pullet houses varies uniformly from 0 to 1.5 percent, for an average of 0.75 percent. As with layer houses, we estimate that 26 percent of houses that are environmentally positive also will have eggs that test positive (Ref. 105).

These figures imply that 12 million eggs from affected farms would be diverted due to environmental testing in the pullet house and follow-up eggs testing and diversion. We expect eggs to be positive at a rate of 2.75 per 10,000 in an SE-positive house (Ref. 92). Therefore, we estimate that an average of 3,200 SE-positive eggs would be diverted annually. Given a total estimated number of positive eggs of 1.5 million, we estimate that diversion would decrease the number of SE-related illnesses by 0.2 percent. This translates to potentially 306 illnesses (valued at about $5.5 million) prevented annually.

The chick and pullet program will potentially prevent 320 illnesses per year, for a total benefit of about $5.7 million. The total annual cost per illness of the program is $6,500. The annual net benefits for the chick and pullet provisions are $3.6 million.[79]

j. *Summary of costs and benefits of on-farm SE prevention measures.* Table 28 of this document summarizes the costs and benefits of the on-farm SE prevention measures. In this paragraph we emphasize some of the key features of these summary estimates. First, because the effectiveness of rodent and other 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 provisions. Therefore, table 28 reflects the incremental effects of each provision starting from a baseline of no new regulation. 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 some of the provisions are substitutes in benefits, particularly diversion and rodent and other pest control, the actual benefits of combinations of provisions, as well as the final 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 of this document.

TABLE 28—SUMMARY OF ANNUAL COSTS AND BENEFITS OF ON-FARM MEASURES

	Costs (millions of dollars)	Cases of SE averted (eventual)	Cost per case of SE averted	Total benefits (millions of dollars)	Net benefits (millions of dollars)
Rodent and Pest Control[4]	$21.4	38,954	$529	$697.3	$675.9
Biosecurity		[1]	[1]	[1]	[1]
Cleaning and Disinfecting	0.3	[1]	[1]	[1]	[1]
Refrigeration	20.2	44,727	451	800.6	780.4
Environmental Tests (average)	4.6	[2, 3]	[2, 3]	[2, 3]	[2, 3]
Egg Tests	9.7	[2]	[2]	[2]	[2]
Diversion	12.5	15,312	1,343	274.1	261.6
SE Monitored Chicks and Pullets	2.1	320	6,494	5.7	3.6

[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.
[4] This calculation nets out feed savings.

[79] These figures are correct if the chick procurement provisions and the pullet provisions are put in place simultaneously, so the costs and benefits of the pullet provisions are net the effect of the change in SE prevalence due to the chick procurement provision. Because the chick procurement provisions alone only reduce prevalence by about 0.01 percent, the difference, if calculated separately, is less than 1 illness per year.

k. *Other on-farm prevention measures considered.* This section analyzes the costs and benefits of two prevention measures, SE-monitored feed, and flock vaccination, considered by the FDA, but not required by the final rule.

i. *SE-negative feed provisions.* We considered requiring 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 BAM 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 report on the feed manufacturing industry estimates that egg producers operated a total of 144 feed mills in 1984 (Ref. 111). In the absence of more recent data, we assume that they operated the same number in 2006. 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. 112). Using this database, we were able to isolate 210 mills that primarily produce poultry and chicken feeds. This figure is our low estimate of the number of independent feed mills producing layer feed. For a high estimate, we assume that all 2,459 establishments that Dun's Market Identifiers reports as producers of animal feed produce layer feed.[80] 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 low and high estimates, 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 tested. In addition, SE-positive feed would have to be treated or destroyed.

The laboratory cost per test has been estimated to be approximately $61.00 per sample.[81] In addition, we estimate that the collection and preparation of each subsample will take approximately 10 minutes. Given an hourly wage of $15.51 for production inspectors at grain and feed mills (Ref. 113), plus 50 percent to include overhead costs, we estimate the cost of labor to be $38.78 ($23.27 x 1.667 hours) for each full sample. The cost of shipping each sample to a lab is estimated to be $30.20.[82] The total cost per composite sample is about $130 ($61.00 + $38.78 + $30.20).

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 three times a week. Consequently, the expected annual cost of testing for a typical feed mill is calculated to be approximately $20,300 ($130 per sample $\times$ 52 weeks $\times$ 3 times a week). The cost of testing all of the approximately 1,450 entities that produce feed is estimated to be $29.4 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 affected farms would be $29.2 million.

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, we assume that the mill would recall this feed and treat or dispose of it, which could be very costly.

iv. *Benefits of monitoring feed for SE.* Feed contaminated with SE is theoretically also a vehicle for the introduction of SE on the farm. Testing for SE in finished layer feed at mills has almost never yielded positive results. However, SE has been isolated in ingredients at feed mills so SE contamination of feed is a potential problem (Ref. 114).

If finished 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.

v. *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.

vi. *Current industry practices; vaccination of flocks.* The Layers study (Refs. 27 and 28) estimates that at least 14.6 percent of all layers on farms with 3,000 or more layers are vaccinated against SE.

vii. *Cost of vaccinating flocks.* Estimation of vaccination costs range from approximately $0.13 per layer (Ref. 115) to $0.15 per layer[83] for an inoculation. The average of these estimates is an expected vaccination cost of $0.14 per layer for an inoculation.[84] Given 272.1 million layers on larger farms and 1.4 million layers on smaller farms, we expect that this provision would result in 232.2 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 $31.2 million.

viii. *Benefits of vaccinating flocks.* While vaccines have shown some promise in the lab, there is insufficient evidence from field trials about their efficacy to estimate any benefit from their use.

In a controlled environment vaccines were found to reduce incidence of intestinal colonization and mean number of SE shed in the feces. Further, in a controlled setting, the same vaccines have been shown to reduce the number of SE-positive eggs laid when compared to non-vaccinated controls (Ref. 116). Hens were vaccinated at 38 weeks of age followed by a booster 4 weeks later and subsequently challenged intravaginally 2 weeks later. Despite the high level of SE recovery from cloacal and vaginal swabs of vaccinated and unvaccinated hens, vaccination resulted in a significant

[80] The low 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.

[81] This is the cost of an Association of Official Analytical Chemists test for *Salmonella* genus and a serotype test at Silliker Laboratories (Ref. 99). One option that mills have is to initially test for the genus of *Salmonella* ($28.00) and then, if the test is positive, follow through with a test for the serotype enteritidis ($33.00). 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.

[82] The cost of shipping a 2-pound package overnight in the United States ranges from $21.15 to $39.25. These figures include a $6 pickup charge. The average charge is estimated to be $30.20 (Ref. 98).

[83] This is based on a per layer cost of $0.035 for vaccine plus $0.10 for labor (Ref. 115), adjusted for inflation.

[84] These costs are recalculated in terms of year 2005 constant dollars using the GDP deflator.

decrease in the number of SE-positive eggs when compared to non-vaccinated controls (19 percent versus 37 percent, respectively). The degree of protection was only partial though, because more than half the population was still shedding SE at a high rate (Ref. 116).

However, the primary test for efficacy of a vaccine is a field trial, and it is common for vaccines to be effective in the laboratory but fail to perform up to expectations under field conditions. In a series of Pennsylvania field studies, despite the use of SE vaccine, 63.6 percent of the houses had SE-positive environmental cultures and 100 percent of the flocks had SE organ positive birds. With regard to all parameters tested, there were no statistical differences between vaccinated or unvaccinated controls—indicating the ineffectiveness of either commercially available bacterins or autogenously manufactured SE vaccines (Ref. 117). Lab results show promise for vaccines to become a useful tool in fighting SE transmission to eggs in the future. However, currently, there is no vaccine that has been shown to be efficacious in the field. Therefore, FDA is not requiring vaccination in this final rule.

2. Administrative Measures

a. *Plan design and recordkeeping.*—i. *Plan design and recordkeeping provisions.* Each farm site with 3,000 or more layers that sells raw eggs to the table egg market, other than directly to the consumer, and does not have the eggs treated, must design and monitor an SE prevention plan. This prevention plan includes 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) refrigeration, and (6) testing and diversion. Records are also required for review and of modifications of the SE prevention plan and corrective actions taken. Farms are 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. 27 and 28), 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.[85] 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 (number of layers)	Number of farms	Houses per farm	Percent of farms on a quality assurance program	Farms affected by the rule	Houses affected by the rule
3,000 to 19,999	1,746	1.4	4.9	1,661	2,325
20,000 to 49,999	925	1.4	27.7	669	936
50,000 to 99,999	248	2.4	58	104	250
100,000 or more	409	7.4	59.7	165	1,219
All farms	3,328	1.4	21.9	2,599	4,730

As table 29 of this document shows, we expect that a total of 2,598 farm sites with 4,730 poultry houses would be affected by plan design and recordkeeping provisions.

iii. *Plan design costs.* The per provision plan design cost is calculated in table 30 of this document. Because information on the costs of designing the SE prevention 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 plan component will take approximately 20 labor hours to design. We add 50 percent to the cost of labor for designing the plan to account for overhead. The cost of designing a plan with one component is expected to be $560 ($27.98 × 20) (Ref. 89). Amortized over 10 years at 7 percent, the total cost of plan design will be about $207,000 ($80 per farm) per provision. Amortized over 10 years at 3 percent, the total cost of plan design for all farms will be about $171,000 ($66 per farm) per provision. For six provisions (rodent and other pest control, biosecurity, cleaning and disinfecting, chick and pullet procurement, refrigeration, and testing and diversion), the total cost of the plan design would be $1.2 million when amortized over 10 years at 7 percent ($1.0 million when amortized over 10 years at 3 percent).

TABLE 30—COST OF PLAN DESIGN PER PROVISION

Farm size (number of layers)	Farms affected by the proposal	Cost per farm	Total costs (in thousands of dollars)
3,000 to 19,999	1,661	$560	$930
20,000 to 49,999	669	560	375
50,000 to 99,999	104	560	58
100,000 or more	165	560	92
All farms	2,599	560	1,455
Amortized over 10 years at 7%	.....	.....	207

[85] 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.

iv. *Recordkeeping costs.* We assume that the time required for recordkeeping is roughly equivalent to the time necessary to monitor and document the food safety 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 control points and monitoring, this assumption tends to overstate the cost of recordkeeping for a provision of this final rule. In particular, we expect that, for each house affected, recordkeeping will take one half hour per week per required provision for provisions that would require weekly or daily monitoring. Records kept for biosecurity measures, rodent and other pest control and refrigeration are assumed to be recorded on a weekly basis.

The cost of weekly recordkeeping for biosecurity and rodent and other pest control, assuming $18.65 an hour for labor, plus 50 percent to reflect overhead costs, would be $727 ($27.98 × 0.5 hours × 52 weeks) per record, per house. The total annual cost for all houses for these two records is $3.4 million ($27.98 × 0.5 hours × 52 weeks × 4,730 houses). Refrigeration records, collected weekly on a farm-by-farm basis, rather than by-house, will cost $1.9 million annually ($27.98 × 0.5 hours × 52 weeks × 2,598 farms).

Environmental and egg sampling and testing, diversion and treatment records [86] together have daily, weekly, and monthly aspects, in the event of an environmental positive. In the case of an environmental positive, the records' annual cost is assumed to be similar to the cost estimated for the weekly records discussed previously, $727 per record, per house. However, as discussed previously in this document FDA estimated that 9.7 percent of houses will test environmentally positive initially and 7.0 percent will test positive after the provisions of this rule have taken effect. Additionally, farms would have to keep records of egg testing, diversion, and treatment if they receive pullets from a house that has tested environmentally positive; FDA estimated that pullet houses will test positive 0.75 percent of the time. The cost for houses that test negative would be similar to keeping an annual record [87]; at a half hour per record the annual cost would be $14 per record, per house. The initial total annual cost of the environmental and egg testing, diversion, and treatment records is $0.4 million (((0.097 × $727) + (0.903 × $14) + (0.0075 × $727)) × 4,730 houses). The eventual total expected cost of the environmental and egg testing, diversion, and treatment records is about $0.3 million (((0.070 × $727) + (0.930 × $14) + (0.0075 × $727)) × 4,730 houses).

Records of chick and pullet procurement and records of cleaning and disinfection will take one half hour each, per year, per house. At a half hour per record, the annual cost will be $14 per record, per house. These two records will cost farms $0.1 million (2 records × $14 × 4,730 houses).

In the event of an environmental positive, the farm must review and modify as necessary its plan design. FDA estimates this will take roughly half the time (10 hours per provision) than it took to originally draft the plan. To calculate how many farms will need to review their plans, the estimation of 9.7 percent of houses testing positive initially and 7.0 percent of houses testing positive eventually is applied.[88] The initial total expected cost of the plan design review and modification records is $0.8 million (0.097 × ($280 × 6 provisions) × 4,730 houses). The eventual total expected cost of the plan design review and modification records is $0.6 million (0.070 × ($280 × 6 provisions) × 4,730 houses).

We assume that pullet growers will keep a record of each environmental test performed on a per house, per flock basis. Each house can hold approximately 3 flocks per year and, as comments to proposed rule state, there are roughly one third as many pullet houses as there are layer houses. At a half hour per record, the annual cost would be $42 per pullet house ($14 × 3 records annually). The total annual expected cost of environmental testing records for pullet houses is $66,200 ($42 × 1,577 houses).

The calculation of the initial and eventual costs of $10.2 million and $9.8 million, respectively, for all records for affected farms is shown in table 31 of this document.

TABLE 31—TOTAL COST OF ON-FARM RECORDKEEPING

Record kept	Total cost (in thousands of dollars)	
	Initial	Eventual
Chick and pullet procurement	$66	$66
Rodent and pest control	3,440	3,440
Biosecurity	3,440	3,440
Cleaning and disinfection	66	66
Refrigeration	1,890	1,890
Testing, diversion, and treatment	419	328
Design plan review and modification	770	556
Environmental testing for pullet houses	66	22
Total	10,158	9,809

b. *Training.* The person responsible for overseeing the SE prevention measures will have to be trained or have equivalent job experience. Under the final rule, one person may oversee the SE prevention measures on more than one farm. Alternatively, more than one person may be trained to oversee a single farm. The latter is likely on some of the larger operations. FDA assumes that, on average, one person will need to be trained to oversee preventions measures on each farm covered by the rule. A training course would last 2 to 3 days. The cost of taking a course

[86] Including stamping documents accompanying diverted egg shipments. The cost of the actual rubber stamp is assumed to be negligible.

[87] The cost of environmental tests to pullet houses is discussed in a separate paragraph.

[88] This may tend to overstate costs because farms with 3,000 layers or more have on average more than one house per farm. Some of the 459 (0.097 × 4,730 houses) houses expected to test positive initially could be located on the same farm and test positive at roughly the same time as one or more other SE-positive houses. This would require only one review and modification of the entire plan.

consists of tuition, the cost of the supervisor's labor while in class (opportunity cost), and any travel related expenditures that may be incurred.

The cost of a recent 3-day HACCP training course was advertised to be $600 to $650 (Ref. 118).[89] The cost of the supervisor's labor is estimated to be $895 (32 hours[90] × $27.98 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 $1,850 ($625 tuition + $895 labor + $330). Not all producers will have to send a supervisor to a class. The 12 percent of large farms with established 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 1,299 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, whether amortized at 7 percent or 3 percent, is estimated to be $0.3 million.

c. *Registration.*—i. *Registration provision.* Under this provision, all farms covered by any part of the rule are required to register with FDA. Registration of all producers covered by any of the SE prevention measures will enable more efficient inspection, as well as better management and oversight of a shell egg recall.

ii. *Current industry practices—registration.* FDA assumes that no farms are currently registered with the FDA.[91] Therefore, this provision will affect all farms with 3,000 or more layers.

iii. *Registration costs.* We assume that the time required for registration under this rule is roughly equivalent to the time necessary to register a domestic facility under the Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 rule (68 FR 5378 at 5392 to 5403, February 3, 2003) (BT registration rule). In particular, FDA expects that it will take farms with access to the Internet, either through their own computer, or through a friend, public library, or internet café, 2 hours to research the requirements, fill out the form and send it in. We expect that for farms without easy access to the Internet, due to increased time for research and to send the documents, the process will take 3 hours.

FDA assumes the number of farms with easy access to the Internet is similar to the number used in the BT Registration Rule (68 FR 5378 at 5392 to 5403), that is, 71 percent of farms. This number has two potential biases. The first is that the 71 percent of farms used in the BT Registration Rule is related to small businesses in general, not specifically to farms. Because farms are typically rural, whereas small business in general may be rural or urban, the estimate for all small businesses may overstate the Internet access for farmers. That being said, FDA believes that the small business estimate is a good proxy for farms, and it is the most detailed data available. The second bias comes from the fact that the survey data used in the BT regulations is relevant to the year 2002. Internet access has certainly increased since that particular data was published.

We estimate that approximately 3,328 farms with 3,000 or more layers are covered by a registration provision. We assume the value of labor is $18.65 per hour, plus 50 percent for overhead costs, for a total cost of $55.95 per producer with Internet access and $83.93 for producers with no Internet access. The total one-time cost to the industry is $0.2 million (($27.98 × 3,328 farms) × ((0.71 × 2) + (0.29 × 3))). Amortized at 7 percent, the annual cost of one-time registration is $30,400. Amortized at 3 percent, the annual cost of registration is expected to be $25,000.

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 are essential for farmers to effectively implement SE prevention measures. Further, the administrative measures are critical for FDA to be able to ensure compliance, and thus for the benefits of the SE prevention measures to be realized.

TABLE 32—ANNUAL COST OF ADMINISTRATIVE PROVISIONS

[Thousands of dollars]

Plan design	$1,243
Recordkeeping	9,809
Training	343
Registration	30
Total	11,425

G. Summary of Benefits and Costs of the Final Rule

In the previous section of this document, we described and estimated the benefits and costs of all of the SE prevention measures we have considered. Here, we summarize and estimate the benefits and costs of the final rule.

1. Coverage

All of the on-farm SE prevention measures in the final rule 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. Only the refrigeration and registration requirements apply to farms whose eggs all receive a treatment to destroy SE. Only the refrigeration requirement applies to persons who transport and supply shell eggs for shell egg processing or egg products facilities.

2. Provisions of the Final Rule

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

[89] The cost of a similar 3-day HACCP training course for egg processors was advertised to be $450 to $550 in 2000 (Ref. 119) and was offered through the U.S. Poultry and Egg Association. It is no longer offered. The course sited above is a course geared towards meat processors. In a conversation with the International HACCP Alliance, FDA confirmed that a similar course geared towards egg farmers, if offered today, would cost roughly the same amount ($600 to $650).

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

[91] Farms are not required to register under FDA's Registration of Food Facilities regulation (68 FR 5378 at 5392 to 5403). If a farm also has a packing or processing facility, then only the packing or processing facility is required to register under the registration rule (68 FR 5378 at 5392 to 5403). If the information that would be provided by an egg producer during registration has already been provided under the registration regulation, the producer may submit its registration number rather than registering again.

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

c. *Administrative provisions.* All of the administrative provisions discussed in this analysis are required by the final rule. In particular, the rule requires that producers maintain records for chick and pullet procurement, biosecurity, rodent and other pest control, cleaning and disinfecting, refrigeration, and testing and diversion.

Farms are required to use SE prevention measures and are required to have a written SE prevention plan. Each farm is required to have a trained or otherwise qualified individual to administer the prevention measures required by the final rule.

Furthermore, all farms covered by any part of the rule are required to register with FDA.

3. Summary of Costs and Benefits

In table 33 of this document, we summarize the costs and illnesses averted of this final 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 final rule will prevent approximately 79,170 cases of SE per year at a cost of $1,000 per illness averted. This value is less than the lowest estimate of the expected value of an SE related illness, shown in table 5 of this document. Furthermore, table 34 shows the cost per estimated QALY saved. Assuming a 7-percent discount rate, we estimate the rule will save approximately 5,055 QALYs annually. Assuming a 3-percent discount rate, the estimated number of QALYs saved annually is 8,708. This translates to $16,100 per QALY saved using a 7-percent discount rate and $9,300 per QALY saved using a 3-percent discount rate.[92] Either estimate falls well below our most conservative estimate of $100,000 for the value of a quality adjusted statistical life year.

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

TABLE 33. SUMMARY OF ANNUAL COSTS AND BENEFITS OF FINAL RULE

	Costs (Millions of Dollars)		Illnesses Averted		Cost per Illness Averted (Thousands of Dollars)		Total Benefits (Millions of Dollars)		Net Benefits (Millions of Dollars)	
Provision	Initial	Eventual	Initial	Eventual	Initial	Eventual	Initial	Eventual	Initial	Eventual
On-Farm Measures										
Rodent and Pest Control[1]	$21.4	$21.4	19,477	38,866	$1.4	$0.7	$348.6	$695.7	$327.2	$674.3
Biosecurity	$5.3	$5.3	--[1]		--[1]		--[1]		--[1]	
Cleaning and Disinfecting	$0.3	$0.3	--[1]		--[1]		--[1]		--[1]	
Refrigeration	$20.2	$20.2	33,682	28,888	$0.6	$0.7	$602.9	$517.1	$582.7	$496.9
Environmental Testing (Average)	$4.6	$4.6	--[2,3]		--[2,3]		--[2,3]		--[2,3]	
Egg Testing	$9.7	$7.0	--[2]		--[2]		--[2]		--[2]	
Diversion	$12.5	$9.0	15,312	11,096	$1.7	$1.9	$274.1	$198.6	$261.6	$189.6
Procurement of SE-Monitored Chicks and Pullets	$2.1	$2.1	320	320	$6.5	$6.5	$5.7	$5.7	$3.6	$3.6
On-Farm Administrative Measures										
Plan Design	$1.2	$1.2	--		--		--		--	
Recordkeeping	$10.2	$9.8	--		--		--		--	
Training	$0.3	$0.3	--		--		--		--	
Registration	$0.03	$0.03	--		--		--		--	
Total	$87.7	$81.2	68,790	79,170	$1.3	$1.0	$1,231.3	$1,417.1	$1,143.6	$1,335.9

[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.

BILLING CODE 4164–01–C

TABLE 34—COSTS PER QALY SAVED

	Eventual costs (millions of dollars)	QALYs saved		Cost per QALY saved (thousands of dollars)	
Discount rate		3%	7%	3%	7%
Provision					
On-Farm Measures					
Rodent and Pest Control [1]	$21.4	4,275	2,481	$6.3	$10.9
Biosecurity	5.3	--[1]		--[1]	
Cleaning and Disinfecting	0.3	--[1]		--[1]	

TABLE 34—COSTS PER QALY SAVED—CONTINUED

	Eventual costs (millions of dollars)	QALYs saved		Cost per QALY saved (thousands of dollars)	
Discount rate		3%	7%	3%	7%
	0.0				
Refrigeration	20.2	3,177	1,844	6.3	10.9
Environmental Testing (Average)	4.6	[2,3]		[2,3]	
Egg Testing	7.0	[2]		[2]	
Diversion	9.0	1,221	708	16.9	29.0
Procurement of SE-Monitored Chicks and Pullets	2.1	35	20	59.0	101.7
On-Farm Administrative Measures					
Plan Design	1.2				
Recordkeeping	9.8				
Training	0.3				
Registration	0.0				
Total	81.2	8,708	5,055	9.3	16.1

[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.

The mean estimated dollar values of the benefits, the complete range and discussion of which is shown in table 37 of this document, range from $228 million to over $9.5 billion, depending on the uncertainty in the efficacy of the provisions and baseline number of illnesses, and the assumptions made about VSL, QALY, and the discount rate. The lowest estimate of annual benefits is well above the high estimate of $117 million estimated annual costs of the rule. Using the assumption set resulting in our central estimate (VSL of $5 million, a VSLY of $300,000, and a discount rate of 7 percent) gives us estimated benefits of $1.5 billion, or net benefits in excess of $1.4 billion. Considering the widest range of benefits and costs, net benefits of the final rule could be as low as $111 million annually and as high as $9.4 billion annually.

The benefits of some provisions in the final rule are slightly lower in table 33 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 rule reduces the base line number of illnesses that is used to estimate the benefits of the next provision in the list. In this way, table 33 can also be used to illustrate the costs and lower 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 each is accounted for, these estimates can be added together, or mixed and matched, to achieve a rough estimate of the lower bound effects of different combinations of provisions. Between table 28 of this document and table 33, a bounded estimate of the incremental effect of each provision is achieved.

Table 33 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.

4. Analysis of Uncertainty

In table 33 of this document and elsewhere we present the expected effects of the final 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 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 34 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 final rule will lie between $57.5 million and $116.5 million. A complete description of the distributions underlying the estimates of uncertainty can be found in Ref. 106. While some of the range is driven by uncertainty in unit costs of adopting the provisions, much of the range is a product of uncertainty in baseline practices. Indeed, the largest contributor to the range in total cost, the uncertainty in the cost of the rodent and pest control provisions, is due in large part to the uncertainty in the current baseline practices and extent of current rodent and pest problems.

TABLE 35—COSTS OF THE FINAL RULE: ANALYSIS OF UNCERTAINTY

[Millions of dollars] [1]

On-farm measures	5th Percentile	Mean	95th Percentile
Rodent and Pest Control	$12.0	$22.5	$36.1
Biosecurity	4.9	5.3	5.7
Cleaning and Disinfecting	0.1	0.3	0.5
Refrigeration	15.6	20.2	24.7
Environmental Testing	3.4	4.6	5.7
Egg Testing	4.6	7.0	12.1
Diversion	4.9	9.0	16.1
SE Monitoring of Chicks and Pullets	1.9	2.1	2.2
On-Farm Administrative Measures	10.0	11.3	13.2
Total Costs of Final Rule	57.5	82.2	116.5

[1] *See* Ref. 106 for a description of the distributions underlying this table.

In tables 36 and 37 of this document, we characterize the uncertainties associated with the benefits of the final rule. The expected annual benefits in terms of illness averted from the final rule range from nearly 30,000 SE illnesses averted to over 191,000 cases of SE illnesses averted.

TABLE 36—ILLNESSES AVERTED BY THE FINAL RULE: ANALYSIS OF UNCERTAINTY[1]

Provision on-farm measures	5th Percentile	Mean	95th Percentile
Rodent and Pest Control	6,405	38,866	123,772
Biosecurity	Included in Rodent and Pest Control		
Cleaning and Disinfecting	Included in Rodent and Pest Control		
Refrigeration	9,305	28,888	73,724
Testing and Diversion	3,382	11,096	46,634
SE Monitoring of Chicks and Pullets	21	320	1,233
Total	29,853	79,170	191,273

[1] *See* Ref. 106 for a description of the distributions underlying this table.

Table 37 of this document shows the estimated annual benefits in constant 2005 dollars range from $228 million to $9.5 billion. A complete description of the distributions underlying the estimates of uncertainty can be found in Ref. 106. The large range is due in great part to the uncertainties underlying the economic assumptions and number of baseline illnesses. The range is also affected by the uncertainty that expected target efficacies are met (e.g.: rodent and pest control, biosecurity, and cleaning and disinfecting, and refrigeration), the underlying prevalence of SE (e.g.: testing and diversion), and the uncertainty in baseline practices of all provisions. Under very reasonable economic assumptions, the expected benefits of the final rule exceed the expected costs, regardless of uncertainty in efficacy of the provisions, the underlying prevalence of SE on farms, baseline practices, or even the uncertainty inherent in the estimation of baseline number of illnesses.

TABLE 37—ESTIMATED VALUE OF ALL ILLNESSES AVERTED, GIVEN DIFFERENT ECONOMIC ASSUMPTIONS

[Millions of dollars] [1, 2, 3, 4]

	Discount rate = 3%					
	VSL = $5 million			VSL = $6.5 million		
	5th Percentile	Mean	95th Percentile	5th Percentile	Mean	95th Percentile
VSLY = $100 thousand	$355.9	$943.8	$2,280.2	--	--	--
VSLY = $300 thousand	907.5	2,406.7	5,814.6	926.7	2,457.6	5,937.5
VSLY = $500 thousand	--	--	--	1,478.3	3,920.5	9,471.9
	Discount rate = 7%					
	VSL = $5 million			VSL = $6.5 million		
	5th Percentile	Mean	95th Percentile	5th Percentile	Mean	95th Percentile
VSLY = $100 thousand	$227.6	$603.5	$1,458.1	--	--	--
VSLY = $300 thousand	534.4	1,417.1	3,423.8	553.6	1,468.0	3,546.7

	Discount rate = 7%					
	VSL = $5 million			VSL = $6.5 million		
	5th Percentile	Mean	95th Percentile	5th Percentile	Mean	95th Percentile
VSLY = $500 thousand	__	__	__	860.4	2,281.7	5,512.5

[1] *See* Ref. 106 for a description of the distributions underlying this table.
[2] VSL means Value of a Statistical Life.
[3] VSLY means Value of a Statistical Life Year.
[4] VSL and effects of long term arthritis are annualized over 50 years.

Tables 35 through 37 of this document show that the range of potential costs is much narrower than the range of potential benefits. The monetary estimates of benefits cover a broad range largely because of the different values placed on cases of chronic reactive arthritis that result from SE illness. The higher the VSLY used to value the health effects of chronic reactive arthritis, the higher the estimated monetary benefits of this final rule.

Even the lowest 5th percentile of estimated benefits, under the most conservative reasonable assumptions, exceeds the 95th percentile of estimated costs.

5. Rule as Final Versus Rule as Proposed

Table 38 of this document shows the estimated costs and benefits of the final rule versus the proposed rule. The proposed rule estimates have been updated to correct model errors, add new data, and express costs and benefits in terms of 2005 constant dollars.

TABLE 38—SUMMARY OF ANNUAL COSTS AND BENEFITS AS ESTIMATED FOR THE FINAL AND PROPOSED RULES

[Millions of dollars]

Provision	Costs		Illnesses averted		Total benefits		Net benefits	
	Final	Proposed	Final	Proposed	Final	Proposed	Final	Proposed
On-Farm Measures								
Rodent and Pest Control [1]	$21.4	$21.4	38,866	38,950	$695.7	$697.2	$668.7	$659.3
Biosecurity	5.3	13.7	__[1]		__[1]		__[1]	
Cleaning and Disinfecting	0.3	2.8	__[1]		__[1]		__[1]	
Refrigeration	20.2	13.5	28,888	20,286	517.1	363.1	496.9	349.6
Environmental Testing (Average)	4.6	4.6	__[2, 3]		__[2, 3]		__[2, 3]	
Egg Testing	7.0	6.9	__[2]		__[2]		__[2]	
Diversion	9.0	8.0	11,096	9,541	198.6	170.8	178.1	151.4
Procurement of SE-Monitored Chicks and Pullets	2.1	0.1	320	14	5.7	0.3	3.6	0
On-Farm Administrative Measures								
Plan Design	1.2	1.2	__		__		__	
Recordkeeping	9.8	9.8	__		__		__	
Training	0.3	0.3	__		__		__	
Registration	0.03	0	__		__		__	
Total	81.2	82.2	79,170	68,791	1,417.1	1,231.4	1,335.9	1,149.1

[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.

The annual costs are about $1.0 million higher for the final rule, as provisions were added that were not included in the proposed rule; the most notable additions are the additional refrigeration provisions. However, some costs associated with the biosecurity and cleaning and disinfecting provisions decrease between the proposed and final rule. Cost decreased because, as suggested by comments to the proposed rule, some of the more prescriptive or less effective elements of the provisions were removed.

Illnesses averted (and therefore total benefits) as well as net benefits are much higher in the final rule, due mainly to increased refrigeration provisions and the earlier required environmental test for flocks post-molt. We estimate that the final rule will avert about 10,400 additional illnesses annually and provide for more than $185 million in additional annual net benefits, when compared to the proposed rule.

Table 38 of this document shows the benefits of the rules, with all provisions in place simultaneously. This is worth noting because it appears that the rodent and other pest control, biosecurity, and cleaning and disinfecting provisions are less effective in the final rule. However, this is simply because the chick and pullet provision is more effective in the final rule, so the baseline SE prevalence in flocks upon entry to the layer house is lower in the final rule than in the proposed rule. For the same reason, table 38 likely understates the effectiveness of the refrigeration, and testing and diversion, and other provisions if they were implemented on their own.

VI. Final Regulatory Flexibility Analysis

A. Introduction

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The agency believes that this final rule will have a significant economic impact on a substantial number of small entities. The comments received concerning the Initial Regulatory Flexibility Analysis (IRFA) and Proposed Regulatory Impact Analysis (PRIA) are contained in Section V.C.

B. Economic Effects on Small Entities

1. Regulated Entities

a. *Number of small entities affected.*[93] The Small Business Administration (SBA) defines chicken and egg producers to be small if their total revenues are less than $11.5 million (Ref. 120). A producer that receives $0.45 per dozen eggs and has layers that produce 265 eggs per year would have to have over 1,100,000 layers in production to earn revenues of over $11.5 million. Because only about 400 farms fall into the category of 100,000 or more layers, more than 99 percent of the farms with more than 3,000 layers are considered small by SBA standards, and account for roughly 60 percent of all production.[94]

b. *Costs to small entities.* The final rule will result in costs to small businesses. These costs are presented in Table 39 of this document. For the industry as a whole, the average annual cost of the final rule is estimated to be about $24,100 per farm site covered by the rule. This translates into an average cost of $0.30 per layer. Because almost all farms are defined by SBA to be small, these overall industry costs are representative of the average costs to small farms.

TABLE 39—DISTRIBUTION OF COST BY FARM SIZE, AND AS A PERCENTAGE OF REVENUE

Farm size (number of layers)	Annual per farm cost of rule [1]	Annual per layer cost of rule	Cost as a percentage of revenue [2]
Less than 3,000	$0	$0	$0
3,000 to 19,999	12,295	1.01	7.95%
20,000 to 49,999	13,899	0.49	3.86%
50,000 to 99,999	25,794	0.36	2.83%
100,000 or more	96,847	0.19	1.50%
All farms	24,130	0.30	2.36%

[1] These figures are derived from calculations made in the Regulatory Impact Analysis (RIA).
[2] The average revenue between 2001–2008 was $12.40 per hen. For the purposes of calculating cost as a percentage of revenue, before dividing categorical costs by average revenue, FDA adds the average per hen cost to the average per hen revenue. Thus, we implicitly assume that the costs of the rule will be passed on to the consumer. Although not quantified, it is possible that revenues actually increase after the publication of the rule, as consumers perceive eggs to be safer.

2. Other Affected Entities [95]

a. *Number of small entities affected.* i. *Introduction.* The final rule requires that layer farms use layers that were raised in SE-monitored chick and pullet flocks and that they hold and ship shell eggs under proper refrigeration. In addition to affecting layer farms, the final rule will likely have an impact on some small chick and pullet farmers, trucking companies, and holding facilities.

ii. *Chick and pullet farms.* As with layer farms, nearly 100 percent of all chick and pullet farms are considered small by SBA definition. We were unable to break out the number of chick and pullet farms by data from NAICS or NASS,[96] but, based on comments received, we estimate that there are roughly one third as many pullet-raising farms and chick-raising farms as there are layer farms affected by the rule. Also from comments, we learned that pullet farms participate in state EQAPS at the same rate as layer farms. Accordingly, approximately 1,000 pullet houses will be affected by the rule. Because nearly all chicks are currently raised as certified SE-monitored (95 percent), some 50 or fewer of these facilities will be affected.

iii. *Trucking companies and holding facilities.* SBA defines trucking companies and holding facilities for farm products to be small if their total revenues are less than $23.5 million annually (Ref. 120). By this definition, FDA estimates that over 80 percent of trucking companies and over 60 percent of holding facilities are small (Ref. 121). Thus, more than 300 holding facilities that are affected by the final rule are small by SBA definition.[97]

[93] Please refer to Table 6 for a breakdown of the size of layer farms affected by the rule.

[94] FDA does not know the exact percentage of production that comes from farms with more than 1.1 million layers, since the NASS Census of Agriculture (Ref. 71) does not include detail on the industry above 100,000 layers. For the purpose of this calculation, we assume that half of the eggs produced on farms with more than 100,000 layers are produced on farms that are small by SBA definition.

[95] The costs calculated for layer farms in Table 39 include the costs to chick and pullet farms, transport companies, and holding facilities. FDA believes that layer farms will absorb much of the costs associated provisions affecting these other entities.

[96] NASS does not break pullet farms down by size of operation. The 25,624 pullet farms listed in the 2002 NASS (Ref. 71) are roughly one fourth the total number of layer farms listed. For the purposes of this analysis, we used data received from public comment that indicated there are roughly one third as many pullet farms as there are farms affected by the rule.

[97] FDA only estimated the number of new refrigerated shipments necessary due to the final rule. There are nearly 57,000 general freight trucking establishments (ref. 121). More than 47,000 of these are small by SBA definition. We do not have information on the number of trucking companies that specifically ship eggs from farms with 3,000 or more layers and will therefore be affected by the final rule.

b. *Costs to small entities.* i. *Chick and pullet farms.* We do not have data for the cost of monitoring chicks for SE. However, Morales and McDowell (Ref. 91) 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 in the RIA for this rule to be about $87,000, for a cost of about $1,700 per chick farm if roughly 50 are affected. This cost will be borne by pullet growers but could be passed on to egg farms depending on market conditions.

In addition, pullet houses must be tested for environmental SE before the pullets are transferred to the layer houses. If the environment tests positive, the house must be cleaned and disinfected before another flock enters the house. Furthermore, upon an environmental positive in the pullet house, layer farms must begin egg testing on the positive flock within 2 weeks of the start of egg laying. Farms that test positive for SE in their eggs would be required to divert their eggs for treatment until they are able to show via testing that SE is not present in the eggs produced in the infected house. The cost of the additional steps, cleaning and disinfecting, and egg testing and diversion, depends on the prevalence of SE in pullet houses. From data gathered from comments, FDA estimates that the prevalence of SE in pullet houses is 0 to 1.5 percent. Based on these factors, as shown in detail in the RIA for this rule, FDA estimates the total costs generated by the provisions addressing pullets is about $2 million annually, or about $2,000 per pullet farm, per year. FDA expects that some of these costs could be passed on to the layer farms.[98]

ii. *Trucking companies and holding facilities.* Based on the cost per cubic foot of extra refrigeration necessary to meet the 45 °F threshold, FDA estimates that the refrigeration requirement will cost the smallest holding facilities less than $500 annually and the largest holding facilities (those holding more than 1 million eggs at a time) more than $18,000 annually, for an industry average of nearly $10,000 in increased costs per facility each year. If we assume that the costs for increased refrigeration are proportional to revenues (because costs are directly proportional to the volume of eggs held) the smallest 60 percent of holding facilities will incur increased annual costs of between $500 and $11,000. The larger numbers in this range will be incurred by the larger facilities still meeting SBA's definition of small.

FDA does not have information on the cost of the refrigeration provision to trucking companies. However, FDA estimates that the large majority of eggs are currently shipped in refrigerated trucks. For eggs that are not currently shipped at 45 °F, FDA estimates that the provision will cost approximately $0.02 per dozen eggs shipped, or $1.7 million across the industry.

C. Regulatory Options

1. Exemption for Small Entities

i. 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 previously, under the SBA size standards the vast majority of entities affected by this final rule are small. Small farms include not only farms with a few hundred layers, but also some larger farms with over 100,000 layers.

An alternative approach, implemented in the final rule, exempts producers with fewer than 3,000 layers at a particular farm.[99] While over 90 percent of farm sites have fewer than 3,000 layers, less than 1 percent of the eggs produced in the United States are produced on these farms.

FDA has decided to exempt all farms with fewer than 3,000 layers and those farms that sell all of their eggs directly to consumers.

By exempting these farms, we reduce expected benefits by less than 1 percent while reducing expected costs by more than one half. Table 40 of this document shows a detailed breakdown of the potential costs and benefits of regulating farms with less than 3,000 layers.

TABLE 40—SUMMARY OF ANNUAL COSTS AVERTED AND BENEFITS FOREGONE BY EXEMPTING FARMS LESS THAN 3,000 LAYERS

[Millions of dollars]

	Costs	Illnesses averted	Total benefits	Net benefits
Provision				
On-Farm Measures				
Rodent and Pest Control [1]	$16.0	189	$3.4	−$21.5
Biosecurity	8.3	__ [1]	__ [1]	__ [1]
Cleaning and Disinfecting	0.5	__ [1]	__ [1]	__ [1]
Refrigeration	6.1	147	2.6	−3.5
Environmental Testing (Average)	6.8	__ [2, 3]	__ [2, 3]	__ [2, 3]
Egg Testing	0.0	__ [2]	__ [2]	__ [2]
Diversion	0.3	198	3.6	−3.5
Procurement of SE-Monitored Chicks and Pullets	2.3	21	0.4	−1.9
On-Farm Administrative Measures				
Plan Design	10.9	__	__	__
Recordkeeping	56.9	__	__	__
Training	6.7	__	__	__
Registration	0.42	__	__	__

[98] To see the effects of the costs if passed completely to layer farms, please refer to Tables 39 and 33.

[99] 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.

TABLE 40—SUMMARY OF ANNUAL COSTS AVERTED AND BENEFITS FOREGONE BY EXEMPTING FARMS LESS THAN 3,000 LAYERS—Continued

[Millions of dollars]

	Costs	Illnesses averted	Total benefits	Net benefits
Total	115.3	556	9.9	−105.3

[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.

The exemption of farms with less than 3,000 layers carries over to entities potentially affected by, but not directly regulated by, the rule. Pullet farms supplying layer farms with less than 3,000 layers, will not necessarily need to prove SE-monitored status. Trucks and storage facilities holding eggs only for farms with less than 3,000 layers need not be refrigerated at 45 °F.

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. Because of this, FDA is giving farm sites with 3,000 or more, but fewer than 50,000 layers, 3 years (as opposed to 1 year for larger farm sites) to comply with this rule. The longer compliance period also affects chick and pullet flocks supplied to farms, and the shipment and storage of eggs for farms with between 3,000 and 50,000 layers.

FDA will continue to evaluate the impact of this rule on smaller farms and will consider taking appropriate steps to mitigate those impacts, where it is possible to do so without reducing safety. Further, FDA will publish guidance for all covered egg producers, and small entity compliance guides, which will help inform and educate small businesses on the requirements of the rule. We plan to use guidance, to the extent feasible, as a vehicle to identify areas where compliance could be achieved via flexible approaches that would mitigate the financial impact while preserving the public health benefits of the rule. Stakeholder participation in these documents will be solicited and considered.

D. Description of Recordkeeping and Recording Requirements

The Regulatory Flexibility Act requires a description of the recordkeeping required for compliance with this final rule. Each farm site that sells raw (untreated) eggs to the table egg market, other than directly to the consumer, must design and monitor an SE-prevention plan. This prevention plan includes all measures the farm is taking to prevent SE in its flock. The following elements must be included in the plan: (1) Chicks and pullets, (2) biosecurity, (3) rodent and other pest control, (4) cleaning and disinfecting, (5) refrigeration, and (6) testing and diversion. Records are also required for review and of modifications of the SE-prevention plan and corrective actions taken. Farms are required to have a trained or experienced supervisor that would be responsible for overseeing the plan. Furthermore, all farms covered by any part of the rule are required to register with FDA. The cost of recordkeeping is exhibited in Table 41 of this document. We detail in section V.F of this document how recordkeeping costs are calculated.

TABLE 41—COST OF RECORDKEEPING BY FARM SIZE

Farm size (number of layers)	Per farm cost of recordkeeping	Per layer cost of recordkeeping
Less than 3,000	$0	$0.00
3,000 to 19,999	2,070	0.17
20,000 to 49,999	2,070	0.07
50,000 to 99,999	3,143	0.04
100,000 or more	8,509	0.02
All Farms	2,941	0.04

E. Summary

FDA finds that, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), this final rule will have a significant impact on a substantial number of small entities. More than 1,000 small farms will be affected by the final rule.

VII. Unfunded Mandates

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product.[100] FDA has determined that this final rule is significant under the Unfunded Mandates Reform Act. FDA has carried out the cost-benefit analysis in preceding sections. The other requirements under the Unfunded Mandates Act of 1995 include assessing the rule's effects on:

- Future costs;
- Particular regions, communities, or industrial sectors;
- National productivity;
- Economic growth;
- Full employment;
- Job creation; and
- Exports.

The issues listed above are covered in detail in the cost benefit analysis of the

[100] In table 7 of this document, describing the total costs of the rule, costs are annualized. When costs are not annualized, particularly the first year costs of refrigeration, the total initial costs are clearly more than $127 million.

preceding sections, with the exception of the trade effects of this final rule, which we will discuss here.

Given the fragile and highly perishable nature of table eggs and the restrictions imposed by USDA to ensure safety of imported animals and animal products (9 CFR part 94), few eggs are imported into the United States. Only three countries, Canada, Mexico, and New Zealand are permitted to export shell eggs to the United States. Further, since 2004, only New Zealand continues to send shell eggs to the United States (Ref. 122). In 2006, a firm from New Zealand shipped 55,112 dozen eggs to the United States. These eggs originated from a single farm in New Zealand with a little more than 3,000 layers (Ref. 122). These eggs represent about one one-thousandth of the eggs produced in the United States annually.

In order to qualify to export eggs to the United States, New Zealand egg production is already highly regulated. Therefore, it is unlikely the farm that produces the exports to the United States would bear even the average cost estimated for a similar sized farm in the United States. However, if we assume the costs are similar across countries, the final rule would cost the New Zealand farm, or similar exporting farms, about $3,000 annually, or about $0.04 per dozen eggs produced.

VIII. Small Business Regulatory Enforcement Fairness Act

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 or more; 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 final rule is a major rule for the purpose of congressional review.

IX. Paperwork Reduction Act of 1995

This final 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 and reporting burdens. 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: (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 FDA'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 through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation—Recordkeeping and Registration Provisions Under 21 CFR Part 118.

Description: FDA is requiring shell egg producers to implement measures to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation. Each farm site with 3,000 or more egg laying hens that sells raw eggs to the table egg market, other than directly to the consumer, and does not have all of the eggs treated, must design and monitor an SE prevention plan. This prevention plan includes all measures the farm is taking to prevent SE in its flock. Records are also required for each of the provisions included in the plan and for plan review and modifications if corrective actions are taken. Furthermore, all farms covered by any part of the rule are required to register with FDA.

We have concluded that recordkeeping is necessary for the success of the SE prevention measures. Written SE prevention plans and records of actions taken due to each provision are essential for farms to implement SE prevention plans effectively. Further, they are essential for FDA to be able to determine compliance.

Description of Respondents: Businesses or other for-profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 42—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1, 6]

21 CFR section	Number of record-keepers [2]	Annual frequency of recordkeeping	Total annual records	Hours per recordkeeper	Total hours
118.10(a)(1) [5]	2,600	1	2,600	20	52,000
118.10(a)(2)	4,731	1	4,731	0.5	2,366
118.10(a)(3)(ii)	4,731	52	246,012	0.5	123,006
118.10(a)(3)(i)	4,731	52	246,012	0.5	123,006
118.10(a)(3)(iii) [5]	459	1	459	0.5	230
118.10(a)(3)(iii)	331	1	331	0.5	166
118.10(a)(3)(iv)	2,600	52	135,200	0.5	67,600
118.10(a)(3)(v) through (a)(3)(viii) [3, 4, 5]	471	52	24,492	0.5	12,246
	5,837	1	5,837	0.5	2,919
118.10(a)(3)(v) through (a)(3)(viii) [3, 4]	343	52	17,836	0.5	8,918
	5,965	1	5,965	0.5	2,983
118.10(a)(4) [5]	459	1	459	10	4,590
118.10(a)(4)	331	1	331	10	3,310
Total hours for first year					387,962
Total recurring hours					331,354

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] Some records are kept on a by-farm basis and others are kept on a by-house basis. See section V.F of this document for a detailed description of the breakdown.

[3] The annual frequency of records kept for this provision depends on whether the house actually tests positive for SE.

[4] Calculations include requirements for pullet and layer houses.
[5] First year burden.
[6] Calculations include the burden on foreign firms. FDA identified a single farm with more than 3,000 layers in New Zealand that exports shell eggs to the United States.

FDA estimates the recordkeeping burden of this final rule to be 387,962 hours in the first year, and 331,354 each year thereafter, as shown in table 42 of this document.

The number of recordkeepers estimated in column 2 of table 42 of this document are based on estimates of the total number of layer and pullet houses affected by this final rule from statistics obtained from the Layers study, NASS, and comments to the proposed rule. 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 recordkeeping provisions. Using data from the Layers study (Refs. 27 and 28), 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. The estimated number of layer farms incurring a new recordkeeping burden because of this rule is 2,600, and the number of houses affected is 4,731. A detailed breakdown of this estimation is shown in table 29 of this document.

Plan design (§ 118.10(a)(1)) and refrigeration records (§ 118.10(a)(3)(iv)) will be kept on a per farm basis, so the number of recordkeepers for these provisions is 2,600. Plan design is a first year burden only.

Records of chick and pullet procurement (§ 118.10(a)(2)), rodent and other pest control (§ 118.10(a)(3)(ii)), and biosecurity (§ 118.10(a)(3)(i)) will be kept on a per house basis, so the number of recordkeepers for these provisions is 4,731.

Records of cleaning and disinfection (§ 118.10(a)(3)(iii)) will also be kept on a per house basis, but will only need to be kept in the event that a layer house tests environmentally positive. Design plan and review (§ 118.10(a)(4)) will also need to be performed every time a house tests positive. As discussed in section V.F of this document, FDA estimates that 9.7 percent of houses will test environmentally positive initially and 7.0 percent will test positive after the provisions of this rule have taken effect. Therefore, the number of recordkeepers for these provisions is estimated to be 459 (4,731 houses × 0.097) in the first year and 331 (4,731 houses × 0.070) annually after the first year.

Records of testing, diversion, and treatment (§ 118.10(a)(3)(v) through (a)(3)(viii)) will be kept on a per house basis and will include records on flocks from pullet houses. From data provided by comments, FDA estimates that there are one third as many pullet houses as there are layer houses. Therefore the total number of recordkeepers for these provisions is 6,308 (4,731 + (4,731/3)). The number of annual records kept depends on whether houses test positive for SE or not. This is further discussed in the following paragraphs.

Because information on the costs of designing the SE prevention 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). In particular, we assume that each plan component will take approximately 20 hours to design. In the event of an environmental positive, the farm must review and modify as necessary its plan design. FDA estimates this will take roughly half the time (10 hours per provision) that it took to originally draft the plan.

We assume that the time required for recordkeeping is roughly equivalent to the time necessary to monitor and document the food safety 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 control points and monitoring, this assumption tends to overstate the cost of recordkeeping for a provision of this final rule. In particular, we expect that, for each house affected, recordkeeping will take one half hour per week per provision that would require weekly or daily monitoring. Records kept for biosecurity measures, rodent and pest control, and refrigeration are assumed to be recorded on a weekly basis.

Records for chick and pullet procurement and cleaning and disinfection will only have to be collected roughly once per year and are assumed, as above, to require one half hour to produce each record.

Environmental and egg sampling and testing, diversion and treatment records together have daily, weekly, and monthly aspects, in the event of an environmental positive. In the case of an environmental positive, the record's annual burden is assumed to be similar to the burden estimated for the weekly records discussed previously. If a house tests environmentally negative, the burden is similar to the yearly burden estimated above. In the first year, 471 layer and pullet houses ((4,731 layer houses × 0.097) + ((4731/3 pullet houses) × 0.0075)) are expected to test positive and 5,837 are expected to test negative ((4,731 layer houses × 0.903) + ((4731/3 pullet houses) × 0.9925)). In following years 343 layer and pullet houses ((4,731 layer houses × 0.070) + ((4731/3 pullet houses) × 0.0075)) are expected to test positive [101] and 5,965 are expected to test negative ((4,731 layer houses × 0.930) + ((4731/3 pullet houses) × 0.9925)).

The reporting burden due to the registration requirement is shown in table 43 of this document.

TABLE 43—ESTIMATED ANNUAL REPORTING BURDEN [1, 4]

21 CFR section	FDA form No.	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
118.11 [3]	FDA 3733 [2]	3,329	1	3,329	2.3	7,657

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The term "Form FDA 3733" refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Registration Module, which will be available at *http://www.access.fda.gov* per § 118.11(b)(1).
[3] First year burden.

[101] As discussed in section V.F.1.i of this document, the pullet houses are estimated to test positive at only a rate of 0.75 percent.

[4] Calculations include the burden on foreign firms. FDA identified a single farm with more than 3,000 layers in New Zealand that exports shell eggs to the United States.

The registration requirement will be a new, one time reporting burden for all farms with more than 3,000 layers. FDA used NASS to estimate that there are 3,329 such farms, as detailed in section V.D of this document. Using experience gained from implementing section 415 of the FFDCA (21 U.S.C. 350d), FDA estimates that listing the information required by the final rule and presenting it in a format that will meet the agency's registration regulations will require a burden of approximately 2.3 hours per average facility registration. As detailed in section V.F of this document, FDA expects that it will take farms with access to the Internet 2 hours to register and for farms without easy access to the Internet it will take 3 hours to register. FDA assumes the number of farms with easy access to the Internet is similar to the number used in the BT Registration Rule (68 FR 5378 at 5392 to 5403), that is, 71 percent of farms. The average facility burden hour estimate of 2.3 hours takes into account that some respondents completing the registration may not have readily available Internet access (29 percent).

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 final rule to OMB for review. Interested persons are requested to fax comments regarding information collection by (*see* **DATES**), to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, FAX: 202–395–6974.

Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

X. Analysis of 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.

XI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132 on federalism. We have examined the effects of the requirements of this rule on the relationship between the Federal Government and the States. The agency concludes that preemption of State or local rules that establish requirements for the prevention of *Salmonella* Enteritidis (SE) in shell eggs during production, storage, or transportation that are less stringent than those in this rule is consistent with this Executive order and has added § 118.12(d) to the rule to reflect this preemptive effect.

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 prevention of SE in shell eggs during production, storage, and transportation would undermine the agency's goal of ensuring that shell eggs are produced, stored, and transported using measures that will prevent their contamination with SE. These requirements are the minimal national prevention measures that we believe are necessary to ensure safety. However, the requirements of this final rule do not preempt State and local laws, regulations, and ordinances that establish more stringent requirements with respect to prevention of SE in shell eggs during production, storage, or transportation.

Section 4(e) of the Executive order provides that, ''when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.'' As required by the Executive order, FDA provided the States and local governments with an opportunity for appropriate participation in this rulemaking when it sought input from all stakeholders through publication of the proposed rule in the **Federal Register** on September 22, 2004 (69 FR 56824 at 56889). In the proposal, FDA specifically described this preemptive effect. The proposal stated that, through this notice of proposed rulemaking, State and local governments have a chance to participate in the proceedings, and that 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 that proposed rule. In addition, we sent facsimiles of a **Federal Register** document announcing a public meeting of 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.

Further, subsequent to the publication of the proposed rule, the agency held three public meetings to discuss the provisions of the rule, answer questions, and solicit comments from stakeholders. Meetings were held October 28, 2004, in College Park, MD; November 9, 2004, in Chicago, IL; and November 16, 2004, in Los Angeles, CA. Additionally, presentations on the proposed rule were made to the following groups: Iowa Egg Industry Symposium in Ames, IA, on November 10, 2004; Central Atlantic States Association of Food and Drug Officials Meeting in Laurel, MD, in December 2004; Agricultural Research Service—Food Safety and Inspection Service Joint Food Safety Meeting in Shepherdstown, WV, in Spring 2005; National Egg Regulatory Officials Meeting in Orlando, FL, in March 2005; National Egg Quality School in Indianapolis, IN, in May 2005; and National Egg Regulatory Officials Meeting in Oklahoma City, OK, in March 2006. Both State and local government officials attended and participated in these meetings.

As a result of the extensive outreach FDA conducted during the proposed rule notice and comment period to provide State and local officials with the opportunity for meaningful input, we received comments from numerous State government agencies. Many of the comments support FDA in developing a national standard for the prevention of SE in shell eggs during production, storage, and transportation. In fact, one State agency commented that ''we completely agree with proposed regulations that make measures already taken by many producers voluntarily, mandatory for all producers * * *.'' Another State agency stated that, ''Overall FDA's proposal to require SE prevention measures for egg production would provide for an effective nationwide program to reduce SE. The prevention measures outlined in the proposal have proven to be effective in the existing State programs.''

FDA recognizes that existing voluntary State programs using egg quality assurance plans (EQAPs) have been successful in reducing SE contamination in poultry houses in certain states, as discussed in section I.G of this document. However, as discussed in response to comment 1 in section III of this document, these programs are not uniformly administered or equally comprehensive in their prevention measures. In addition, currently the EQAPs that exist are voluntary for shell egg producers. Although the existing EQAPs have similar requirements, they vary in how those requirements are implemented. This rule will establish uniform, nationwide requirements to prevent SE in shell eggs during production, storage, and transportation. FDA believes that these uniform, nationwide requirements will further reduce SE illness and deaths associated with egg consumption.

Although comments received from the State agencies agreed that uniform, nationwide requirements would be most effective, many States commented that inspections and enforcement by State Departments of Agriculture would be the most effective method of implementing these nationwide requirements. They commented that many States have been conducting similar inspections to ensure compliance with state EQAPs and have the expertise and knowledge to conduct inspections for FDA. We agree that we can enlist the assistance of existing EQAP organizations and State and/or local officials in implementing FDA's regulation. The rule provides that a State or locality may, in its own jurisdiction, enforce this rule by carrying out inspections under § 118.12(b) and by using the administrative remedies in § 118.12(a) unless FDA notifies the State or locality in writing that its assistance is no longer needed. FDA plans to provide guidance to States and localities through an enforcement and implementation guidance subsequent to this final rule.

In conclusion, the agency has determined that the preemptive effects of this final rule are consistent with Executive Order 13132.

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. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. Centers for Disease Control and Prevention, ''Fact Sheets: Salmonella,'' Office of Communication Media Relations, July 16, 1999.
2. Centers for Disease Control and Prevention Memorandum from Chief, Foodborne Diseases Epidemiology Section, February 8, 1996.
3. Swerdlow, D.L., L.A. Lee, R.V. Tauxe, N.H. Bean, and J.Q. Jarvis, ''Reactive Anthropathy Following a Multistate Outbreak of *Salmonella* typhimurium Infections,'' Abstract 916, Thirtieth Interscience Conference on Antimicrobial Agents and Chemotherapy.
4. Zorn, D.J. and K. Klontz, Appendix: The Value of Consumer Loss to Foodborne Reactive Arthritis (63 FR 24253, May 1, 1998).
5. Voetsch, A.C., T.J. Van Gilder, F.J. Angulo, M.M. Farley, S. Shallow, R. Marcus, P.R. Cieslak, V.C. Deneen, R.V. Tauxe, for the Emerging Infections Program FoodNet Working Group. FoodNet estimate of the burden of illness caused by nontyphoidal *Salmonella* infections in the United States. *Clinical Infectious Diseases* 2004; 38 (Suppl 3): S127–34.
6. Mead, P.S., L. Slutsker, V. Dietz, L.F. McCaig, J.S. Bresee, C. Shapiro, P.M. Griffin, and R.V. Tauxe, ''Food-Related Illness and Death in the United States,'' *Emerging Infectious Diseases* 5:607–625, 1999.
7. Centers for Disease Control and Prevention, *Salmonella* Surveillance Annual Tabulation Summary, 2001.
8. Centers for Disease Control and Prevention, *Salmonella* Surveillance Annual Tabulation Summary, 2004.
9. Centers for Disease Control and Prevention, Salmonella Surveillance Annual Tabulation Summary, 2005.
10. Centers for Disease Control and Prevention, Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food—10 States, 2008. MMWR 2009; 58:333–337.

11–12. Centers for Disease Control and Prevention, ''Outbreaks of *Salmonella* Serotype Enteritidis Infection Associated with Eating Raw or Undercooked Shell Eggs—United States, 1996–1998'', MMWR 2000; 49:73–79.

13. CDC memorandum, Frederick J. Angulo to the Record, July 10, 2007.
14. Mishu, B., J. Koehler, L.A. Lee, D. Kodrigue, F., Hickman Brenner, P. Blake, and R.V. Tauxe, ''Outbreaks of *Salmonella* Enteritidis infections in the United States'', 1985–1991, *Journal of Infectious Disease* 169: 547–552, 1994.
15. Centers for Disease Control and Prevention, ''Outbreaks of *Salmonella* Serotype Enteritidis Infection Associated with Eating Shell Eggs—United States, 1999–2001'', MMWR 2003; 51:1149–1152.
16. U.S. Department of Health and Human Services, Healthy People 2010: Understanding and Improving Health. 2nd ed. Washington, DC: U.S. Government Printing Office, November 2000. Accessed online at *http://www.healthypeople.gov/Document/tableofcontents.htm#under*, June 26,2009.
17. Memorandum of estimates presented by Christopher Braden of Centers for Disease Control and Prevention at the public meetings for ''Prevention of *Salmonella* Enteritidis in Shell Eggs During Production; Proposed Rule'', Oct. 28, 2004, Nov. 9, 2004, and Nov. 16, 2004.
18. Keller, L.H., C.E. Benson, K. Krotec, and R.J. Eckroade, ''*Salmonella* enteritidis Colonization of the Reproductive Tract and Forming of Freshly Laid Eggs of Chickens,'' *Infection and Immunity* 7:2443–2449, 1995.
19. Snoeyenbos, G.H., C.F. Smyser, and H. Van Roekel, ''*Salmonella* Infections of the Ovary and Peritoneum of Chickens,'' *Avian Diseases* 13:668–670, 1969.
20. Humphrey, T.J., ''Contamination of Egg Shell and Contents with *Salmonella* enteritidis: A Review,'' *International Journal of Food Microbiology* 21:31–40, 1994.
21. Baker Jr., A.R., E.D. Ebel, R.M. McDowell, R.A. Morales, W.D. Schlosser, and R. Whiting, *Salmonella* Enteritidis Risk Assessment Team, *Salmonella* Enteritidis Risk Assessment: Shell Eggs and Egg Products, Washington, DC: United States Department of Agriculture, June 12, 1998.
22. Coleman, M., E. Ebel, N. Golden, A. Hogue, A. Kadry, J. Kause, H. Latimer, H. Marks, N. Quiring, W. Schlosser, and C. Schroeder, Risk Assessments of *Salmonella* Enteritidis in Shell Eggs and *Salmonella* spp. in Egg Products, Washington, DC: United States Department of Agriculture, October 2005.
23. Ebel, E. and Schlosser, W. ''Estimating the annual fraction of eggs contaminated with SE in the U.S.'' International Journal of Food Microbiology. 61:51–62, 2000.

24. American Egg Board, ''Egg Industry Facts Sheet,'' February 3, 2000.
25. National Agricultural Statistics Service, United States Department of Agriculture, Layers and Egg Production 1998 Summary, January 1999.
26. National Agricultural Statistics Service, ''Table 20. Poultry Inventory and Sales: 1997 and 1992,'' 1997 Census of Agriculture: United States Summary and State Data, vol. 1, part 51, U.S. Department of Agriculture, Accessed at *http://www.agcensus.usda.gov/Publications/1997/Vol_1_Chapter_1_U._S._National_Level_Data/us-51/us1_19.pdf*, June 2009.
27. National Animal Health Monitoring System, Animal and Plant Health Inspection Service, United States Department of Agriculture, ''Layers '99, Part I: Reference of 1999 Table Egg Layer Management in the U.S.'' October 1999.
28. National Animal Health Monitoring System, Animal and Plant Health Inspection Service, United States Department of Agriculture, ''Layers '99, Part II: Reference of 1999 Table Egg Layer Management in the U.S.'' January 2000.
29. National Animal Health Monitoring System, Animal and Plant Health Inspection Service, United States Department of Agriculture, ''Layers '99: *Salmonella* enterica serotype Enteritidis in Table Egg Layers in the U.S.'' October 2000.
30. Pennsylvania Poultry Federation, ''Pennsylvania Egg Quality Assurance Program,'' revised April 1997, 500 N. Progress Ave., Harrisburg, PA 17109.
31. California Egg Industry, ''California Egg Quality Assurance Program,'' California Department of Food and Agriculture, 1220 N Street, rm. A–107, Sacramento, CA 95814.
32. New York State, ''New York State Egg Quality Assurance Program,'' 1 Winners Circle, Albany, NY 12235.
33. Maryland Department of Agriculture, ''Egg Quality Assurance Program,'' April 2, 1997, 50 Harry S. Truman Pkwy., Annapolis, MD 21401.
34. Ohio Poultry Association, ''Ohio Egg QA Program,'' 5930 Sharon Woods Blvd., Columbus, OH 43229.
35. United Egg Producers, ''UEP 5-Star Total QA Program,'' 1303 Hightower Trail, suite 200, Atlanta, GA 30350.
36. United States Animal Health Association, ''National Standardized *Salmonella* Enteritidis Reduction Program for Eggs,'' 8100 3 Chopt Rd., suite 203, P.O. Box K227, Richmond, VA 23288.
37. E-mail Correspondence between J. Bradley Brown, FDA, and Jim Austin, June 21 and October 13, 2005.
38. E-mail memorandum dated February 16, 2007 from Barbara Robinson of Agricultural Marketing Service to John Sheehan of Center for Food Safety and Applied Nutrition.
39. Axtell, R.C., ''Integrated Fly-Control Program for Caged-Poultry Houses,'' Journal of Economic Entomology 63:400–405, 1970.
40. Scott, H.G. and K.S. Littig, ''Flies of Public Health Importance and Their Control, Training Guide-Insect Control Series,'' U.S. Department of Health, Education, and Welfare, Public Health Service, Communicable Disease Center, Atlanta, GA 30333.
41. Meyer, J.A., B.A. Mullens, T.L. Cyr, and C. Stokes (1990) Commercial and Naturally Occurring Fly Parasitoids (Hymenoptera: Pteromalidae) as Biological Control Agents of Stable Flies and House Flies (Diptera: Muscidae) on California Dairies, *Journal of Economic Entomology* 83(3):799–806.
42. Andress, E.R. and J.B. Campbell (1994) Inundative Releases of Pteromalid Parasitoids (Hymenoptera: Pteromalidae) for the Control of Stable Flies, Stomoxys calcitrans (L.) (Diptera: Muscidae) at Confined Cattle Installations in West Central Nebraska, *Journal of Economic Entomology* 87(3):714–722.
43. Weinzierl, R.A. and C.J. Jones (1998) Releases of *Spalangia nigroaenea* and *Muscidifurax zaraptor* (Hymenoptera: Pteromalidae) Increase Rates of Parasitism and Total Mortality of Stable Fly and House Fly (Diptera: Muscidae) Pupae in Illinois Cattle Feedlots, *Journal of Economic Entomology* 91(5):1114–1121.
44. Kaufman, P.E., S.J. Long, D.A. Rutz, and J.K. Waldron (2001) Parasitism Rates of *Muscidifurax raptorellus* and *Nasonia vitripennis* (Hymenoptera: Pteromalidae) After Individual and Paired Releases in New York Poultry Facilities, *Journal of Economic Entomology* 94(2):593.598.
45. Hinton, J.L. and R.D. Moon (2003) Arthropod Populations in High-Rise, Caged-Layer Houses After Three Manure Cleanout Treatments, *Journal of Economic Entomology* 96(4):1352–1361.
46. Kim, C.J., D.A. Emery, H. Rinkle, K.V. Nagaraja, and D.A. Halvorson, ''Effect of Time and Temperature on Growth of *Salmonella* enteritidis in Experimentally Inoculated Eggs,'' *Avian Diseases* 33:735–742, 1989.
47. Humphrey, T.J., ''Growth of Salmonellas in Intact Shell Eggs: Influence of Storage Temperature,'' *The Veterinary Record,* 126:292, 1990.
48. Bradshaw, J.G., D.B. Shah, E. Forney, and J.M. Madden, ''Growth of *Salmonella* enteritidis in Yolk of Shell Eggs from Normal and Seropositive Hens,'' *Journal of Food Protection* 53:1033–1036, 1990.
49. Coleman, M., E. Ebel, N. Golden, A. Hogue, A. Kadry, J. Kause, H. Latimer, H. Marks, N. Quiring, W. Schlosser, and C. Schroeder, Draft Risk Assessments of *Salmonella* Enteritidis in Shell Eggs and *Salmonella* spp. in Egg Products, Washington, DC: United States Department of Agriculture, October 22, 2004.
50. Memorandum from Richard Wood, Food Animal Concerns Trust, to Lou Carson, Food and Drug Administration, August 25, 2000.
51. United States Department of Agriculture, PA Poultry Producers, PA Poultry Federation, Egg Association of America, PA Department of Agriculture, PA State University, and the University of PA, ''*Salmonella* Enteritidis Pilot Project Progress Report,'' May 22, 1995.
52. Holt, P.S., ''Effect of Induced Molting on the Susceptibility of White Leghorn Hens to a *Salmonella* Enteritidis infection,'' *Avian Diseases* 37:412–417, 1993.
53. United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, Balmer, M.F., ''Traceback and On Farm Investigations of *Salmonella* Enteritidis Outbreaks,'' 1996 to 2003.
54. FDA memorandum, Qian Graves to the Record, September 9, 2004.
55. Relative Effectiveness of Selective Plating Agars for Recovery of *Salmonella* Species from Selected High-Moisture Foods, P.S. Sherrod, R.M. Amaguana, W.H. Andrews, G.A. June and T.S. Hammack, *Journal of AOAC International* Vol. 78, No. 3, 1995.
56. Centers for Disease Control and Prevention, *Salmonella* Surveillance Annual Tabulation Summary, 2000.
57. FoodNet, Foodborne Diseases Active Surveillance Network, *1999 Surveillance Results: Preliminary Report* Centers for Disease Control, March 2000.
58. Buzby, Jean C., T. Roberts, C.T. Lin, and J.M. MacDonald, *Bacterial Foodborne Disease: Medical Costs & Productivity Losses,* Washington, DC: Economic Research Service, U.S. Department of Agriculture, 1996.
59. Cutler, D.M. and E. Richardson, ''Measuring the Health of the U.S. Population,'' Brookings Paper, Microeconomics 1997, pp. 217–271.
60. Scharff, R.L. and A. Jessup, ''Valuing Chronic Disease for Heterogeneous Populations: The Case of Arthritis,'' working paper, 2000.
61. Williams, R.M., ''The Costs of Visits to Emergency Departments,'' *The New England Journal of Medicine* 334(10): 642–646, 1996.
62. *Consumer Price Index—All Urban Consumers,* Bureau of Labor Statistics, accessed online October 26, 2005.
63. Healthcare Cost and Utilization Project, *Nation Inpatient Sample (NIS)—2001,* Washington, D.C., Agency for HealthCare Research and Quality, 2003.
64. Garber, A.M. and C.E. Phelps, ''Economic Foundations of Cost-Effectiveness Analysis,'' *Journal Health Economics,* vol. 16, pp. 1–31, 1997.
65. U.S. Census Bureau, Statistical Abstract of the United States, pp. 413–416 and 436, 2002.
66. Viscusi, W.K. and J.E. Aldy, ''The Value of a Statistical Life: A Critical Review of Market Estimates throughout the World,'' *AEI–Brookings Joint Center for Regulatory Studies,* January 2003.
67. Alberini, A., M. Cropper, A. Krupnick, and N.B. Simon, ''Does the Value of a Statistical Life Vary with Age and Health Status? Evidence from the United States and Canada,'' *Resources for the Future,* Discussion Paper 02–19, April 2002.
68. *Campylobacter FAQ Page,* New Mexico Department of Health, accessed online August 11, 2000.
69. Humphrey, T.J., ''Contamination of Eggs and Poultry Meat with *Salmonella* Enterica Serovar Enteritidis,'' in *Salmonella Enterica Serovar Enteritidis*

in Humans and Animals, Iowa State University Press, Ames, IA, 1999.
70. Stadelman, W.J., ''Chapter 4: The Preservation of Quality in Shell Eggs,'' in *Egg Science and Technology,* Fourth Edition, Food Products Press, NY, 1995.
71. National Agricultural Statistics Service, ''Table 27. Poultry Inventory and Number Sold: 2002 and 1997,'' *2002 Census of Agriculture: U.S. National Level Data,* vol. 1, chapter 1, U.S. Department of Agriculture, Accessed at *http://www.agcensus.usda.gov/Publications/2002/Volume_1,_Chapter_1_US/st99_1_027_029.pdf*, June 2009.
72. E-mail Correspondence between Robert Scharff, FDA, and Deanna Baldwin, May 31, 2000.
73. E-mail Correspondence between Robert Scharff, FDA, and Michael Opitz, June 1, 2000.
74. E-mail Correspondence between Robert Scharff, FDA, and Phillip Debok, June 1, 2000.
75. National Agricultural Statistics Service, *Chicken and Eggs,* Washington, DC, United States Department of Agriculture, accessed online, February 20, 2007.
76. PA Poultry Federation. ''Comparison of PEQAP and Other Programs,'' 500 N. Progress Ave., Harrisburg, PA 17109.
77. FDA Memorandum, J. Bradley Brown to the Record, July 16, 2008.
78. Hoelscher, Clifford E., ''Poultry Pest Management,'' Texas Agricultural Extension Service, The Texas A&M University System, 1997.
79. ''Biosecurity for Poultry,'' Publication 408–310, Virginia Cooperative Extension Service, 1989.
80. Halvorson, David A., Good Management Practices for *Salmonella* Risk Reduction in the Production of Table Eggs, University of Minnesota Extension Service, 1997.
81. Evans, S.J., R.H. Davies, and C. Wray, ''Chapter 28: Epidemiology of *Salmonella* Enterica Serovar Enteritidis Infection in British Poultry Flocks'' in *Salmonella Enterica Serovar Enteritidis in Humans and Animals,* Iowa State University Press, Ames, IA, 1999.
82. FDA Memorandum, Research Triangle Institute to the Record, June 18, 2002.
83. Henzler, D.J. and H.M. Opitz, ''Role of Rodents in the Epidemiology of *Salmonella* Enterica Enteritidis and Other *Salmonella* Serovars in Poultry Farms,'' chapter 30 in *Salmonella Enterica Serovar Enteritidis in Humans and Animals Epidemiology, Pathogenesis, and Control,* Editor A.M. Saeed, Iowa State University Press, Ames, IA, 1999.
84. Wray, C. and R.H. Davies, ''Environmental Problems in Poultry Production: Dust and Pests,'' International Symposium on Food-Borne *Salmonella* in Poultry, Baltimore, MD, July 25–26, 1998.
85. Olsen, A.R. and T.S. Hammack, ''Isolation of *Salmonella* spp. from the Housefly, Musca domestica L., and the Dump Fly, *Hydrotaea aenescens* (Wiedemann) (Diptera: MU.S.C.idae), at Caged-Layer Houses,'' *Journal of Food Protection* 63:958– 960, 2000.
86. Berry, Joe, ''Rodent Control in the Poultry House'' Cooperative Extension Program, Division of Agriculture, Oklahoma State University, June 1987.
87. Thornberry, Fred D., ''Pest Control,'' Texas Agricultural Extension Service, The Texas A&M University System.
88. *Leonard Safety Equipment Catalog,* accessed online, October 18, 2006.
89. Bureau of Labor Statistics, *2005 National Occupational Employment and Wage Estimates,* Washington, DC, U.S. Department of Labor, accessed online October 16, 2006.
90. Carey, J.B., J.F. Prochaska, and J.S. Jeffrey, *Poultry Facility Biosecurity,* Texas Agricultural Extension Service, 1997.
91. Morales, R.A. and R.M. McDowell, ''Chapter 25: Economics Consequences of *Salmonella* Enterica Serovar Enteritidis Infection in Humans and the U.S. Egg Industry'' in *Salmonella Enterica Serovar Enteritidis in Humans and Animals,* Iowa State University Press, Ames, IA, 1999.
92. Schlosser, W.D., D.J. Henzler, J. Mason, D. Kradel, L. Shipman, S. Trock, S.H. Hurd, A.T. Hogue, W. Sischo, and E.D. Ebel, ''The *Salmonella* Enterica Serovar Enteritidis Pilot Project,'' Chapter 32 in *Salmonella Enterica Serovar Enteritidis in Humans and Animals Epidemiology, Pathogenesis, and Control,* Editor A.M. Saeed, Iowa State University Press, Ames, IA, 1999.
93. FDA Memorandum, Conversation with Roger Glasshoff about egg processor statistics, October 24, 2006.
94. FDA Memorandum, Roger Glasshoff, United States Department of Agriculture to the Record, November 2, 2006.
95. FDA Memorandum, Research Triangle Institute to the Record, September 3, 2000.
96. Energy Information Administration, *Average Retail Price of Electricity to Ultimate Consumer by End-Use Sector,* Energy Information Administration, accessed online, October 17, 2006.
97. Riemann, H., S. Himathongkham, D. Willoughby, R. Tarbell, and R. Breitmeyer, ''A Survey for *Salmonella* by Drag Swabbing Manure Piles in California Egg Ranches,'' *Avian Diseases,* vol. 42, pp. 67–71, 1998.
98. Federal Express, *FedEx Standard Overnight Per-Pound Rates,* Federal Express, accessed online October 24, 2006.
99. Memorandum to the record of phone conversation between J. Bradley Brown, FDA, and Silliker Laboratories, October 23, 2006.
100. E-mail Correspondence between Wallace Andrews, FDA, and Michele Smoot, September 29, 2005.
101. National Agricultural Statistics Service, *Egg Products* (issues covering January through December 1999), Washington, DC: U.S. Department of Agriculture, accessed online February 2, 2000.
102. Agricultural Marketing Service, *Grain Transportation Report,* United States Department of Agriculture, January 4, 2000.
103. Agricultural Marketing Service, *USDA AMS, Poultry Market News,* data accessed online through the Institute of Food and Agricultural Sciences, University of Florida, April 24, 2000.
104. Agricultural Marketing Service, *USDA AMS, Poultry Market News,* data accessed online through the North Carolina Department of Agriculture & Consumer Services, Division of Marketing, Market News, April 24, 2000.
105. Memorandum of estimates given by Phillip Debok at the Egg Safety Workshop, January 10–14, 2000.
106. FDA Memorandum, A detailed look at the testing and diversion model and underlying distributions behind uncertainty and variability analysis, January 19, 2007
107. Hogue, Allan, Chairperson, *Salmonella* Enteritidis Review Team, *Salmonella* Enteritidis Review Team Report, Washington, DC: Food Safety Inspection Service, U.S. Department of Agriculture, January 18, 1997.
108. Memorandum of estimate given by Michael Opitz at the Egg Safety Workshop, January 10–14, 2000.
109. E-mail Correspondence between Robert Scharff, FDA, and Andrew Rhorer, August 15, 2000.
110. Rhorer, A.R., ''Chapter 27: Control of *Salmonella* enterica Serovar Enteritidis Under the National Poultry Improvement Plan'' in *Salmonella enterica Serovar Enteritidis in Humans and Animals,* Iowa State University Press, Ames, IA, 1999.
111. Economic Research Service, *The Formula Feed Manufacturing Industry,* 1984, Washington, DC: U.S. Department of Agriculture, accessed online August 21, 2000.
112. Dun and Bradstreet, Dun's Market Identifiers, The Dialog Corp. Mountain View, CA, August 22, 2000.
113. Bureau of Labor Statistics, *2005 National Occupational Employment and Wage Estimates,* Washington, D.C., U.S. Department of Labor, accessed online October 23, 2006.
114. McChesney, D.G., G. Kaplan, and P. Gardner, ''FDA Survey Determines *Salmonella* Contamination,'' Feedstuffs 67, February 13, 1995.
115. Wood, Richard, ''The Comments of the Food Animal Concerns Trust About the Egg Safety Action Plan,'' Food and Drug Administration Docket No. 00N–0504.
116. Gast, R.K., H.D. Stone, P.S. Holt, ''Evaluation of the Efficacy of Oil-Emulsion Bacterins for Reducing Fecal Shedding of *Salmonella* Enteritidis by Laying Hens,'' *Avian Diseases* 37: 1085–91, 1993.
117. Miyamoto, T., D. Kitaoka, G.S.K. Withanage, T. Fukata, K. Sasai, and E. Baba. 1999. ''Evaluation of the Efficacy of *Salmonella Enteritidis* Oil-emulsion Bacterin in an Intravaginal Challenge Model in Hens.'' *Avian Diseases.* 43:497–505.
118. *International HACCP Alliance Training Activities,* HACCP Alliance, accessed online, November 14, 2004.
119. *U.S. Poultry & Egg Association Educational Programs,* U.S. Poultry and

Egg Association, accessed online August 8, 2000.
120. Small Business Association, ''Small Business Size Standards by NAICS Industry'', United States Small Business Association, accessed online via GPO Access, October 4, 2007.
121. Small Business Association, ''U.S. receipt size of firm by major industry group, 1997 & 2002'', United States Small Business Association, accessed online, October 4, 2007.
122. FDA Memorandum, On U.S. shell and egg product imports, November 20, 2007.

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, 21 CFR parts 16 and 118 are 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, STORAGE, AND TRANSPORTATION OF SHELL EGGS

Sec.

Authority: 21 U.S.C. 321, 331–334, 342, 371, 381, 393; 42 U.S.C. 243, 264, 271.

§ 118.1 Persons covered by the requirements in this part.

(a) 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:

(1) If any of your eggs that are produced at a 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.

(2) 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(e) for production of eggs on that farm and with the registration requirements in § 118.11.

(b) If you transport or hold shell eggs for shell egg processing or egg products facilities, you must comply with the refrigeration requirements in § 118.4(e). This section applies only to eggs from farms with 3,000 or more laying hens.

§ 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 the limiting of visitors on the farm and in poultry houses, maintaining personnel and equipment practices that will protect against cross contamination from one poultry house to another, preventing stray poultry, wild birds, cats, and other animals from entering poultry houses, and not allowing employees to keep birds at home, to ensure that there is no introduction or transfer of *Salmonella* Enteritidis (SE) onto a farm or among poultry houses.

Egg products facility means a USDA-inspected egg products plant where liquid, frozen, and/or dried egg products are produced.

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 animal including, but not limited to, rodents, flies, and larvae.

Positive flock means a flock that has had an egg test that was positive for SE. A flock is considered positive until that flock meets the egg testing requirements in § 118.6(c) 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 at any time during the life 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 a structure used to house poultry. For structures comprising more than one section containing poultry, each section that is separated from the other sections is considered a separate house.

Producer means a person who owns and/or operates a poultry house containing laying hens which produce shell eggs for human consumption.

Shell egg (or egg) means the egg of the domesticated chicken.

Shell egg processing facility means a facility that processes (e.g., washes, grades, packs) shell eggs for the table egg market.

Treatment (or treated) 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 follow the SE prevention measures set forth in this section. In addition, you must have and implement a written SE prevention plan that is

specific to each farm where you produce eggs and that includes, at a minimum, the following SE prevention measures:

(a) *Pullets.* You must procure pullets that are SE monitored or raise pullets under SE monitored conditions. ''SE monitored'' means the pullets are raised under SE control conditions that prevent SE, including:

(1) *Procurement of chicks.* Chicks are procured from SE-monitored breeder flocks that meet the National Poultry Improvement Plan's standards for ''U.S. S. Enteritidis Clean'' status (9 CFR 145.23(d)) or equivalent standard;

(2) *Environmental testing.*

(i) The pullet environment is tested for SE when pullets are 14 to 16 weeks of age;

(ii) If the environmental test required in paragraph (a)(2)(i) of this section is negative, you do not need to perform any additional testing of those birds or their environment until the environmental test at 40 to 45 weeks of age specified in § 118.5(a); and

(iii) If the environmental test required in paragraph (a)(2)(i) of this section is positive, you must begin egg testing, as specified in § 118.6, within 2 weeks of the start of egg laying.

(3) *Cleaning and disinfection.* If the environmental test required in paragraph (a)(2) of this section is positive, the pullet environment is cleaned and disinfected, to include:

(i) Removal of all visible manure;

(ii) Dry cleaning the positive pullet house to remove dust, feathers, and old feed; and

(iii) Following cleaning, disinfection of the positive pullet house with spray, aerosol, fumigation, or another appropriate disinfection method.

(b) *Biosecurity.* As part of this program, you must take steps to ensure that there is no introduction or transfer of SE into or among poultry houses. Among such biosecurity measures you must, at a minimum:

(1) Limit visitors on the farm and in the poultry houses;

(2) Maintain practices that will protect against cross contamination when equipment is moved among poultry houses;

(3) Maintain practices that will protect against cross contamination when persons move between poultry houses;

(4) Prevent stray poultry, wild birds, cats, and other animals from entering poultry houses; and

(5) Not allow employees to keep birds at home.

(c) *Rodents, flies, and other pest control.* 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 flies by spot cards, Scudder grills, or sticky traps or another appropriate monitoring method and, when monitoring indicates unacceptable fly activity within a poultry house, use appropriate methods to achieve satisfactory fly 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 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; and

(3) Following cleaning, disinfect the positive poultry house with spray, aerosol, fumigation, or another appropriate disinfection method.

(e) *Refrigeration.* You must hold and transport eggs at or below 45 °F ambient temperature beginning 36 hours after time of lay. If the eggs are to be processed as table eggs and are not processed for the ultimate consumer within 36 hours from the time of lay and, therefore, are held and transported as required at or below 45 °F ambient temperature, then you may then hold them at room temperature for no more than 36 hours just prior to processing to allow an equilibration step to temper the eggs.

§ 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 plan, 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 plan to ensure that all measures are being properly implemented and

(ii) Begin egg testing (described in § 118.6), unless you divert eggs to treatment as defined in § 118.3 for the life of the flock in that poultry house. Results of egg testing must be obtained within 10-calendar days of receiving notification of the positive environmental test.

(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 at 4 to 6 weeks after the end of any molting process.

(1) If an environmental test at 4 to 6 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 at 4 to 6 weeks after the end of the molting process.

(2) If the environmental test at 4 to 6 weeks after the end of a molting process is positive, then you must:

(i) Review and make any necessary adjustments to your SE prevention plan to ensure that all measures are being properly implemented; and

(ii) Begin egg testing (described in § 118.6), unless you divert eggs to treatment as defined in § 118.3 for the life of the flock in that poultry house. Results of egg testing, when conducted, must be available within 10-calendar days of receiving notification of the positive environmental test.

§ 118.6 Egg testing for Salmonella Enteritidis (SE).

(a)(1) If the environmental test for pullets at 14 to 16 weeks of age required by § 118.4(a) is positive, you must divert eggs to treatment (defined in § 118.3) for the life of any flock or conduct egg testing within 2 weeks of the start of egg laying, as specified in paragraphs (b) through (e) of this section.

(2) 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.

(f) If you are diverting eggs, the pallet, case, or other shipping container must be labeled and all documents accompanying the shipment must contain the following statement: ''Federal law requires that these eggs must be treated to achieve at least a 5-log destruction of *Salmonella* Enteritidis or processed as egg products in accordance with the Egg Products Inspection Act, 21 CFR 118.6(f).'' The statement must be legible and conspicuous.

§ 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 sampling plan appropriate to the poultry house layout.

(b) *Egg sampling.* When you conduct an egg test required under § 118.6, you must 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 collect and deliver for testing a minimum of 1,000 intact eggs representative of a day's production. The 1,000-egg sample must be tested according to § 118.8. You must 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 collect and deliver for testing a minimum of 1,000 intact eggs representative of 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 ''Environmental Sampling and Detection of *Salmonella* in Poultry Houses,'' April 2008, or an equivalent method in accuracy, precision, and sensitivity in detecting SE. The April 2008 Environmental Sampling and Detection of *Salmonella* Web site is located at *http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/ucm114716.htm*, current as of June 26, 2009. The Director of the Federal Register approves the incorporation by reference of ''Environmental Sampling and Detection of *Salmonella* in Poultry Houses,'' April 2008, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The FDA will request approval to incorporate by reference any updates to this Web site. The FDA will change the date of the Web site in this paragraph with each update. You may obtain a copy from Division of Microbiology (HFS–710), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2364, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD, 301–436–2163, 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 Chapter 5 of FDA's Bacteriological Analytical Manual (BAM), December 2007 Edition, or an equivalent method in accuracy, precision, and sensitivity in detecting SE. Chapter 5 of FDA's Bacteriological Analytical Manual, December 2007 Edition, is located at *http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/ucm070149.htm,* current as of June 26, 2009. The method is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The FDA will request approval to incorporate by reference any updates to this Web site. The FDA will change the date of the Web site in this paragraph with each update. You may obtain a copy from Division of Microbiology (HFS–710), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2364, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD, 301–436–2163, 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 plan.

You must have one or more supervisory personnel, who do not have to be on-site employees, to be responsible for ensuring compliance with each farm's SE prevention plan. This person must have successfully completed training on SE prevention measures for egg production that is 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 this person to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum. This person is responsible for:

(a) Development and implementation of an SE prevention plan that is appropriate for your specific farm and meets the requirements of § 118.4;

(b) Reassessing and modifying the SE prevention plan as necessary to ensure that the requirements in § 118.4 are met; and

(c) Review of records created under § 118.10. This person does not need to have performed the monitoring or created the records.

§ 118.10 Recordkeeping requirements for the Salmonella Enteritidis (SE) prevention plan.

(a) *Records:* You must maintain the following records documenting your SE prevention measures:

(1) A written SE prevention plan required by § 118.4;

(2) Documentation that pullets were ''SE monitored'' or were raised under ''SE monitored'' conditions, including environmental testing records for pullets, as required by § 118.4(a)(2);

(3) Records documenting compliance with the SE prevention measures, as follows:

(i) Biosecurity measures;

(ii) Rodent and other pest control measures;

(iii) Cleaning and disinfection procedures performed at depopulation, when applicable;

(iv) Refrigeration requirements;

(v) Environmental and egg sampling procedures, when applicable, performed under § 118.7;

(vi) Results of SE testing, when applicable, performed under § 118.8 as required in §§ 118.4(a)(2), 118.5, and 118.6;

(vii) Diversion of eggs, if applicable, as required in § 118.6; and

(viii) Eggs at a particular farm being 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(a)(2).

(4) Records of review and of modifications of the SE prevention plan and corrective actions taken.

(b) *General requirements for records maintained by shell 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. The written SE prevention plan must be dated and carry the signature(s) (not initials) of the person(s) who administers the plan as described in § 118.9, 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, except for the written SE prevention plan, offsite. 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.

§ 118.11 Registration requirements for shell egg producers covered by the requirements of this part.

(a) Shell egg producers covered under § 118.1(a) of this part are required to register their farms with the FDA within 30 days of becoming an egg producer or, if already an egg producer, by the applicable effective date of this regulation.

(b) Shell egg producers may register their farms by any of the following means:

(1) *Electronic registration.* To register electronically, you must register at *http://www.access.fda.gov*, which will be available for registration 24 hours a day, 7 days a week beginning May 10, 2010. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes.

(i) An individual authorized by the owner or operator of a farm, such as an agent in charge, may also register a farm electronically.

(ii) FDA strongly encourages electronic registration for the benefit of both FDA and the registrant.

(iii) Once you complete your electronic registration, FDA will automatically provide you with an electronic confirmation of registration and a permanent registration number.

(iv) You will be considered registered once FDA electronically transmits your confirmation and registration number.

(2) *Registration by mail or by fax.* If, for example, you do not have reasonable access to the Internet through any of the methods described in paragraph (b)(1) of this section, an individual authorized by the owner or operator of a farm, such as an agent in charge, may register by mail or fax.

(i) You must register using FDA Form No. 3733. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, or by requesting the form by phone at 1–888–INFO–FDA (1–888–463–6332).

(ii) When you receive the form, you must fill it out completely and legibly and either mail it to the address in paragraph (b)(2)(i) of this section or fax it to the number on the form.

(iii) If any required information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a registration form for revision, FDA will use the means by which the form was received by the agency (i.e., by mail or fax).

(iv) FDA will enter complete and legible mailed and faxed registration submissions into its registration system, along with CD–ROM submissions, as soon as practicable, in the order FDA receives them.

(v) FDA will then mail to the address or fax to the fax number on the registration form a copy of the registration as entered, confirmation of registration, and your registration number. When responding to a registration submission, FDA will use the means by which the registration was received by the agency (i.e., by mail or fax).

(vi) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration. If any information you previously submitted that was correct at the time of submission subsequently changes, you must update your facility's registration within 60 calendar days.

(vii) Your facility is considered registered once FDA enters your facility's registration data into the registration system and the system generates a registration number.

(3) *Registration by CD–ROM for multiple submissions.* If, for example, you do not have reasonable access to the Internet through any of the methods provided under paragraph (b)(1) of this section, you may register by CD–ROM.

(i) Registrants submitting their registrations in CD–ROM format must use ISO 9660 (CD–R or CD–RW) data format.

(ii) These files must be submitted on a portable document format (PDF) rendition of the registration form (FDA Form No. 3733) and be accompanied by one signed copy of the certification statement that appears on the registration form.

(iii) Each submission on the CD–ROM must contain the same preferred mailing address in the appropriate block on FDA Form No. 3733.

(iv) A CD–ROM may contain registrations for as many facilities as needed up to the CD–ROM's capacity.

(v) The registration on the CD–ROM for each separate facility must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company.

(vi) You must mail the CD–ROM to the U.S. Food and Drug Administration,

10903 New Hampshire Avenue, Silver Spring, MD 20993.

(vii) If FDA receives a CD–ROM that does not comply with these specifications, it will return the CD–ROM to the submitter unprocessed.

(viii) FDA will enter CD–ROM submissions that comply with these specifications into its registration system, along with the complete and legible mailed and faxed submissions, as soon as practicable, in the order FDA receives them.

(ix) For each facility on the CD–ROM, FDA will mail to the preferred mailing address a copy of the registration(s) as entered, confirmation of registration, and each facility's assigned registration number.

(x) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration. If any information you previously submitted that was correct at the time of submission subsequently changes, you must update your facility's registration within 60 calendar days.

(xi) Your facility is considered registered once FDA enters your facility's registration data into the registration system and the system generates a registration number.

(c) No registration fee is required.

(d) You must submit all registration information in the English language. All information must be submitted using the Latin (Roman) alphabet.

(e) Each registrant must submit the following information through one of the methods described in paragraph (b) of this section:

(1) The name, full address, and phone number of the farm; and

(2) The average or usual number of layers of each house and number of poultry houses on the farm.

(3) A statement in which the shell egg producer certifies that the information submitted is true and accurate. If the individual submitting the form is not the shell egg producer in charge of the farm, the registration must also include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit registration, and identifies by name, address, and telephone number, the individual who authorized submission of the registration. Each registration must include the name of the individual registering the farm submitting the registration, and the individual's signature (for paper and CD–ROM options).

(f) Registered egg producers must submit an update to a registration within 60-calendar days of any change to any of the information previously submitted by any of the means as provided in § 118.11(b).

(g) Registered egg producers must notify FDA within 120 days of ceasing egg production by completing sections 1b, 1c, and 2 of Form 3733. This notification is not required if you are a seasonal egg producer or you temporarily cease operation due to labor disputes, fire, natural disasters, or other temporary conditions.

§ 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 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. A state or locality may substitute, where necessary, appropriate State or local officials for designated FDA officials in this section. 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, or may utilize comparable State or local hearing procedures if such procedures satisfy due process.

(d) *Preemption.* No State or local governing entity shall establish, or continue in effect any law, rule, regulation, or other requirement regarding prevention of SE in shell eggs during production, storage, or transportation that is less stringent than those required by this part.

Dated: July 2, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–16119 Filed 7–7–09; 1:30 pm]

BILLING CODE 4164–01–P