Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

7 CFR Part 59

[Docket No. 96–035A]

RIN 0583–AB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 100

[Docket No. 97N–0322]

RIN 0583–AC52

Salmonella Enteritidis in Eggs

AGENCIES: Food Safety and Inspection Service, USDA; Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; request for comments.

SUMMARY: Eggs contaminated with *Salmonella* Enteritidis (SE) are associated with significant numbers of human illnesses and continue to be a public health concern. SE infected flocks have become prevalent throughout the country, and large numbers of illnesses have been attributed to consumption of mishandled SE-contaminated eggs. As a result, there have been requests for Federal action to improve egg safety. The Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) share Federal regulatory responsibility for egg safety. However, regulation of shell eggs is primarily the responsibility of FDA. Through joint issuance of this notice, FSIS and FDA are seeking to identify farm-to-table actions that will decrease the food safety risks associated with shell eggs. The agencies want to explore all reasonable alternatives and gather data on the public benefits and the public costs of various regulatory approaches before proposing a farm-to-table food safety system for shell eggs. Interested persons are requested to comment on the alternatives discussed in this advance notice of proposed rulemaking (ANPR), suggest other possible approaches, and provide information that will help the agencies weigh the merits of all alternatives. In addition to the actions contemplated in this ANPR, both agencies are planning to take actions that address adoption of refrigeration and labeling requirements that are designed to reduce the risk of foodborne illness.

DATES: Comments must be received on or before August 17, 1998.

ADDRESSES: Send an original and two copies of comments to: FSIS Docket Clerk, Docket No. 96–035A, Room 102 Cotton Annex Building, 300 12th St, SW., Washington, DC 20250–3700. Reference material cited in this document and any comments received will be available for public inspection in the FSIS Docket Room from 8:30 a.m. to 1:00 p.m. and 2:00 p.m. to 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Mr. Ralph Stafko, Food Safety and Inspection Service, USDA, Washington, DC, 20250, (202) 720–7774, or Dr. Marilyn Balmer, Center for Food Safety and Applied Nutrition, Food and Drug Administration, HHS, Washington, DC 20204, (202) 205–4400.

SUPPLEMENTARY INFORMATION:

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Background

This section provides information on the egg industry, data that associate eggs with an epidemic of cases of human salmonellosis caused by *Salmonella* Enteritidis, and past efforts and current plans to alleviate this public health problem.

1. Egg Production and Marketing

Eggs are a nutrient-dense food that play an important part in most Americans' diets, either alone or as a constituent of another food. On a per capita basis, Americans consume about 234 eggs a year. The National Agriculture Statistics Service (NASS) of the Department of Agriculture (USDA) estimates the total value of the table eggs (eggs produced for human consumption, not hatching) produced in the U.S. in 1995 at $3.96 billion.

The egg industry is fairly stable in terms of overall production. U.S. production has increased only slightly in absolute terms in recent years, from about 60 billion eggs in 1984 to about 63 billion in 1995. About 70 percent are sold as whole ''shell'' eggs. The remaining 30 percent are processed into liquid, frozen or dried pasteurized egg products, the majority of which are destined for institutional use or further processing into other foods such as cake mixes, pasta, ice cream, mayonnaise, and bakery goods.

International trade is a small but growing part of the U.S. egg market. The U.S. does not import a significant quantity of shell eggs and imports only 0.2 percent of processed egg products. Exports now amount to more than 2 percent of the total U.S. production. In 1996, exports of eggs and egg products reached a market value of nearly $20 million.

There are essentially three kinds of flocks associated with egg production: breeder flocks, multiplier flocks, and laying flocks (including both immature pullets and mature laying hens). There are roughly 300,000 breeding hens (grandparents), 3 million multipliers (parents), and 300 million laying hens. NASS estimates the value of the laying flocks alone to be close to $1 billion.

Geographically, commercial egg production in the western United States is concentrated in California, and in the east it is centered in Ohio, Indiana, and Pennsylvania. According to NASS, which surveys the number of egg laying flocks of 30,000 or more hens, California and Ohio each have about 25 million layers, and Indiana and Pennsylvania each have about 20 million. Other states in which major producers are located

include Iowa, Texas, Minnesota, and Georgia. Twenty-one other states are reported as having fewer than 10 million, but more than 2 million, layers in production.

Egg production is being concentrated in fewer, larger firms. Federal Regulations require commercial flocks of more than 3,000 hens to be registered with USDA. USDA's Agricultural Marketing Service (AMS) currently has 757 such egg producers registered. The United Egg Producers (UEP), a cooperative that provides a variety of services to member egg producers, reports that the number of major producers (those with flocks of 75,000 or more, which produce about 94 percent of America's table eggs) declined in just 3 years from 380 producers in 1994 to 329 producers in 1996.

Modern egg production facilities are increasingly large, ''in-line'' facilities. They integrate laying, packing, and even processing of egg products at one location. Freshly laid eggs go directly into a processing system where they are cleaned, sorted, and packed for distribution.

A significant portion of production, however, is still ''off-line.'' Off-line operations are those that are not integrated with laying facilities, but rather have eggs shipped from laying facilities at other locations. The fresh eggs are collected and shipped from the laying facilities periodically, usually once a day but sometimes less often. These eggs are frequently placed in coolers at the laying facility before shipment to a facility where they are processed and packed.

Most packers either own or have contractual relationships with their suppliers. Their laying hens are bred and cared for to ensure the largest possible numbers of consistent quality eggs, and are housed together in large hen houses.

Although shell egg cleaning and packing is configured differently in different plants, after collection the eggs generally are (1) washed, (2) rinsed and sanitized, (3) dried, (4) candled, sorted, and graded, (5) packed in cartons and crates onto shipping pallets, and (6) placed in a cooler pending shipment. Eggs that are found to be cracked or otherwise unsuitable for sale as whole shell eggs are by law ''restricted.'' USDA allows a certain percentage of some classes of restricted eggs to be moved in commerce. If restricted eggs sent to a federally inspected facility (often referred to as a ''breaker plant'') are determined acceptable, they are broken, inspected for wholesomeness, pooled, and then processed into a pasteurized liquid, frozen, or dried egg product.

After packing, shell eggs usually are loaded into refrigerated transports for shipment to market. Some producers use their own trucks, while others contract with trucking firms to deliver eggs to their customers. Some are delivered directly to retail outlets, and others are delivered to warehouses and other intermediate distribution points before going to the retail store or food service facility where they reach the consumer.

2. Salmonella and the Salmonellosis Epidemic

Salmonella is a gram-negative, motile, rod-shaped bacteria that can grow under both aerobic and anaerobic conditions. *Salmonella* has evolved into a successful human pathogen because of its survival characteristics and virulence. The organisms are ubiquitous, and are commonly found in the digestive tracts of animals, especially birds and reptiles. Human illnesses are usually associated with ingestion of food or drink contaminated with *Salmonella,* but infection may also be acquired from an infected person by the fecal-oral route through poor personal hygiene, or from pets.

More than 2,300 different serotypes have been identified and are associated with a variety of animal reservoirs, geographic locations, and frequencies. However, microbiologists are finding that atypical biotypes have emerged that are difficult to identify and detect by conventional means, placing more value on new molecular methods and other technologies for identifying them.[1]

Epidemiologically, salmonellae can be grouped as follows:

1. *Those that infect mainly humans.* These include human pathogens such as *S.* Typhi and *S.* Paratyphi (A and C) which cause typhoid (enteric) and paratyphoid fevers, respectively, the most severe of the *Salmonella* disease*S. S.* Typhi may be found in blood, as well as in stool and urine before enteric fever develops. Typhoid fever has a high mortality rate; the paratyphoid syndrome is generally milder. These diseases are spread through food and water contaminated by feces and urine of patients and carriers.[2]

2. *Those that infect mainly animals.* These include animal pathogens such as *S.* Gallinarum (poultry), *S.* Dublin (cattle), *S.* Abortus-ovis (sheep), and *S.* Choleraesuis (swine). Some of the organisms in this group are also human pathogens and can be contracted through foods.

In general, salmonellae are quite resilient and able to adapt to extremes in environmental conditions. They are resistant to freezing and drying. They are able to grow within a wide temperature range; from extremes as low as 2–4°C (36–39°F), and as high as 54°C (129°F). They have been reported to grow within a pH range of 4.5 to 9.5. Salmonellae do not grow in foods with a water activity of 0.93 or less, and are inhibited by the presence of salt at levels between 3 and 4 percent. Preconditioning to thermal and acid stress has been shown to allow strains to adapt to greater extremes.[3] These properties make many food products more likely to support the growth of these organisms, such as many refrigerated products, fermented foods, and cheeses.

The human infectious dose is highly variable, depending largely on the strain, the food, and the susceptibility of the human host. Recent evidence suggests that as few as one to ten *Salmonella* cells can cause infection in humans. Human diarrheagenic response and enterocolitis result from the migration of the pathogen from the mouth at ingestion to the intestinal tract and mesenteric lymph nodes, and the coinciding production of bacterial enterotoxin. *Salmonella* also produce a cytotoxin that inhibits protein synthesis and causes lysis of host cells, helping the organisms to spread to other tissues.[4]

The Centers for Disease Control and Prevention (CDC), which has classified salmonellosis as a reportable disease since 1943, has found it to be one of the most commonly reported bacterial infections of any kind in the United States. Human salmonellosis is the second most prevalent foodborne disease in the U.S. after illnesses from *Campylobacter* (a generally milder illness associated with raw and undercooked poultry, raw milk, and untreated water as well as improper handling and preparation of food). In 1996, 39,027 confirmed cases of human salmonellosis were reported to CDC by State and local departments of health. Although this number of cases is below the peak year of 1985, when 57,896 cases were reported, the number of cases is significant. From 1985 through 1996, there have been 508,673 reported cases of salmonellosis.[5]

Salmonella usually cause an intestinal infection accompanied by diarrhea, fever, and abdominal cramps starting 6 to 72 hours after consuming a contaminated food or drink. The illness is usually 4 to 7 days in duration, and most people recover without antibiotic treatment. About 2 percent of affected persons may later develop recurring joint pains and arthritis.[6] In

the very young, the elderly, and persons with compromised immune systems, the infection can spread to the bloodstream, and then to other areas of the body such as the bone marrow or the meningeal linings of the brain, leading to a severe and occasionally fatal illness unless treated promptly with antibiotics.[7]

Because many cases are not reported, these cases may represent only a small fraction of the actual number of illnesses that occur. Not all infected persons develop symptoms severe enough that they seek medical attention, and physicians may not have patients' stool analyzed. It is estimated that there are an additional 20 to 100 cases of salmonellosis for every reported case, or some 800,000 to 4 million actual cases each year in the U.S.[8]

The cost to Americans is considerable. The patient-related costs of salmonellosis from medical expenses and loss of income were estimated in 1988 to be about $1,560 per reported case and about $250 for each unreported case.[9] By applying the cost per reported case to the 41,222 cases and probable illnesses reported in 1995, the cost of salmonellosis in 1995 can be estimated to be between $350 million and $1.5 billion.

CDC's surveillance data on isolates reported by State and territorial epidemiologists list close to 600 different serotypes that have caused human illness in the U.S. Based primarily on outbreak data, where Federal, State, and local epidemiologists have sought to identify the source of infection, some serotypes are linked to particular food vehicles. The three illness-causing serotypes most frequently reported—*S.*Typhimurium, *S.* Heidelberg, and *S.* Enteritidis—are most often traced to poultry or eggs when a food vehicle is found.

Salmonella Enteritidis emerged in epidemic proportions in the United States about a decade ago in the northeast. Over the last 20 years, SE-associated illnesses have increased greatly in number. The proportion of reported *Salmonella* isolates that were SE increased from 5 percent in 1976 to 26 percent in 1994.[10] SE was the most frequently reported *Salmonella* serotype in 1994, 1995, and 1996.

CDC surveillance data show that the rates of isolation of SE increased in the U.S. during 1976–1994 from 0.5 to 3.9 per 100,000 population, and that illnesses are occurring throughout the U.S. While the trends for the years 1990–1994 show a decrease in the SE isolation rate in the northeast from 8.9 to 7.0 per 100,000 population, the rate increased approximately threefold for the Pacific region, particularly for southern California, which had rates as high as 14 per 100,000.[11]

From 1985 through 1996, there have been 660 SE outbreaks reported to CDC. Associated with these outbreaks, there have been 77 reported deaths, 2,508 reported hospitalizations, and 25,935 reported cases of illness. The peak year for outbreaks was 1989 with 77 reported. Deaths have occurred in all years. In 1995 and 1996, there were 57 and 51 reported outbreaks respectively with 8 deaths in 1995 and 2 deaths in 1996. The majority of the outbreaks occur in the commercial venue with the implicated food containing undercooked eggs.

There is evidence that this increase in SE infections is global. World Health Organization data show increases in SE on several continents, including North America, South America, Europe, and perhaps Africa.[12] The trend towards centralized large-scale food processing with wide distribution means that when contamination occurs, it can affect large numbers of people over a large area. Although most eggs are consumed individually, large numbers are sometimes pooled during the production or preparation of some foods. This increases the likelihood of SE being in the raw product. This potential was illustrated by a major 1994 SE outbreak attributed to ice cream. FDA reported the most likely cause was contamination of the pasteurized ice cream mix by hauling it in a tanker improperly cleaned after carrying a load of unpasteurized liquid eggs. The ice cream mix was not heat treated after receipt from the contaminated tanker, and the ice cream was distributed widely.[13]

In 1995 surveys, SE phage-type 13A was found to be the predominant phage-type in egg laying flocks in the United States, followed by phage-type 8 and, increasingly, phage-type 4. This represents a significant change since 1991, when phage-type 8 was predominant and phage-type 4 was undetected in laying flocks.[14]

3. Salmonella in Eggs; the Risk

a. Contamination Through the Shell; Current Egg Cleaning Practices

Eggs have long been valued for their natural protective packaging. Having evolved to protect the developing embryonic bird inside, the egg provides an inhospitable environment for *Salmonella* as well as other bacterial contaminants. A fresh egg is fairly resistant to invasive bacteria, a fact relied upon in many countries where shell eggs are not refrigerated. The egg's defenses are both mechanical and chemical.

Mechanically, there are essentially four layers of protection preventing bacteria from reaching the nutrient rich yolk: (1) the shell, (2) the two membranes (inner and outer) between the shell and the albumen, (3) the albumen (eggwhite), and (4) the vitelline (yolk) membrane which holds the yolk.

When laid, the egg shell is covered on the outside by the cuticle, a substance similar in composition to the shell membranes. When the cuticle dries, it seals the pores and hinders initial bacterial penetration. However, the cuticle usually is removed along with debris on the surface of the shell during the cleaning process. Some processors add a thin coating of edible oil or wax to eggs after they are washed and dried to close the shell pores in a manner similar to the cuticle.

The shell, although porous and easily penetrated by bacteria, protects the outer membrane from physical abuse. The dry and much less porous outer shell membrane is much more difficult for bacteria to penetrate. The inner shell membrane and the yolk membrane also present barriers. Perhaps the most substantial line of defense against bacteria is provided by the egg albumen.

In fresh eggs, the albumen has a high viscosity, which both anchors the yolk protectively in the center of the shell and prevents movement of bacteria toward the yolk. (Eggs are stored with the blunt end up to help keep the yolk, which has a lower specific gravity, from drifting toward the inner membrane.) In addition, the albumen has chemical properties that inhibit bacterial growth.

Originally, the potential for *Salmonella* to contaminate shell eggs was primarily a matter of the organisms passing through the shell into the egg's contents because of, mostly, environmental conditions. With salmonellae other than SE, this still is the most likely means of potential contamination of intact shell eggs.[15]

It has long been known that the laying environment can contribute to egg shell contamination. The surface of the egg can become contaminated with virtually any microorganism that is excreted by the birds. Many serotypes of *Salmonella* as well as other bacteria have been isolated from laying flocks. Contact with feces, nesting material, dust, feedstuffs, shipping and storage containers, human beings, and other creatures all contribute to the likelihood of shell contamination. Penetration into the egg contents by both salmonella and spoilage bacteria increases with duration of contact with contaminated material, especially during storage at

high temperatures and high relative humidities. Therefore, eggs should be collected as frequently as possible, and kept as clean and cool as possible (short of freezing, which can damage the shell).

Other sources of shell contamination are always present in the production environment. Producers should clean and sanitize equipment and facilities as necessary to prevent egg contamination, and not rely simply on egg washing to remove contaminants after the fact. One recent study found high levels of *Salmonella* isolates from egg belts, egg collectors, and ventilation fans (64–100 percent of samples on different farms) as compared to isolates from egg shells before collection (8 percent overall).

Cleaning the exteriors of shell eggs to remove fecal material and other debris reduces the risk that pathogenic bacteria will have an opportunity to penetrate the egg shell. The cleaning process provides consumers with clean egg surfaces not likely to promote contamination of the egg by penetration of bacteria through the intact shell or by cross contamination upon cracking open the egg for use.

Most modern egg washing machines are spray-washers. The typical continuous egg washer consists of three stages: a wash chamber where the eggs are washed with warm water and detergent using moving brushes or high pressure jets, a rinse chamber which usually includes a sanitizing agent, and a drying chamber.

If not done properly, washing can contribute to microbial contamination of the egg's contents and may contribute to increased spoilage rates. Organisms have the potential to concentrate in the recirculating wash water, and the liquid can be aspirated into the egg through the shell under certain conditions. In particular, when wash water outside the egg shell is colder than the eggs' contents, as the eggs' contents cool it creates low pressure on the inside of the egg shell that draws liquid outside the shell into the egg through the shell's pores. This observation led to the USDA egg grading requirement that wash water be at least 20° F warmer than the eggs being washed. Typically, U.S. processors use a hot wash water (110–120° F) to ensure temperatures hostile to most organisms that may collect in the wash water as well as to ensure that the 20° F egg-wash water temperature difference is maintained even when cleaning quite warm eggs, which are common in in-line facilities. However, the use of hot water damages or removes the cuticle, which if left intact, helps prevent bacterial contamination.

After washing, the eggs should be quickly and completely dried to reduce the risk that any bacteria remaining on the surface of the eggs are aspirated into the eggs as they cool to ambient temperature. They must be handled carefully thereafter to avoid recontamination.

b. Transovarian Contamination of Egg Contents With SE

The increase in SE outbreaks associated with shell eggs in the 1970's and 1980's raised suspicions of transovarian contamination.[16] This mode of contamination was confirmed by an experiment in which laying hens were infected with SE and found to produce eggs contaminated with the same strain of SE.[17] The site of infection is usually the albumen near the yolk membrane.

Based on USDA data, it can be estimated that such transovarian SE contamination occurs in about 1 out of every 10,000 eggs produced in the U.S. This prevalence is based on a model applying data on the frequency of SE positive eggs from infected flocks to an estimation of the number of infected flocks in the U.S. The frequency of infected eggs in an infected flock can be determined from USDA tests of eggs produced by SE-positive flocks. The number of positive flocks is based on USDA's nationwide survey in 1995 of SE in spent hens at slaughter and unpasteurized liquid eggs at breaker plants. Application of the model resulted in a distribution of prevalences ranging from 0.2 to 2.1 positive eggs per 10,000 with a mean of 0.9 positive eggs per 10,000.[18] The problem is nationwide, although there are some regional differences.[19]

Although a prevalence of 1 in 10,000 seems low, it is significant in terms of exposure. That frequency amounts to about 4.5 million SE-contaminated eggs annually in the U.S., exposing a large number of people to SE.

Salmonellosis outbreaks commonly occur when mishandling permits the SE organisms to multiply and inadequate cooking or mishandling during preparation or service results in live pathogens being ingested with the food. However, the dose required to make a person ill may vary with the individual. The biggest factor in determining whether illness occurs, and how severe it may be, appears to be the age and health of the person ingesting the organisms.

4. Mitigating the Risk; Current Efforts

Mitigation of risks associated with SE in eggs requires analysis of everything in the food production-distribution-consumption continuum from the farm to table that might affect the likelihood that consumers will become ill from SE in eggs.

a. Production: Preventing Introduction of SE Into Laying Flocks and From Hens to Eggs

The Federal government has devoted significant efforts to investigating and controlling SE in laying hens. Between 1990 and 1995, USDA's Animal Plant Health Inspection Service (APHIS) conducted an SE control program (9 CFR Parts 71 and 82; 56 FR 3730; January 30, 1991). Under that program, APHIS restricted the movement of eggs from flocks that tested positive for SE. In cooperation with FDA, CDC, and State authorities, eggs implicated in SE outbreaks were traced back to their farms of origin. If initial tests of manure and egg transport machinery indicated the presence of SE, the flock became a ''test flock.'' Blood and internal organ testing was done on the test flocks, and if any were found positive, the flock was designated ''infected.'' The eggs from test and infected flocks could not be sold as table eggs but could be sent to processors for pasteurization, hard boiling, or export. A flock's status as a ''test'' or ''infected'' flock was not lifted until extensive testing, including additional tests of internal organs of birds, detected no SE. Establishments had to clean and disinfect the hen houses before installing replacement flocks.

In 1995, shortly after transfer of the program from APHIS to FSIS, funding for the entire program was removed from the USDA's 1996 appropriations. FDA, which had worked closely with APHIS on its tracebacks, assumed responsibility for all aspects of investigating outbreaks, tracing back egg-associated SE illnesses to particular producers/flocks, diverting eggs, collecting flock data to help track the spread of SE, encouraging better quality control measures by producers, and adoption by States of egg quality assurance programs. State and county health departments usually perform the epidemiological investigations of outbreaks.

The APHIS-sponsored National Poultry Improvement Plan (NPIP), a cooperative Federal-State program, provides assistance to breeders and hatchers on keeping birds free of egg-transmitted diseases. In 1989, an SE control program was developed to reduce the prevalence of SE organisms in hatching eggs and chicks. Participants in the program follow sanitation and other control procedures at breeder farms and hatcheries. Forty-

six SE-positive isolates have been found since its inception, with a decline evident in recent years. Only two were found in 1995, and one in 1996.[20]

A third APHIS program resulted in a variety of voluntary flock control programs that appear to have had some effect in reducing the numbers of infected flocks. In 1992, in the wake of APHIS tracebacks implicating flocks in Pennsylvania, APHIS cooperated with industry representatives, State government officials, and academic experts to develop a program to reduce the prevalence of SE in laying hens. In the *Salmonella* Enteritidis Pilot Program (SEPP), flock owners purchased chicks from hatcheries participating in the NPIP program, imposed strict rodent control measures, cleaned and disinfected hen houses between flocks, controlled feed, and implemented other biosecurity measures. The program relied on APHIS testing of environmental samples to determine positive flocks, and egg testing by commercial laboratories when environmental samples were positive.

In recent years, several other voluntary programs for controlling SE in shell eggs have been developed. California's Egg Quality Assurance Plan calls for producers and processors to apply current good manufacturing practices and to implement risk reduction measures for all hazards throughout the production and processing environments. The New England Risk Reduction Program for SE in eggs is being adopted by producers in Maine and other northeast States. United Egg Producers has developed a ''Five Star'' program for its members, which requires participants to ensure (1) poultry house cleaning and disinfecting, (2) rodent and pest elimination, (3) proper egg washing, (4) biosecurity measures, and (5) egg refrigeration during transport and storage. UEP has recently added testing provisions for verification. The U. S. Animal Health Association, a professional association of veterinarians, developed ''Recommended Best Management Practices for a SE Reduction Program for Egg Producers,'' guidelines intended for use by producers without a State or industry program. Other States are working on egg quality programs, and an increasing proportion of producers seem to be adopting SE-control programs.

Much remains unknown about how SE infects flocks, and how the organism contaminates eggs. USDA scientists believe that among birds in an SE-infected flock, only a small number are shedding SE organisms at any given time, and that an infected bird might easily lay many normal, uncontaminated eggs, only occasionally laying an egg contaminated with SE. There is speculation that the likelihood of infection or the laying of contaminated eggs also may be related to factors other than environmental conditions, such as the genetics of the birds, the age of the birds, the site of infection in the hen, and whether the birds have been stressed (e.g., because of molting).[21] At this time, it may not be possible to design an SE control program that will remove all possibility of egg-laying chickens producing SE contaminated eggs. The agencies seek comments on this issue.

b. Processing and Distribution: Preventing Growth of SE in Eggs

In addition to the presence of SE in shell eggs, many other factors may influence the number and severity of salmonellosis cases. Key factors are pathogenicity and virulence of the organism, the dose level, and the numbers and susceptibility of the people exposed. In general, the greater the dose, the greater the chance that the person ingesting it will become ill.

The likelihood of SE multiplying depends primarily on the variables of time and temperature, although other factors such as the site of the egg contamination and the presence in the albumen of free iron also appear to play a role.[22] The site of contamination normally is the albumen. Over time, beginning after the egg is laid, the albumen proteins break down, ultimately rendering the albumen watery and less viscous and reducing the mechanical as well as the chemical defenses against bacterial motility and growth. At the same time, the yolk membrane degrades and becomes more porous. This degradation of the albumen and yolk membrane permits bacteria to reach the nutrient-rich yolk and multiply. The rate at which this degradation takes place relates to the temperature of the egg, with degradation delayed at cold temperatures and occurring more rapidly at warm temperatures.[23]

Studies of the growth of SE adjacent to the yolk indicate that there are three distinct phases in the growth curve of SE in eggs. The first phase takes place in the first 24 hours after lay, when the pH of the albumen rises from about 7 to about 9 and, it is suggested, the bacterium have enough iron reserves of their own to support about four generations. Studies suggest the numbers of salmonellae can increase about 10-fold during that initial phase, before entering a lag phase during which numbers remain fairly constant. The length of that lag phase is largely temperature-dependent, and its end, the beginning of the third phase, is signaled by penetration of the yolk membrane by the bacteria and resumption of rapid growth.[24]

Failure to cool eggs clearly contributes to SE multiplication. One study found that SE in eggs artificially inoculated in the albumen and stored at 20 °C (68 °F) grew rapidly after they had been stored for approximately 3 weeks, but that rapid growth occurred within 7 to 10 days when storage temperatures fluctuated between 18 °C (64 °F) and 30 °C(86 °F).[25] A different study of eggs with SE inoculated under the shell membrane found that after only 48 hours at 26 °C (78.8 °F) yolks contained high levels of SE.[26] Although there is consensus on the advisability of keeping eggs cool to prevent SE growth, there is debate on precisely what temperature is required. Because the studies referenced above rely on inoculated eggs, they may not accurately represent naturally occurring strains or the numbers of organisms that occur and grow in eggs under similar conditions. The conclusions suggest that internal egg temperatures of 7 °C (approx. 45 °F) or lower are unlikely to promote SE growth should SE be present in the egg.

Although the studies suggest that there is a delay of at least several days before the egg's natural defenses start breaking down, they also suggest that the rate at which degradation occurs is temperature related, and that eggs should be chilled as soon as possible.[27] The sooner an egg is chilled, the longer its defenses will be retained and the less likely that any SE present will have an opportunity to replicate.

The time it takes for an egg's contents to reach a temperature of 45 °F is affected by many things, including the temperature of the egg when received at the packing plant, heat added during processing, temperature when packed, insulation effect of the packaging, how packed eggs are stacked in coolers during storage and transportation, and the ambient air temperature and air circulation provided at all points after packing.

Egg processing procedures in the U.S. typically result in eggs being warmed. Warming begins as the eggs are loaded onto the conveyance system, and increases as they are washed; surface temperatures of eggs immediately after washing will approach that of the wash water, which is normally about 43–40 °C or 110–120 °F.[28] As noted, hot wash water temperatures are intended to provide adequate cleaning of the shell surface and an adequate temperature differential between the wash water and

the egg. USDA studies have shown that water temperatures colder than the internal egg temperatures cause the eggs' contents to cool leading to a pressure gradient that pulls in water and any bacteria in the water through the shell.[29]

After the eggs emerge from the wash and are dried with forced ambient air, internal temperature at the time they are packed is often in the 70–80 °F range. After packing, most processors hold eggs in coolers at an ambient air temperature of 45–55 °F, and transport eggs at an ambient air temperature of 60 °F or less. However, the ambient air temperature does not correlate to egg temperature. The temperature of the eggs' contents at the time they are transported from the packer will range between 50 °F and 80 °F, depending on the starting temperature, the packaging, how the crates are packed and stacked, and the length of time they are in the cooler before shipping.

The rate at which eggs chill after leaving the processor is similarly dependent on the initial temperature, packaging, loading configurations, and the capability of the refrigeration equipment. Transporters contend that their refrigeration units are designed to maintain—not reduce—temperatures, and that they cannot be relied upon to reduce the temperatures of products being transported. Further, the driver of a truck making multiple deliveries must open the truck door frequently, and if the outside temperature is warm, it would be virtually impossible to maintain the ambient air temperature uniformly throughout the load. Similarly, most retail stores' display cases have been designed to keep products cool, not to cool down products. Eggs received by retail stores are frequently at temperatures well above 45 °F.

Ideally, reliance on the use of ambient air temperature of 45 °F during distribution and retail as a reasonable measure of whether the eggs are being maintained under appropriate conditions would necessitate the eggs being chilled to an internal temperature of 45 °F before they are shipped. Significantly, there are a number of actions processors may take to reduce the temperature at which eggs are packed, and to cool them before shipment, including lowering the wash temperatures and pre-pack chilling of eggs. Recent research has shown that new technologies are available to processors to rapidly cool shell eggs. One study found that carbon dioxide, as a cryogenic gas, can be used instead of air chilling to rapidly chill eggs and results in no increase in cracked shells.

c. Rewashing/Repackaging: Preventing Growth of SE in Eggs

It appears that eggs are occasionally removed from retail establishments when they are within a few days of the expiration or sell-by date stamped on the carton and returned to the processing plant. These eggs are co-mingled with eggs that are being cleaned for the first time, go through the hot water/sanitizing process again, and are graded. The rewashed eggs are then packed into cartons and are redistributed for sale. These eggs receive a new expiration or sell-by date.

On April 17, 1998, USDA announced that as of April 27, 1998, repackaging of eggs packed under its voluntary grading program will be prohibited while the Department reviews its policies on egg repackaging and engages in any necessary rulemaking. The prohibition on repackaging affects eggs packed in cartons that bear the USDA grade shield. About one-third of all shell eggs sold to consumers are graded by USDA.

In the wake of the USDA action, FDA is considering appropriate measures to take to address this issue. FDA requests comments on how widespread this practice is and on whether any aspect of rewashing/repackaging of eggs significantly increases the risk that consumers will contract SE-related illness from these eggs. FDA notes, for example, that repackaged eggs are subjected to warming during rewashing. Inasmuch as an egg's natural barriers to the multiplication of SE may be compromised at temperatures above 45 °F (see discussion in section 4b), does the warming of shell eggs during rewash significantly increase the risk that SE (if present) will multiply in rewashed/repackaged eggs during distribution or while held for sale, service, or preparation? Does it significantly increase the risk of illness for the consumer if the egg is not thoroughly cooked before consumption?

Are there important aspects, for example, safety risks or otherwise, of rewashed/repackaged eggs that would raise the question whether rewashed/repackaged eggs should be labeled in the same manner as other shell eggs? Are rewashed/repackaged eggs different enough from other shell eggs such that label statements in addition to ''expiration'' or ''sell-by'' dates would be necessary to adequately describe the product? If, for some segments of the U.S. population, the standard egg labeling practices are not appropriate for rewashed/repackaged eggs, how should these eggs be labeled to enable consumers to understand the nature of this product and to communicate other important information to the purchaser?

The issue of rewashing and repackaging of eggs also calls attention to current practices regarding the expiration dating of eggs in establishments that function primarily under State regulatory oversight. While a few States have regulations governing expiration dating of eggs, most do not and egg packers determine what expiration dating practices they will employ. Processors that do not use USDA's grading service, and that are not covered by State requirements, typically choose to place a 30- or 45-day expiration date on egg cartons. Some processors do not provide any expiration date. Section 403(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA) states that a food is misbranded if its labeling is false or misleading in any particular. FDA requests comments on the latter two practices described above could violate 403(a) or other provisions of the Act. It also seeks comments on whether the variety of expiration dating practices for eggs could be misleading to consumers given their expectations when they purchase eggs. FDA will evaluate comments received regarding expiration dating and will consider providing guidance to the States on appropriate controls. FDA also requests comments on whether any such guidance should address appropriate practices for use of eggs that are not sold by the expiration date.

d. Preparation and Consumption: Preventing Ingestion of SE from Eggs

Another risk factor is exposure—the number of people who ingest SE organisms from SE-contaminated eggs. Pathogens like SE usually become a public health problem as a consequence of changes in the agent itself, the host, or the environment. Examples of such changes include the types of food people eat, the sources of those foods, and the possible decline in public awareness of safe food preparation. Antibiotic-resistant strains of pathogens are emerging, and people are exposed to new pathogens originating in other regions and other parts of the world. People today have increased life expectancies, and there are increasing numbers of immuno-compromised persons, increasing the population susceptible to severe illness after infection with foodborne pathogens.[30]

Finally, preparation and consumption patterns can greatly influence the likelihood of foodborne illness from eggs. However, SE outbreaks of foodborne illness from eggs continue to be associated with the use of recipes

calling for uncooked eggs or with undercooking of eggs. Low numbers of SE organisms in prepared foods can increase if the foods are held at room temperature or are cross contaminated with other foods. The risk is further amplified in commercial or institutional food service settings where larger quantities of food are served to larger groups of persons over extended periods of time.

As the proportion of food that is eaten outside homes in the U.S. increases, outbreaks associated with these foods increase in importance. They accounted for more than 90 percent of reported foodborne disease outbreaks in the 1990s.

5. Current Regulation of Shell Eggs

Federal authority to regulate eggs for safety is shared by FDA and USDA. FDA has jurisdiction over the safety of foods generally, including shell eggs, under the FFDCA (21 U.S.C. 301, *et seq.*). FDA also has authority to prevent the spread of communicable diseases under the Public Health Service Act (PHSA)(42 U.S.C. 201, *et seq.*). This authority would include the authority to regulate foods when the foods may act as a vector of disease, as is the case with eggs and SE. USDA has primary responsibility for implementing the Egg Products Inspection Act (EPIA)(21 U.S.C. 1031, *et seq.*), although FDA shares authority under the statute (see, for example, 21 U.S.C. 1034). USDA's Food Safety and Inspection Service and Agricultural Marketing Service share responsibilities under the EPIA. FSIS has primary responsibility for the inspection of processed egg products to prevent the distribution into commerce of adulterated or misbranded egg products (7 CFR 2.53), while AMS conducts a surveillance program to ensure proper disposition of restricted shell eggs.

Under Federal regulations, all major commercial egg producers—the 757 producers who have more than 3,000 laying hens and collectively are responsible for close to 94 percent of the nation's eggs—are required to register with AMS. They are subject to periodic on-site visits by AMS to ensure that eggs packed for commercial sale have no more than the percentage of restricted eggs allowed for the grade of eggs being packed, that they are properly labeled, and that proper disposition is made of inedible and restricted eggs. Exempted from this oversight are approximately 80,000 small egg producers.

States may have their own laws governing eggs, as long as they are consistent with Federal laws (e.g., 21 U.S.C. 1052(b)(2)). Generally, State laws and regulations specifically govern egg grading and labeling in each of the States. These laws influence how eggs are packed and shipped for sale and then handled by retail stores, restaurants, and other food service establishments in those jurisdictions.

FDA and FSIS work with the States to encourage uniformity among the State laws affecting food safety in retail and food service establishments. The principal mechanism for this is the *Food Code*, a model code published by FDA intended for adoption by State and local authorities for governing retail food and food service establishments. The provisions of the *Food Code* are modified periodically with input from a broad spectrum of organizations—industry, academia, consumers and government agencies at the Federal, State, and local levels. In addition, training programs on the *Food Code* recommendations have been conducted yearly with State agencies.

The *Food Code* states that ''potentially hazardous foods,'' including shell eggs, should be received and maintained at a temperature of 41 °F or less, or, if permitted by other law to be received at more than 41 °F, be reduced to that temperature within 4 hours. Because eggs are often received at temperatures well above 41 °F, the 1997 edition of the *Food Code* contains an exception for shell eggs, requiring only that they be placed upon receipt in refrigerated equipment that is capable of maintaining food at 41 °F.

The *Food Code* specifies that shell eggs, when prepared for service, are to be cooked to specified temperatures for a specified time. If the egg is not served immediately, hot and cold hold temperatures are specified. The *Food Code* further specifies that pasteurized eggs be substituted in delicatessen and menu items that typically contain raw eggs unless the consumer is informed of the increased risk. Pasteurized egg substitution is specified for eggs that are held before service of vulnerable individuals.

In recent years, many States have enacted laws requiring specified ambient air temperatures for shell egg storage and handling. While many States specify 45 °F or less for that purpose, others retain the 60 °F temperature requirement traditionally required under the USDA grading standards, and some have no requirement. A number of States have stated that they are waiting for USDA implementation of the EPIA shell egg refrigeration requirements before instituting any State law governing shell egg refrigeration.

The egg industry clearly has an interest in finding a way to constructively address the public concern about SE in eggs, and many in the industry have communicated their desire to work with the government toward an effective regulatory solution.

In November 1996, Rose Acre Farms, Inc., submitted a detailed petition (Docket No. 96P–0418) to the Federal agencies that have played a role in the regulation of shell eggs—FDA, FSIS, APHIS, and AMS—requesting that in regulating the presence of pathogens in shell eggs, the agencies ''adopt a comprehensive, coordinated regulatory program to replace the patchwork of approaches they currently take.'' The petitioner acknowledged the need to reduce the prevalence of SE in shell eggs, but advocated a broad-based regulatory program that goes beyond the traceback-and-sanction approach that, the petitioner contended, is both inadequate to protect consumers and unfairly burdens producers. The petitioner called for a collaborative process in developing incentives to encourage improved handling of eggs throughout the farm-to-table cycle and other modifications to promote greater levels of food safety.

In May of 1997, the Center for Science in the Public Interest submitted a petition (Docket No. 97P–0197) requesting that FDA issue regulations requiring that shell egg cartons bear a label cautioning consumers that eggs may contain harmful bacteria and that they should not eat raw or undercooked eggs. The petitioner further requested that all egg producers be required to implement on-farm HACCP programs to minimize the risk that their eggs will be contaminated with SE.

FDA and FSIS are responding to these petitions by initiating such a comprehensive, coordinated process with this ANPR.

Finally, USDA and FDA intend to encourage and assist in additional research on how hens become infected with SE, the factors that relate to infected hens' production of SE-contaminated eggs, better ways to identify specific strains of SE, the virulence and other characteristics of emerging SE strains, the extent of the potential public health risk from SE, and identification of effective controls and intervention strategies.

Because of the number of outbreaks of foodborne illness caused by *Salmonella* Enteritidis that are associated with the consumption of shell eggs, FDA and FSIS have tentatively determined that there are actions that can be taken even at this time to reduce the risk of foodborne illness from shell eggs while

additional measures are being considered pursuant to this ANPR. FSIS intends to act to amend its regulations to require that shell eggs packed for consumer use be stored and transported under refrigeration at an ambient temperature not to exceed 45 °F, and that these packed shell eggs be labeled to indicate that refrigeration is required. FDA intends to act to publish shortly a proposal to (1) require that retail food stores and food service establishments hold shell eggs under refrigeration and (2) require safe handling statements on the labeling of shell eggs that have not been treated to destroy *Salmonella* microorganisms that may be present.

6. Need for Additional Information and Analysis.

In 1991, the EPIA was amended in the wake of publicity about foodborne disease outbreaks attributed to *Salmonella* in shell eggs. The amendment requires, essentially, that shell eggs packed for consumers be stored and transported under refrigeration at an ambient air temperature not to exceed 45 °F. (21 U.S.C. §§ 1034, 1037). Congress also provided that these provisions would be effective only after promulgation of implementing regulations by USDA.

After reviewing the issue in 1996, FSIS concluded and informed Congress that a regulation establishing an ambient air temperature at which eggs must be held and transported would not address the underlying food safety problems, and that the problem could be dealt with effectively only in the context of a broader process examining a variety of issues in addition to ambient air temperatures. As part of the 1998 Appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies (P.L. 105–86), however, Congress provided that $5 million of FSIS' annual appropriation will be available for obligation only after the Agency promulgates a final rule to implement the refrigeration and labeling requirements included in the 1991 EPIA amendments.

FSIS and FDA are now looking at how best to address the food safety concerns associated with shell eggs in the context of their mutual, HACCP-based, farm-to-table food safety strategy. FSIS and FDA believe that comprehensive shell egg regulations must address the public health risks identified; that such regulations must be fully considered in an open, public process; and that each regulation adopted must have been considered in light of available alternatives and be consistent with other laws and regulations.

FSIS and FDA, in furtherance of their commitment to develop a comprehensive strategy for shell eggs, have undertaken the following actions:

(1) *Time-temperature Conference.* A 3-day technical conference on November 18–20, 1996, provided a forum for information on temperature control interventions and verification techniques in the transportation and storage of meat, poultry, seafood, and eggs and egg products. The egg session included many informative technical presentations and policy discussions on the issue of implementing the EPIA's 45 °F ambient temperature requirement. The opportunity to submit written comments to supplement the record was provided.

(2) *Transportation ANPR.* In a related activity, FSIS and FDA published a joint ANPR (61 FR 58780) soliciting information on issues related to ensuring the safety of potentially hazardous foods during transportation. The agencies posed a range of regulatory and non-regulatory options, and solicited information to help them assess the risks and decide what approaches are best suited to addressing those risks. The comment period on this ANPR closed on February 20, 1997. Fifty-two comments have been received.

(3) *Risk Assessment.* The agencies are conducting a quantitative risk assessment for shell eggs. The project is being conducted by a multidisciplinary team of scientists from USDA, FDA, and academia. Begun in December, 1996, it is intended to (a) provide a more definitive understanding of the risks of egg-associated foodborne disease; (b) assist in evaluating risks and ways in which the risks might be reduced; and (c) verify data needs and prioritize data collection efforts. A draft report on risks of SE in eggs and egg products is on the FSIS Homepage and was presented at a technical meeting in September 1997. The draft report of the risk assessment team will be available for public comment and subject to modification based on that input before being made final. Interested persons are encouraged to provide any data or information relevant to the risk assessment for use in the analysis.

(4) *Research.* The Agencies are undertaking efforts to initiate:

—a nationwide surveillance program for SE and SE phage-type 4 to track the spread among layer flocks.

—research (in conjunction with USDA's Agricultural Research Service) on the molecular and virulence comparison of U.S. SE phage-type 4 with isolates from other parts of the world (human and poultry).

(5) *Dialogue.* FDA and FSIS intend to engage affected industry, Federal and State regulatory agencies, and business organizations in an open, on-going dialogue regarding steps they might take voluntarily to address the SE problem and ways in which the Federal agencies might help such efforts.

(6) *Forthcoming FDA/FSIS Actions.* As stated above, because there are actions that can be taken at this time to reduce the risk of foodborne illness from shell eggs, FDA intends to publish shortly a proposal to (1) require that retail food stores and food service establishments hold shell eggs under refrigeration and (2) require safe handling statements on the labeling of shell eggs that have not been treated to destroy *Salmonella* microorganisms that might be present. In that proposal, FDA will solicit comments and information concerning these two matters. FDA requests that comments or information submitted in response to this ANPR also be submitted in response to FDA's proposed rule if such comments or information are relevant to the issues raised therein. In addition, as stated above, FSIS intends to act to amend its regulations to require that shell eggs packed for consumer use be stored and transported at an ambient temperature that does not exceed 45 °F.

Information Requested

FDA and FSIS have available a wide range of mechanisms for administering the laws for which they are responsible. The agencies are interested in the public's views on what regulations may be required to reduce the public health risk of SE in shell eggs, including any performance standards that might be developed.

One approach might be a process-oriented rule similar to the agencies' HACCP regulations for meat, poultry, and seafood. Regulations may be proposed to mandate HACCP-like process controls to reduce the microbiological and other food safety hazards in shell egg production, processing and handling. Such an approach requires each business to develop controls that are best suited to its particular processes and products. The agencies are interested in comments on whether HACCP-like controls could be effective against SE in eggs, in how many producers are presently using HACCP-like controls, and in the overall costs of these controls. The agencies are interested in how such a program would affect small entities.

The agencies may achieve public health objectives by providing guidance to interested parties as a companion to or in lieu of regulations. The agencies

provide a variety of technical information and guidance materials to industries that must comply with Federal laws, to State and local officials, and to consumers. These materials range from general advice to fairly detailed examples or ''models'' of ways in which a plant may ensure compliance with a particular statutory or regulatory provision. Such guidance may be particularly useful for smaller plants with limited resources.

A third general approach would be a Federal-State cooperative program under which overall regulatory oversight is left primarily to State agencies using mutually agreed-upon standards and procedures and Federal assistance. The agencies frequently work cooperatively with State and local government authorities. FDA currently participates in a formal Federal-State cooperative program for the interstate shipment of two commodities, Grade A milk and shellfish.

The agencies believe that a comprehensive, effective program for the control of SE in shell eggs is likely to require some combination of these three general approaches. The following sets out questions the answers to which, the agencies believe, will help them to shape a program that will be useful in reducing risk at each stage in the shell egg farm-to-table continuum.

Production

Should the patchwork of voluntary quality assurance (QA) programs be made consistent with a single, national standard for flock-based quality assurance programs, and be applicable to all producers? Does there need to be more uniformity among the QA programs to assure consumers that producers in all States are uniformly doing all they can to reduce the frequency of SE-contaminated eggs, and to provide ''a level playing field'' among competing producers in the various States?

Should the agencies establish minimum QA requirements for all commercial shell egg producers? This might be accomplished through rulemaking or some form of cooperative program with the States. Should the microbiological testing under such a program be done by a third party (someone other than the producer) to ensure test uniformity and the integrity of the program? Should the agencies require the submission of testing data so that they can identify ways to improve the program, including possible justification for regional variations, verify the overall effectiveness of the program, track the prevalence of emerging strains of SE and, as necessary, identify the need for additional testing programs or other interventions required to protect human or animal health? Should a QA program be voluntary?

Processing

In-shell pasteurization of shell eggs is a relatively new technological development by which harmful bacteria are destroyed without significantly altering the nature of the egg. Were this technology viable for broad scale adoption by producers, it could conceivably significantly reduce the risk of foodborne illness through the destruction of any SE in the egg at the time of processing. The agencies seek comments and information that would address the current viability of in-shell pasteurization for eggs. What factors will determine whether and when in-shell pasteurization of eggs could be applied to the whole industry? Comments should address technological and cost factors.

FSIS and FDA believe that there are many interventions that might be applied during processing that would reduce the risk to consumers from SE in shell eggs. The agencies could continue to defer to States, or processors could be required to use only shell eggs from production facilities adhering to a QA program meeting national standards. This would enable each processor to identify and control all hazards, including SE, that might be introduced into the product during processing. The systems would address those factors known to influence SE growth in shell eggs during processing (principally the age and temperature of the eggs), precluding the necessity of developing detailed prescriptive regulations attempting to specify how such control should be achieved. The agencies would like comments on how such processing requirements might best be structured.

Another alternative might be a sliding scale approach similar to that under consideration by the European Union. Under this approach, a specific egg temperature is not required, but a ''sell by'' date is mandatory, which would vary depending on the temperatures at which eggs are maintained. Assuming packed eggs are transported and stored at an ambient air temperature of 45 °F, the primary determinant of the temperature of eggs in commercial channels will be the temperature of the eggs when they are shipped from the packer. To provide an incentive for processors to chill eggs before shipping, yet retain flexibility to accommodate reasonable alternatives to an absolute temperature requirement, a regulation might prescribe a range of ''sell-by'' dates based on the egg temperature achieved by the packer. However, such an approach might be difficult to verify and enforce. The agencies would like comments on the feasibility and advisability of this kind of approach.

Retail

FDA intends shortly to propose regulations to require that food retail and food service establishment hold eggs under refrigeration. As explained elsewhere in this document, FDA believes that these actions are measures that can be taken at this time to reduce the risk of foodborne illness from shell eggs. Pursuant to this ANPR, both agencies will consider other matters that affect eggs at retail as part of the comprehensive farm-to-table solution that the agencies ultimately put in place.

The agencies are interested in whether retail stores should require their suppliers to use temperature recording devices, or affix temperature indicating devices on the egg cases or cartons, to help ensure that the eggs have not been subject to temperature abuse during transportation. Could any requirement for delivery at 45 °F be enforced effectively as a matter of contract between the processors (vendors) and the retail stores (purchasers)? Should the agencies consider regulations to effect these changes?

Restaurants and Food Service Operations

Restaurants, food service operators, and many retail stores that prepare food for immediate consumption are regulated primarily by State and local governments. Should the agencies take a more direct role, or should they continue to rely on the *Food Code* to provide guidance on the maintenance and preparation of eggs and encourage State and local authorities to adopt and enforce those standards?

The agencies believe that much of what must be done to reduce the risk of foodborne disease transmission in restaurants and other food service facilities involves education and training. Food service managers play an increasingly important role in food safety, and they must place a high priority on employee hygiene and proper food handling techniques. Thus, the Federal agencies are currently exploring with industry representatives (the major associations representing retail stores and restaurants as well as major food producer groups), representatives of State and local regulatory agencies, and consumer groups the possibility of a partnership

that would build on current programs to develop a comprehensive, national food safety education and training campaign directed at people who work in restaurants and other food service facilities, people who work in retail stores, and at consumers. This campaign would include lesson plans and materials for classroom training that could be used in public school curricula as well as in food service settings.

Household Consumers

A primary tool for reducing the risk of foodborne disease among consumers is education. To ensure that consumers are fully and adequately informed of the significant risks associated with SE in eggs and how to best avoid these risks, FDA shortly will be proposing certain labeling requirements for eggs. The agencies also plan to intensify their consumer education efforts in the coming months and to institute permanent food safety education programs that will help consumers protect themselves from all food safety hazards.

Thus, by this notice, FDA and FSIS are requesting comments and information on a variety of issues concerning ways to reduce the risk to the public health from SE in shell eggs. These issues need to be addressed comprehensively by the agencies. FSIS and FDA welcome discussion and comments on the issues in this notice and other issues related to the subject. The agencies are particularly interested in comments about alternatives that would minimize the impact on small entities.

Done in Washington, DC, on May 11, 1998.

Thomas J. Billy,

Administrator, FSIS.

William B. Schultz,

Deputy Commissioner for Policy, FDA.

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DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 273 and 274

RIN 0584–AC61

Food Stamp Program: Electronic Benefits Transfer Benefit Adjustments

AGENCY: Food and Nutrition Service, USDA.

ACTION: Proposed Rule.

SUMMARY: This rule proposes to revise Food Stamp Program regulations pertaining to State agencies' ability to make adjustments to a recipient account in an Electronic Benefits Transfer (EBT) system, in order to correct a system error or an out-of-balance condition. EBT stakeholders have proposed the changes so that States and their processors can correct errors when they are identified, rather than 10 days after the advance notice has been sent to the household. The changes would enable State agencies to correct errors in a more timely manner, and bring EBT closer in line with current commercial Electronic Funds Transfer (EFT) practices. This rule also proposes to revise the formula