federal register

Tuesday
July 6, 1999

Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 16, 101, and 115

Food Labeling: Safe Handling Statements: Labeling of Shell Eggs; Shell Eggs: Refrigeration of Shell Eggs Held for Retail Distribution; Proposed Rule

Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rule to Require Refrigeration of Shell Eggs at Retail and Safe Handling Labels; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 101, and 115

[Docket Nos. 98N–1230, 96P–0418, and 97P–0197]

RIN 0910–AB30

Food Labeling: Safe Handling Statements: Labeling of Shell Eggs; Shell Eggs: Refrigeration of Shell Eggs Held for Retail Distribution

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require safe handling statements on labels of shell eggs that have not been treated to destroy *Salmonella* microorganisms. The agency is also proposing to require that, when held by retail establishments, shell eggs be stored and displayed under refrigeration at a temperature of 7.2 °C (45 °F) or less. FDA is taking these actions because of the number of outbreaks of foodborne illnesses and deaths caused by *Salmonella* Enteritidis that are associated with the consumption of shell eggs that have not been treated to destroy this pathogen. These actions complement regulations of the Food Safety and Inspection Service (FSIS) that require that shell eggs be stored and transported at a temperature of 7.2 °C (45 °F) or less and that the consumer containers of shell eggs be labeled to indicate that refrigeration is required. FDA's proposal also responds, in part, to petitions from Rose Acres Farm, Inc., and the Center for Science in the Public Interest (CSPI). FDA expects that by requiring this information, consumers will be able to take measures to protect themselves from illness or deaths associated with consumption of shell eggs that have not been treated to destroy *Salmonella* Enteritidis.

DATES: Written comments by September 20, 1999. See section VII for the proposed effective date of a final rule based on this proposal.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of this proposed rule are available on the Internet at ''http://www.fda.gov/cfsan''.

FOR FURTHER INFORMATION CONTACT: Geraldine A. June, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

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I. Background

A. Epidemiology of Salmonellosis

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

The disease salmonellosis results from an intestinal infection with *Salmonella* microorganisms and is characterized by diarrhea, fever, abdominal cramps, headache, nausea, and vomiting. Symptoms of salmonellosis usually begin within 6 to 72 hours after consuming a contaminated food or liquid and last for 4 to 7 days. Most healthy people recover without antibiotic treatment. However, the infection can spread 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 severe and fatal illness (Ref. 1). This spreading phenomenon of salmonellosis is more likely in children, the elderly, and persons with weakened immune systems. In addition, about 2 percent of those who recover from salmonellosis may later develop recurring joint pains and arthritis (Ref. 2).

Salmonellosis is a serious health concern. It is a notifiable disease, i.e., physicians are required to report cases (i.e., single occurrences of illness) to the local health departments. These cases are then, in turn, reported to state health departments, which report the annual totals to the Centers for Disease Control and Prevention (CDC). However, these reports are made only if there are test results identifying the *Salmonella* microorganism that caused the illness.

In a 1979 to 1980 epidemiological study, CDC estimated that about 45 percent of those persons from whom *Salmonella* isolates[1] were reported were hospitalized for their illness and that 1.3 percent of them died from complications associated with the illness (Ref. 3). Very similar proportions were found in a 1984 to 1985 study. Using these proportions, CDC estimated that, in 1988, the approximately 43,000 reported cases represented a minimum of 19,000 hospitalizations and 500 deaths. Reported cases likely represent only a small portion of the actual number of illnesses that occur because: (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 simply treat the symptoms; and (3) medical professionals do not always report *Salmonella* cases to CDC. It is estimated that the actual number of cases per year may be 20-fold to 100-fold greater than the number of reported cases. Therefore, the number of actual cases of salmonellosis in 1988 was estimated to be from 800,000 to 4 million (Ref. 4). In 1996, there were 39,027 confirmed cases[2] of human salmonellosis reported to the CDC.

CDC surveillance data list close to 600 different *Salmonella* serotypes (a group of related microorganisms distinguished by their antigens) that have caused illness in the United States. The three serotypes most frequently reported as

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

[2] A case of illness is confirmed as salmonellosis only if an isolate is confirmed by a laboratory as being *Salmonella*. Thus, although all cases may not be confirmed, all confirmed cases are associated with isolates of *Salmonella*.

causing illness are *Salmonella* Enteritidis (SE), *S.* Typhimurium, and *S.* Heidelberg (Ref. 5). These microorganisms are found in poultry and eggs.

Since 1976, SE-associated cases of salmonellosis have increased and have been found throughout the country. SE accounted for only about 5 percent of the number of all reported *Salmonella* isolates in 1976. In 1985, 1990, 1994, 1995, 1996, and 1997, SE constituted 9.8 percent, 20.6 percent, 26 percent, 24.7 percent, 24.5 percent, and 22.9 percent, respectively, of all *Salmonella* isolates. Currently, SE is one of the most predominant reported serotypes. There were 7,924 SE isolates reported in 1997 (Ref 7).

CDC surveillance data show that the overall rates of isolation[3] of SE increased 680 percent during the period between 1976 to 1994 (Ref. 6). Initially, the increases in the United States largely occurred in the Northeast. Later, the increase spread throughout the country. While the trends for the years 1990 to 1994 show a 21 percent decrease in the SE isolation rate in the Northeast, the rate increased approximately 300 percent for the Pacific region.

In 1985, the States reported 26 SE-related outbreaks (i.e., occurrences of 2 or more cases of a disease related in time and place) to CDC but 77 outbreaks were reported by 1989. In 1996, there were 51 reported SE outbreaks (Ref. 9). From 1985 through 1996, there have been a total of 660 SE-related outbreaks reported to CDC. Associated with these outbreaks, there have been 25,935 reported cases of illness, 2,508 reported hospitalizations, and 77 reported deaths. Deaths have occurred in all years of this time period. In 1997, there were 44 reported outbreaks (Ref. 10). Many SE outbreaks were attributed to food served in commercial establishments, such as restaurants and other commercial food service establishments, hospitals, nursing homes, schools, prisons, private gatherings, and ships, with the implicated food containing undercooked eggs (Ref. 11). Although most deaths linked to reported SE-related outbreaks in recent years have occurred among the elderly in hospitals and nursing homes (Ref. 3), salmonellosis can be fatal to an otherwise healthy person if a sufficient dose is ingested, and proper treatment is not administered (Ref. 12).

Until the mid-1980's, eggs were not associated with many *Salmonella* outbreaks. Since the mid-1980's, however, the number of egg-associated salmonellosis outbreaks have increased. Shell eggs are now the predominant source of SE-related cases of salmonellosis in the United States where a food vehicle is identified (Ref. 13). From 1985 to 1993, consumption of eggs was associated with 83 percent of SE-related outbreaks where a food vehicle was identified (Ref. 14). Recent data indicate that egg-associated SE outbreaks still represent a significant portion of the total number of all SE outbreaks reported to CDC. In 1996, 1997, and 1998, 60 percent, 70 percent, and 58 percent of the SE outbreaks reported to CDC implicated foods containing eggs (Ref. 14A).[4]

The Foodborne Diseases Active Surveillance Network (FoodNet[5]), an active surveillance system for foodborne pathogens, recently reported a 44 percent decrease in the isolation rate for SE (2.5 to 1.4 per 100,000 U.S. population) from 1996 to 1998 (Ref. 14B). This decrease is substantial; however, the results are preliminary and the reasons for this decrease are under investigation. Implementation of egg quality assurance programs that included microbiological testing and egg diversion may have contributed to this reported decrease. However, the reported decrease may also be explained by a decline in the presence of *Salmonella* isolated from poultry and meat products because of recently implemented HACCP programs, or by some combination of egg quality assurance and meat/poultry HACCP program. In any event, FDA believes that the incidence of SE is still too high and that additional measures can and should be put in place with respect to shell eggs to reduce the incidence even further.

B. Salmonella Contamination of Eggs

Having evolved to protect the developing chick embryo, an egg provides a uniquely inhospitable environment for *Salmonella* and other bacterial contaminants. An egg's natural defenses are both mechanical and chemical. Mechanically, there are four barriers that must be overcome for bacteria to reach the nutrient-rich yolk where they can rapidly multiply: (1) The shell, (2) the two membranes (inner and outer) between the shell and the albumin (egg white), (3) the albumin, and (4) the vitellin (yolk) membrane that holds the yolk. Additionally, when laid, the egg shell is covered on the outside by the cuticle, a substance similar to the shell membrane. When the cuticle dries, it seals the egg's pores, thereby inhibiting initial bacterial penetration. Consequently, a fresh egg is fairly resistant to invasive bacteria. However, the cuticle is generally removed along with debris on the surface of the shell during the cleaning process employed to prepare eggs for commercial sale. Thus, this outermost defense is generally not available to protect against trans-shell penetration of bacteria.

The albumin is probably the most formidable defense against microorganisms that have entered an egg. In a fresh egg, the albumin has a high viscosity that both anchors the yolk in the center of the egg and inhibits movement of microorganisms toward the yolk. Chemical defenses of the albumin include: (1) A very alkaline pH (>9), (2) low available nitrogen, and (3) proteins that have an anti-bacterial effect, specifically, ova-transferrin and lysozyme. If, however, conditions occur that allow SE to transverse the mechanical and chemical barriers in an egg and reach the nutrient rich yolk, the microorganisms may then increase in number.

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

While environmental contamination is still a route for *Salmonella* contamination, it has recently been found that an egg's contents can become contaminated with SE before the egg is laid. Though the mechanism is still not well understood, SE will infect the ovaries and oviducts of some egg laying hens, permitting ''transovarian'' contamination of the interior of the egg while the egg is still inside the hen (Refs. 15 and 16). The site of contamination is usually the albumin.

It is believed that only a small number of hens in an infected flock shed SE at any given time and that an infected hen

[3] Rates of isolation are the number of reported isolates divided by 100,000 total population.

[4] The total number of SE outbreaks implicating eggs is equal to the total number of SE outbreaks minus the number of outbreaks where the vehicle is unknown or where the implicated food is one other than eggs, i.e., chicken or turkey.

[5] FoodNet is a collaborative project among CDC, FSIS, FDA, and 8 sites in the U.S. where foodborne disease data are being collected. To identify cases of foodborne illness, surveillance personnel contact clinical laboratories weekly or monthly to obtain data on numbers of cases.

may lay many uncontaminated eggs (Refs. 15 and 17). Nonetheless, it has been estimated that of the 47 billion shell eggs consumed annually as shell eggs, 2.3 million are SE-positive, exposing a large number of people to the risk of illness (Ref. 8). FDA believes that it is this transovarian contamination that is responsible for the increased number of SE-related salmonellosis cases described in section I.A of this document.

C. Infectious Dose

In general, the greater the numbers of microorganisms ingested, the greater the likelihood of disease. The likelihood of disease is also affected by the virulence of the microorganism and the susceptibility of the host (Ref. 18). However, there is evidence that the infectious dose (i.e., amount of microorganisms capable of causing disease) for SE can be very low. For example, in a 1994 outbreak attributed to consumption of SE-contaminated ice cream, the highest level of contamination found in the implicated ice cream was only six microorganisms per half-cup (65 gram) serving (Ref. 19). Another report showed that by using a different method of determining levels of SE in the implicated ice cream, the infective dose per serving was 25 microorganisms (Ref. 20). These reports indicate that low level contamination of foods with SE, and thus, low doses, can lead to illness. It is generally believed that SE-contaminated eggs initially contain only a few microorganisms (less than 20 microorganisms (Ref. 21)). Thus, the small number of microorganisms that initially may contaminate the egg may be sufficient to cause illness.

D. Inappropriate Handling of Eggs by Consumers and Other Food Preparers

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

Temperature abuse gives SE the opportunity to multiply, thereby increasing the number of viable microorganisms ingested, especially when eggs are consumed raw. Temperature abuse and consumption of raw eggs were associated with an SE outbreak at a catered wedding reception in New York, where Caesar salad dressing was implicated as the cause of SE illnesses. The Caesar salad dressing was made with 18 raw shell eggs, left unrefrigerated for 2 hours at the catering establishment, held in an unrefrigerated truck until delivered, and served at the reception 4½ hours later (Ref. 6).

Incomplete cooking of eggs (as in soft-boiled eggs or sunny-side up eggs) also allows ingestion of viable microorganisms if any of the eggs were initially contaminated. Incomplete cooking of eggs was associated with an SE outbreak in Tennessee, where the consumption of Hollandaise sauce served in a restaurant was linked to SE illnesses. Review of the food handling practices showed that the sauce had been prepared from eggs that were pooled, incompletely cooked, and served more than one hour after preparation (Ref. 12). Another outbreak of SE illness in an Indiana nursing home was linked to the consumption of baked eggs. The baked eggs were prepared by pooling 180 Grade A raw shell eggs, mixing with a whisk, and baking in a single pan at 204 °C (400 °F) for 45 minutes to 1 hour. Investigators believed that inadequate cooking occurred because the mixture was not stirred while baked (Ref. 6).

FDA is also aware that many consumers eat foods containing raw or undercooked eggs. An FDA survey indicated that 53 percent of respondents (total 1,620) ate foods containing raw eggs at some time (Ref. 22). Raw egg-containing foods mentioned in this survey included cookie batter, homemade ice cream, homemade eggnog, Caesar salad, frosting, homemade shakes, homemade Hollandaise sauce, and homemade mayonnaise. The Menu Census Survey (1992 to 1995) (Refs. 23 and 24) showed that frosting accounted for 53 percent and salad dressing 19 percent of occasions when raw egg-containing products were consumed.

The 1996 to 1997 Food Consumption and Preparation Diary Survey (Ref. 24) showed that 27 percent of all egg dishes consumed were undercooked (described as being runny or having a runny yolk or runny white). On average, each person consumed undercooked eggs 20 times a year. Within those groups at risk, women over 65 and children under 6 consumed undercooked eggs 21 times a year and 8 times a year, respectively. Moreover, consumer focus group research showed that many participants did not realize that certain foods such as chocolate mousse or key lime pie may contain raw or undercooked eggs, and, therefore, are potentially hazardous (Ref. 25).

E. Current Commercial Practices for Handling Eggs

Egg production facilities are either ''in-line'' facilities or ''off-line'' facilities. An in-line facility integrates laying, packing, and processing at one location. Freshly laid eggs go directly into a processing system where they are cleaned, sorted, and packed for distribution. An ''off-line'' facility receives eggs from laying facilities at other locations. Generally eggs are cleaned before they are packed. Typically, U.S. processors use hot water (43 to 49 °C (110 to 120 °F)) to wash eggs. After the eggs are washed, they are dried with forced ambient air and then packed. At the time that eggs are packed, the internal temperatures are often in the 21 to 27 °C (70 to 80 °F) range. Most processors hold packed eggs in coolers at an ambient temperature of 7 to 16 °C (45 to 60 °F).

Currently, eggs are held at various temperatures for various times prior to purchase by the consumer. The U.S. Department of Agriculture (USDA) estimates the following times and temperatures in the distribution of shell eggs: (1) 2 to 72 hours at temperatures of 7.2 to 32 °C (45 to 90 °F) at the processor, (2) 1 to 24 hours at temperatures of 7.2 to 32 °C (45 to 90 °F) during transportation, (3) 0 to 60 days at temperatures of 4 to 32 °C (40 to 90 °F) at retail (Ref. 8). These data indicate that, especially at retail, eggs are being held, for long periods of time, at temperatures that will not inhibit growth of SE. Currently, 37 States and the District of Columbia require ambient temperatures of 7.2 °C (45 °F) or less for egg storage and handling at retail. The other States either require ambient temperatures of 16 °C (60 °F) or less (i.e., the temperature required under USDA grading standards) or have no temperature requirements for egg storage and handling at retail.

These ambient temperatures, however, do not correlate to the internal temperature of the egg. The internal temperature of the egg when the eggs are transported ranges between 10 and 27 °C (50 and 80 °F), depending on the egg's temperature at the time of packing, the way the eggs are packaged, how the crates are packed and stacked, and the length of time they are in the cooler before they are shipped (Ref. 26).

F. Limiting the Numbers of Salmonella Microorganisms in Eggs

Because studies suggest that infectious dose for SE can be low, FDA

believes that the ideal solution to this public health problem would be to adopt measures to eliminate viable SE in shell eggs, either through preventing transovarian and trans-shell contamination or through processing to destroy viable SE in shell eggs, with distribution safeguards to prevent subsequent recontamination. However, FDA has tentatively concluded that eliminating viable SE in shell eggs in either of these two ways is not yet practicable. Other measures that can limit SE and inform consumers how to avoid the risks posed by SE are, however, practicable and thus FDA is proposing in this regulation to put such measures in place. The agency has also, jointly with USDA, published an advance notice of proposed rulemaking (ANPRM) (63 FR 27502, May 19, 1998; ''the 1998 ANPRM'') that requests comments on farm-to-table actions that will decrease the food safety risks associated with shell eggs.

As mentioned previously, although fresh shell eggs provide a particularly inhospitable environment for *Salmonella* and other microorganisms to multiply, the chemical and physical barriers against bacterial movement and growth degrade over a period of time. Consequently, as a result of degradation, SE and other bacteria, if present, are better able to move into the nutrient rich yolk, which provides a favorable environment for growth of SE.

Studies demonstrate that the rate of this degradation is time and temperature related. C. J. Kim et al. (Ref. 27) found that SE inoculated into the albumin of whole shell eggs multiplied to high numbers if the inoculated eggs were not properly refrigerated. This study examined the growth of SE inoculated into the albumin of shell eggs in numbers ranging from approximately 2 to 200,000 organisms per egg and held for 10, 20, or 30 days at 1 of 5 different temperatures from 4 °C (39 °F) to 27 °C (81 °F).

The investigators in this study found that, of the variables studied, temperature was the most important in determining the growth of SE (Ref. 27). Furthermore, they found that the growth response was directly proportional to the temperature at which the inoculated eggs were held. The study demonstrated that SE inoculated in shell eggs can multiply to substantial levels if held at 10 °C (50 °F) or higher for up to 30 days. The authors concluded that ''because the number of SE present at the time an infected egg is laid is probably very low, egg storage at 4 °C (39 °F) could be expected to result in a smaller risk to the public health than higher storage temperatures'' (Ref. 27). Thus, although albumin is inhibitory to *Salmonella*, these experiments show that SE inoculated into shell egg albumin, even at low levels, can multiply to substantial levels if held at 10 °C (50 °F) or higher for a significant period of time.

A subsequent study by Humphrey et al., (Ref. 21), of 5,700 eggs from flocks naturally infected with SE, appears to show that albumin is seeded with SE during passage of the egg through the oviduct. These SE microorganisms remain dormant even in eggs stored at room temperature (21 °C (70 °F)) for 2 to 3 weeks. However, after that period of time, nutrients or factors that negate the inhibitory properties of albumin appear to leak out of the yolk, possibly because of changes in the yolk membrane. These substances obtain levels close to the yolk in a sufficiently high concentration to support large populations of SE.

In a study of laying hens that were experimentally infected with SE, R. K. Gast and C. W. Beard (Ref. 28) also found that infected hens can produce eggs with SE contaminated contents. Their study indicates that transovarian infection followed by limited room temperature storage (25 °C (77 °F)) resulted in contamination of the yolk membrane or albumin, or both, but not the contents of the yolk. In the Gast and Beard experiments, all eggs were held at room temperature for 4 days before sampling. Although the number of microorganisms per egg was not measured, indirect evidence, such as the higher recovery frequency of SE from egg contents when incubated in broth for 48 hours versus 24 hours, suggests that the number of microorganisms per egg was low after holding the eggs for 4 days at room temperature.

Clay and Board (Ref. 29), by inoculating SE into the air cell of eggs, were able to show that the movement of the microorganism from the shell membrane to albumin and to the yolk was associated with aging related changes in the egg structure. These changes, such as changes in the relative densities of the albumin and yolk and enlargement of the air cell, result in movement of the yolk towards the inoculated SE during storage. These changes have the effect of bringing the yolk closer to the contaminated shell membranes when the egg is incubated in a position with the air cell uppermost. These investigators found that gross contamination of the albumin with SE was inhibited when the eggs were stored at 4 °C (39 °F) although the microorganism was viable throughout 30 days of storage. However, storage of eggs at 4 °C (39 °F) or 10 °C (50 °F) for 20 days followed by an increase in temperature to 25 °C (77 °F) led to generalized infection of the egg contents. Clay and Board state that their observations suggest that refrigerated storage of eggs should be a part of a protective barrier between the laying flock and the consumer, and to be effectively realized, refrigerated storage would have to be imposed shortly after the egg is laid and continue until immediately before cooking and consumption.

T. J. Humphrey (Ref. 30) studied the effect of storage temperatures of 8, 10, 12, and 15 °C (46, 50, 54, and 59 °F) on *Salmonella* growth in artificially inoculated eggs. No growth was observed after 3 weeks at 8 °C (46 °F). Growth of SE phage type 4 and 13a was observed at 10, 12, and 15 °C (50, 54, and 59 °F). SE phage 8 showed no growth at temperatures below 12 °C (54 °F).

Bradshaw et al. (Ref. 30A) studied the effect of storage temperatures on the growth of SE inoculated into the yolks of shell eggs. The inoculated yolks were incubated at 37, 15.5 and 7 °C (99, 59, and 45 °F). They observed no significant growth when the eggs were held at 7 °C (45 °F) for up to 94 days.

FDA finds that the scientific evidence on the growth of SE in eggs shows that control of storage temperature of shell eggs can effectively prevent the multiplication of any SE that may be present. While there is some debate about the precise optimum storage temperature for eggs, the research cited previously clearly indicates that refrigerating shell eggs at 8 °C (46 °F) and 7.2 °C (45 °F) or less greatly extends the time that an egg can maintain its defenses against movement of contaminating bacteria such as *Salmonella* to the nutrient rich yolk, and, therefore, substantially reduces the likelihood that any SE that is present will be able to increase in numbers. Moreover, there is evidence that cooling eggs reduces the heat resistance of SE microorganisms, making any microorganisms that may be present in an egg more likely to be killed when the egg is less than completely cooked (Refs. 30 and 31). Thus, FDA believes that sustained refrigeration of eggs plays an important role in reducing the likelihood that any SE present will reproduce.

Although continued refrigeration of eggs reduces likelihood of outgrowth of any SE that may be present, another measure a consumer may take to reduce the likelihood of consuming contaminated eggs is to thoroughly cook eggs. CDC reports that thorough cooking normally kills *Salmonella* that may be present in eggs (Ref. 32). However, some

cooking techniques commonly used for eggs or egg-containing foods do not thoroughly cook the eggs. For example, eggs that are liquid or runny after light cooking (e.g., soft boiled eggs, and sunny-side up eggs) can still contain viable *Salmonella* microorganisms. FDA's Food Code (a model code that is published by FDA and intended for adoption by States and local authorities for governing food retail and food service establishments) requires that raw eggs that are broken and prepared in response to a consumer's order be cooked at 63 °C (145 °F) for 15 seconds. Other raw eggs are required to be cooked 15 seconds at 68 °C (155 °F) (Ref. 33).

G. Current Efforts

FDA and the Food Safety and Inspection Service (FSIS) of the USDA share Federal authority to regulate eggs for safety. FDA has jurisdiction over the safety of foods (except meat and poultry) generally, including shell eggs, under section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, *et seq.*) and under the Public Health Service Act (PHS Act) (42 U.S.C. 201 *et seq.*).

USDA has primary responsibility for implementing the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*). Under the EPIA, FSIS, and USDA's Agricultural Marketing Service (AMS) share responsibility to inspect processed egg products and to ensure proper distribution of eggs that are cracked or otherwise unsuitable for sale as whole shell eggs.

Federal agencies are working cooperatively with egg producers and others to enhance the safety of eggs that are sold to consumers. USDA's Extension Service, FSIS, AMS, and FDA all provide educational material on egg production methods that enhance food safety. FDA and FSIS work with States to encourage uniformity among state laws in retail and food service establishments through adoption of the Food Code. In addition, FDA, which has responsibility for investigating reports of SE outbreaks from foods in interstate commerce, performs trace backs to identify the source of the implicated eggs, environmentally tests flocks, diverts eggs from SE positive flocks, collects flock data to help track the spread of SE among layer flocks, and encourages better quality control.

In recent years, several programs have been created for the purpose of controlling the spread of SE on farms. One such program, the National Poultry Improvement Plan (NPIP), a cooperative Federal-State program sponsored by USDA's Animal Plant Health Inspection Service (APHIS), was developed to provide assistance to breeders and hatcheries in keeping flocks free of egg-transmitted diseases. In 1989, the NPIP developed an SE control program to reduce the prevalence of SE in hatching eggs and chicks through sanitation and other control measures. Another APHIS-sponsored joint Federal, State, and academic program, the *Salmonella* Enteritidis Pilot Program, was started in Pennsylvania in 1992. The objectives of the program were to develop effective and efficient procedures for monitoring SE and effective and efficient ways to prevent SE from contaminating eggs. The findings from the pilot program were incorporated into the Pennsylvania Egg Quality Assurance Program (PEQAP). The success of the PEQAP was indicated by a study, conducted in 1995, that demonstrated a decline in the number of SE-positive samples in houses that had been in the program from 1992 to 1995 (Ref. 34). Other programs have been developed to address the spread of SE to eggs, such as California's Egg Quality Assurance Plan, the New England Risk Reduction Program for SE, the United Egg Producers' Five Star Program, and the United States Animal Health Association's Best Management Practices for a *Salmonella* Enteritidis Reduction Program For Egg Producers.

A spent hen and liquid egg survey conducted by USDA in 1991 and repeated in 1995 showed that, despite the efforts described previously, the nation-wide prevalence of SE-positive flocks and the incidence of SE in shell eggs increased (Ref. 35). Because of the number of human illnesses and deaths attributable to SE in shell eggs, FDA and USDA are concerned that the current regulatory program for shell eggs is not adequate. Consequently, FDA and USDA are looking at ways of addressing the ''farm to table'' safety of shell eggs. FDA and FSIS recently have taken several steps to address the issue of reducing the risk of SE associated with shell eggs.

For example, in 1990, FDA reclassified eggs as a ''potentially hazardous food'' in the Food Code. The 1999 Food Code stipulates that potentially hazardous foods, including eggs, be maintained at 5 °C (41 °F) or less (Ref. 33). However, because of the number of illnesses associated with eggs and the fact that not all States have adopted this aspect of the Food Code, FDA tentatively concludes that stronger measures are necessary regarding handling of shell eggs.

On November 18 to 20, 1996, FDA and FSIS sponsored a 3-day technical conference that provided a forum for discussion on temperature control interventions and verification techniques in the transportation and storage of meat, poultry, seafood, and eggs and egg products. FSIS and FDA also published a joint ANPRM (61 FR 59372, November 22, 1996) soliciting information on issues related to ensuring the safety of potentially hazardous foods during transportation and storage. Comments to that document are being analyzed.

In addition, in December 1996, FSIS began a science based risk assessment for shell eggs and egg products. This project was conducted by a multidisciplinary team of scientists from academia and USDA. The project goals were to provide an understanding of egg-associated foodborne disease, assist in evaluating farm to table risks and ways to reduce risks, and verify additional data needs. The final report was issued June 12, 1998.

On September 3, 1997, FDA and FSIS jointly held a public meeting to review the current science, including technological and safety factors, relating to shell eggs and egg products and to identify intervention options that are most effective in reducing the public health risk in a cost-effective manner. Experts from industry, academic, regulatory, and consumer sectors presented information on illnesses and the epidemiology of outbreaks arising from shell eggs and foods containing raw and undercooked eggs; current concerns with emerging pathogens; procedures for processing eggs; and new and existing technology to control pathogens in shell eggs and egg products. Comments from this meeting were considered in the risk assessment project.

In addition, FDA and USDA recently published in the **Federal Register** an ANPRM seeking to identify farm-to-table actions that will decrease the food safety risks associated with shell eggs. Information gathered from the foregoing measures will be considered as part of the two agencies' approaches for a comprehensive program to address the safety of shell eggs from farm to table. Because rulemaking to address a comprehensive program will likely take considerable time, FDA believes that it can meet an immediate goal of reducing the risk of foodborne illness from SE by ensuring that shell eggs at retail are held at appropriate temperatures and by providing safe handling statements for shell eggs. In addition, as stated in section II.A of this document, USDA published a final rule in the **Federal Register** of August 27, 1998 (63 FR 45663), amending its regulations to require that shell eggs packed for

consumer use be stored and transported at an ambient temperature that does not exceed 7.2 °C (45 °F) and that containers of shell eggs be labeled to indicate that refrigeration is required. Both FDA and FSIS will consider actions based on comments to the ANPRM to address issues other than labeling and refrigeration of eggs while held for retail distribution.

H. Petitions to the Agency

FDA received a petition from Rose Acres Farms, Inc., (filed November 4, 1996, Docket No. 96P–0418) requesting, among other things, that the agency amend § 101.17 (21 CFR 101.17) by adding a requirement that shell eggs bear a label statement that informs consumers of safe handling practices for the product. In support of its request, the petition contended that practically all SE outbreaks and deaths have involved mishandling of eggs. The petition stated that, therefore, reducing practices such as temperature abuse or inadequately cooking eggs would virtually eliminate the problem. The petition also asserted that some egg producers may not wish voluntarily to include safe handling information on their labels because they fear their competitors may not include the same information, and, therefore, their product would seem less safe by comparison. However, if FDA required safe handling instructions on all cartons of shell eggs, then no producer would be at a competitive disadvantage. The petition suggested the following label statement: ''Keep refrigerated and cook thoroughly before eating. Use pasteurized egg products for any recipe which does not require that the eggs be thoroughly cooked.''

FDA also received a petition from CSPI (filed May 14, 1997, Docket No. 97P–0197) requesting, among other things, that the agency require that the carton of shell eggs bear a label statement cautioning consumers that eggs may contain harmful bacteria, and that consumers should not eat raw or undercooked eggs. In support of its request, CSPI stated that SE in eggs is a serious health problem and that illnesses caused by SE in the United States have increased. CSPI further stated that consumers have no way of knowing that an egg is contaminated because eggs that are contaminated with SE have a normal appearance. The petition suggested the following label statement: ''Caution: Eggs may contain illness-causing bacteria. Do not eat raw. Cook until yolk is firm.''

The petition also requested, among other measures, that the agency require that eggs be refrigerated to an internal temperature of 5 °C (41 °F) as soon as possible and kept at that temperature at all points up to and including the point of retail sale. This temperature, according to CSPI, will ensure that SE cannot multiply.

USDA/FDA received approximately 73 responses to the 1998 ANPRM, each containing one or more comments. Responses were received from egg farmers, egg packers, associations for the egg industry, other trade associations, consumers, consumer interest groups, animal interest groups, academia, State government agencies, and foreign government agencies. Many of these comments addressed issues not relevant to this proposed rule, e.g., implementation of national standards for QA programs, implementation of HACCP, transportation of shell eggs, sell-by and expiration dates for shell eggs, housing and forced molting of chickens, repacking of eggs, and exportation of SE-contaminated into other countries. FDA will not address those comments in this proposed rule. There were, however, several comments that did raise issues relevant to this proposed rule such as the extent of the SE problem, refrigeration of shell eggs, and safe handling instructions on consumer packages of shell eggs. Although most of these comments supported the approach proposed in this document, some comments suggested different approaches than those in this proposal. These latter comments are addressed below in the appropriate sections of this document.

II. The Proposal to Require Refrigeration of Shell Eggs in Retail Establishments

A. Rationale for Proposal

As noted previously, the incidence and geographical distribution of egg-associated SE illnesses have made SE a significant public health concern. As discussed in section I.F of this document, one currently practicable measure that can limit the number of viable SE present in shell eggs is refrigeration, because it helps to maintain the effectiveness of the egg's natural defenses against SE and slows the growth rate of SE. Many of the comments to the 1998 ANPRM maintained that refrigeration of eggs is an essential measure to inhibit the growth of SE. Although there is the potential for SE to be present in shell eggs in infective doses regardless of adequate handling, temperature abuse increases the likelihood for the growth of any microorganisms present, thus increasing the risk of illness.

As noted previously, USDA has the responsibility of implementing the EPIA. Amendments to the EPIA in 1991 (Pub. L. 102–237) require that shell eggs packed for consumers be stored and transported under refrigeration at an ambient temperature (i.e., the air temperature maintained in an egg storage facility or transport vehicle) not to exceed 45 °F and that the egg containers be labeled to indicate that refrigeration is required. FSIS has amended its regulations to require that no shell egg handler shall possess any shell eggs that are packed in containers destined for the ultimate consumer unless they are stored and transported under refrigeration at an ambient temperature of no greater than 45 °F (7.2 °C). In its regulation, FSIS defines an egg handler as any person, excluding the ultimate consumer, who engages in any business in commerce that involves buying or selling any eggs or processing any egg products, or otherwise using any eggs in the preparation of human food. FSIS defines an ultimate consumer as any household consumer, restaurant, institution, or other party who has purchased or received shell eggs or egg products for consumption. This regulation is effective August 27, 1999.

Once the amendments to the EPIA are implemented, requirements will be in place for the refrigeration of packed shell eggs up to the point of retail distribution except that egg producers with a flock of 3,000 hens or less are exempt from this requirement. However, without the continued refrigeration of shell eggs up to the time the eggs are cooked, there would be an opportunity for the egg's defenses to degrade and growth of SE to occur. FSIS's regulation does not require the ultimate consumer to maintain shell eggs under refrigeration. Consequently, the failure to refrigerate shell eggs in facilities such as restaurants and institutions could result in SE outgrowth. Therefore, to ensure that shell eggs are maintained under refrigeration throughout retail distribution up until they are cooked. FDA tentatively concludes that it should propose requirements that shell eggs throughout retail distribution be kept refrigerated until they are cooked. Without these requirements, the effectiveness of refrigeration in any part of the farm-to-table continuum would not be maximized.

B. Legal Authority for FDA to Require Refrigeration of Shell Eggs

FDA is proposing these regulations under both the PHS Act and the act. FDA's legal authority to require refrigeration of eggs at retail derives from the provisions of sections 311, 361,

and 368 of the PHS Act (42 U.S.C. 243, 264, and 271) that relate to communicable disease. The PHS Act authorizes the Department of Health and Human Services (DHHS) to make and enforce such regulations as ''are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States * * * or from one State * * * into any other State'' (section 361(a) of the PHS Act (42 U.S.C. 264(a))).

Salmonellosis is a communicable disease that can be caused by SE-contaminated eggs. Temperature abuse can lead to the multiplication of SE in shell eggs, and thereby, increase the likelihood of illness if the eggs are not thoroughly cooked. Therefore, the agency tentatively concludes that a regulation to require refrigeration is necessary to prevent the spread of communicable disease.

Although the egg market is largely regional, it involves significant shipment of eggs from State to State. Moreover, shipment of SE-contaminated eggs from one State to another has contributed to the geographical spread of disease outbreaks in the U.S. human population. For example, eggs from Pennsylvania were implicated in an outbreak of SE infection reported in Asbury Park, NJ, involving at least 47 persons, and eggs from Maryland were implicated in an outbreak in Livonia, NY, where 12 patrons of a restaurant reported gastroenteritis illness linked to consumption of omelets made from pooled grade A eggs (Ref. 36). As discussed in section I.D of this document, an SE outbreak at a wedding reception in New York was associated with the consumption of Caesar salad dressing. Eggs used to make the dressing were traced to a Pennsylvania producer (Ref. 6).

FDA tentatively concludes that a regulation to require refrigeration of shell eggs at retail (proposed § 115.50(b)) also should apply to eggs that are not shipped across State lines by producers or retailers because there have been SE outbreaks that were associated with such eggs (Ref. 37). Therefore, the agency believes a regulation to require refrigeration of eggs produced and sold within a State would reduce the risk of illness. In addition, the agency tentatively concludes that the spread of salmonellosis among States from SE-contaminated eggs cannot be fully controlled without extending the refrigeration requirement to sales within one State. FDA believes that consumers who shop across State borders may purchase SE-contaminated shell eggs from one State and carry the eggs across State lines. Thus, FDA is concerned that if it does not require refrigeration of shell eggs that are laid, processed, and sold in one State, the regulations will not prevent the introduction of SE contaminated eggs into other States and, thus, will not prevent the introduction of salmonellosis from one State to another.

The agency also notes that in the normal course of business, many food service establishments, e.g., restaurants, serve out-of-State customers, e.g., truck drivers, tourists, and others who regularly travel for work. The agency is concerned that if these out-of-State consumers become ill with salmonellosis from SE-contaminated eggs purchased through intrastate commerce, the disease could spread from one State to another. For these reasons, the agency tentatively concludes that refrigeration should also be required on all shell eggs to prevent the spread of a communicable disease among States.

FDA's legal basis to require refrigeration of shell eggs also derives from sections 402(a)(4), and 701(a) of the act (21 U.S.C. 342(a)(4) and 371(a)). Under section 402(a)(4) of the act, a food is adulterated if it is prepared, packed, or held in insanitary conditions whereby it may have been contaminated with filth or may have been rendered injurious to health. Under section 701(a) of the act, FDA is authorized to issue regulations for efficient enforcement of the act. Thus, a regulation that prohibits food from being held under insanitary conditions would provide for efficient enforcement.

FDA has traditionally not conducted enforcement activities in retail establishments. The agency has, instead relied on State and local authorities to provide enforcement at the retail level. Nonetheless, the agency has been active in the retail arena in a number of ways. First and foremost, FDA participates in the Conference on Food Protection which is the cooperative body responsible for making recommendations to FDA concerning the Food Code. FDA also publishes the Food Code. In addition, FDA interacts with State and local regulatory agencies in a number of ways to coordinate retail enforcement efforts. Within FDA, the Division of Federal-State Relations, located in the Office for Regulatory Affairs, in the Office of the Commissioner, was created to enhance interactions between Federal, State, and local officials. The Division of Federal-State Relations serves as the focal point for providing cohesive and uniform food policies to State associations and cooperating State and local officials. Retail food specialists work with State and local retail food regulatory agencies to assist them, when the Code has been adopted, in implementing the Food Code and to ensure through standardization of local and State health officials that the Food Code criteria are uniformly applied. Retail food specialists are located in FDA regional offices. Some districts may have partnership agreements with States. Goals of these partnerships include increasing staff proficiency, improving consistency of enforcement activities, and empowering cooperating organizations. This may also include assisting with implementation of retail food programs. FDA has structured the proposed regulation to take into account the traditional sharing of responsibilities of food safety at retail, augmented by a clear quantitative Federal standard for temperature control.

Under the PHS Act, the Federal, State, and local governments have a long tradition of cooperation, and the PHS Act specifically recognizes cooperation between the Federal government and State and local governments as an important tool for public health officials. Previously, in the area of food safety, FDA has used those portions of the PHS Act (e.g., sections 310 and 311 (42 U.S.C. 242n and 243)) that focus on Federal assistance to the States. Indeed, the Conference on Food Protection and the Model Food Code are a result of Federal/State/Local cooperation and Federal assistance to the States and localities under the PHS Act. However, section 311 of the PHS Act not only recognizes Federal assistance to the States, it also recognizes that the States and localities may be able to assist the Federal Government. This section provides in part: ''The Secretary is authorized to accept from State and local authorities any assistance in the enforcement of quarantine regulations made pursuant to this chapter which such authorities may be able and willing to provide.''

FDA believes that, under sections 311 and 361 of the PHS Act, there are several ways the agency could accept assistance from the States in the enforcement of the egg refrigeration regulation. For example, FDA could accept State and local assistance in the inspection of retail establishments and then use those inspections as the basis for detention and diversion or destruction under proposed § 115.50(f) (as discussed in section II.C of this document) or as the basis for an enforcement action under the act. Another option would be to authorize

the States and localities to conduct inspections and enforce the refrigeration requirement through the administrative enforcement remedies set out in proposed § 115.50(f) (as discussed in section II.C of this document), while FDA could hear appeals, with judicial review available after FDA's decision. FDA also believes it could follow the example set out in the Nutrition Labeling and Education Act, which allows the States, if certain conditions are met, to bring an action to enforce various food labeling provisions in the act. See 21 U.S.C. 337; 21 CFR 100.2. Finally, FDA believes that section 311 of the PHS Act, in conjunction with section 361 of the PHS Act, authorizes the agency to issue a regulation that would allow States and localities to enforce the refrigeration regulation themselves.

After examining these options, FDA is concerned that all except the last option (allowing States and localities to enforce the regulation themselves) would prove too cumbersome, especially in light of the straightforward requirement at issue. Although a few comments maintained that the regulatory responsibility of egg handling and preparation in retail establishments remains at the State and local level, other comments supported a federal-State cooperative approach. FDA agrees that a cooperative approach would be the most effective means to enforce the refrigeration requirement. Therefore, FDA has tentatively concluded to propose to allow agencies of those States and localities that are able and willing under section 311 of the PHS Act, and that are authorized to inspect or regulate retail establishments, to enforce the refrigeration regulation along with FDA. FDA has tentatively concluded that this option will allow for the most effective and efficient use of Federal, State, and local food safety resources because it recognizes that States and localities, more than FDA, currently do this kind of enforcement. Accordingly, proposed § 115.50(e) provides that those States and localities that are able and willing are authorized under sections 311 and 361 of the PHS Act to enforce proposed § 115.50(b) as set out in proposed § 115.50(f). With respect to the hearing procedures, the proposed regulation recognizes that many States and localities already have administrative procedures in place for hearings by allowing them to use a similar hearing process as long as that process satisfies basic due process requirements.

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

C. Proposed Refrigeration Requirements at Retail

FDA is proposing in new § 115.50 to require that shell eggs held for retail distribution be promptly placed under refrigeration and be stored and displayed under refrigeration at an ambient temperature not greater than 7.2 °C (45 °F) while held at the retail establishment.

The evidence discussed in section I.A of this document shows that shell eggs have been vehicles for salmonellosis. USDA's proposed requirement for refrigeration of shell eggs includes storage at the producer and storage during transportation, but does not include storage or holding at all retail establishments. FDA tentatively finds that the weight of the available evidence on the growth of SE in eggs shows that this microorganism can multiply to high levels in eggs if the eggs are not properly refrigerated during their shelf-life. Failure to refrigerate shell eggs during retail handling of shell eggs provides favorable conditions for degradation of the egg's defenses, movement of SE to the yolk, and subsequent multiplication of SE. Therefore, FDA tentatively concludes that it is necessary to require that eggs at retail be held at temperatures that will help maintain the natural defenses of the egg and limit the growth and reproduction of SE.

As discussed in section I.F of this document, research indicates that SE multiplies at temperatures of 10 °C (50 °F) and above but that multiplication of SE is inhibited at lower temperatures, e.g., 8 °C (46 °F), 7.2 °C (45 °F), and 4 °C (39 °F). Therefore, the agency tentatively concludes that it should require a refrigeration temperature lower than 10 °C (50 °F) to ensure the safety of shell eggs. As noted as follows in this section, the Food Code recommends that potentially hazardous foods be maintained at a temperature of 5 °C (41 °F). A temperature of 5 °C (41 °F) not only inhibits the growth of *Salmonella*, but also, inhibits the growth of *Listeria monocytogenes*, which has been shown to grow at 7.2 °C (45 °F). The agency also notes that, as required under the Egg Products Inspection Act, USDA has amended its regulations to require that shell eggs packed for consumer use be stored and transported at an ambient temperature of 7.2 °C (45 °F). Based upon the data discussed in section I.F of this document, FDA tentatively concludes that 7.2 °C (45 °F), i.e., the same temperature required by USDA under the EPIA for the storage and transportation of shell eggs, is sufficient to protect the public health. Because eggs cool down only slightly faster at 5 °C (41 °F) than at 7.2 °C (45 °F), the lower temperature would have a negligible effect on the SE risk.

FDA notes that it is proposing an ambient and not an internal temperature requirement for shell eggs displayed and stored in retail establishments. The majority of comments to the 1998 ANPRM supported refrigeration of shell eggs throughout the distribution chain from packer to consumer. Most of these comments supported a requirement for an ambient temperature of 7.2 °C (45 °F). A few of these comments encouraged the agency to consider an internal temperature requirement of 7.2 °C (45 °F) or ambient or internal temperature requirements of 5 °C (41 °F), which, it was asserted, would result in an additional margin of safety.

As discussed in section I.F, research indicates that refrigeration of shell eggs at 7.2 °C (45 °F) greatly extends the time that an egg can maintain its natural defenses, and, thus, inhibit the growth of SE. FDA acknowledges that an internal temperature of 5 °C (41 °F) or 7.2 °C (45 °F) would also achieve this goal. However, FDA believes that a uniform requirement for an internal temperature would be difficult to monitor. As discussed in section I.E of this document, the internal temperature of eggs when they are transported depends on the temperature of the eggs when they are packed, the way the eggs are packaged, how the crates are packed and stacked, and the length of time they are in the cooler before they are shipped. Further, according to one comment to the 1998 ANPRM, transportation of eggs in refrigerated trucks do not provide cooling, but rather maintain the temperature of the eggs. Moreover, it may be impracticable for egg retailers to determine the internal temperatures of shell eggs. Therefore, the agency tentatively concludes that, to provide a level playing field for all egg retailers, it is appropriate to propose an ambient temperature requirement for the display and storage of shell eggs at retail. FDA requests comment on its tentative conclusion.

The agency notes that some States or localities may have temperature requirements lower than 7.2 °C (45 °F). The agency does not intend that this proposed regulation would, when finalized, preempt the requirements of

the Food Code or other State or local requirements that require a lower temperature. The proposed regulation would, however, preempt any State or local requirements that allow a temperature greater than 7.2 °C (45 °F).

The agency notes that the proposed temperature for storage of shell eggs addresses growth of SE in shell eggs, whereas the temperature required by the Food Code addresses all pathogens that may be present in different types of potentially hazardous foods. Thus, in addressing holding temperatures for potentially hazardous foods generally, the Food Code requires a temperature for retail storage that will prevent or slow the growth of most pathogens, including cold-tolerant pathogens such as *L. monocytogenes*. As previously discussed in this section, the agency tentatively concludes that a maximum storage temperature of 7.2 °C (45 °F) will be effective in inhibiting the growth of SE that may be present in shell eggs. FDA notes that a requirement that shell eggs be stored at 7.2 °C (45 °F) or less does not preclude retailers from maintaining shell eggs at lower refrigeration temperatures. In fact, the agency would encourage it. Moreover, it may be most practicable for establishments to have one requirement for a maximum refrigeration temperature for all potentially hazardous foods. FDA requests comment on the safety implications in the difference between the proposed temperature requirement of 7.2 °C (45 °F) for storage of shell eggs at retail and the refrigeration temperature of 5 °C (41 °F), recommended in the Food Code.

Because failure to refrigerate shell eggs would provide conditions for SE to multiply, the agency tentatively concludes that failure to refrigerate eggs would constitute insanitary conditions that may render the product injurious to health. Accordingly, the agency is proposing that failure of responsible individuals in a retail establishment to comply with the requirements of § 115.50(b) will render the shell eggs adulterated under section 402(a)(4) of the act.

Some shell eggs now available for retail sale have been pasteurized in the shell (in-shell pasteurized) prior to packing and distribution to destroy any *Salmonella* that may have been present in the egg (e.g., *Salmonella* in the egg due to transovarian contamination). FDA is proposing in § 115.50(c) that these eggs be exempt from the refrigeration requirement. However, such pasteurization would not prohibit the in-shell pasteurized egg from subsequently becoming contaminated with harmful microorganisms, if the egg were to come in contact with *Salmonella* or other potentially hazardous microorganisms during distribution and retail sale. The scientific evidence indicates that it is possible for *Salmonella* as well as other potentially harmful microorganisms to pass through the pores of the egg shell and reach the egg yolk, which can then support subsequent growth of the microorganisms, especially when adequate refrigeration is not provided (Ref. 38). Because this proposed regulation addresses the control of SE in shell eggs that are contaminated by transovarian transmission, the agency considers pasteurization an effective means to kill SE that may be present inside the egg when it is laid. Thus, the scope of this proposed regulation does not extend to contamination of eggs other than by transovarian transmission. FDA expects that manufacturers of this premium product would ensure its continued safety. Therefore, although this proposal would not require the refrigeration of in-shell pasteurized shell eggs or any shell eggs that have been otherwise processed to destroy *Salmonella*, because such eggs would not be expected to contain transovarian transmitted *Salmonella*, FDA recommends that such eggs be refrigerated by retail establishments.

In addition, FDA notes that shell eggs that have been processed to destroy *Salmonella* are still considered to be potentially hazardous foods under provisions in the Food Code in part because they are raw eggs that are capable of supporting the growth of SE. Because these eggs are considered potentially hazardous foods, State and local regulations established under the recommendations in the Food Code may have specific refrigeration requirements for these eggs in retail establishments that this regulation would not preempt.

As discussed in section II.B of this document, the agency tentatively concludes that the spread of salmonellosis among States from SE-contaminated eggs cannot be fully controlled without extending the refrigeration requirement to all eggs. Accordingly, FDA is proposing in § 115.50(d) that the requirements of this section are applicable to all shell eggs.

As previously noted, FDA is proposing these regulations under both the act and the PHS Act. Failure to comply with the refrigeration requirement in proposed § 115.50 would render the eggs adulterated under section 402(a)(4) of the act. Enforcement of adulteration regulations under the act is conducted under sections 301 to 304. However, section 361 of the PHS Act authorizes the Secretary, and by delegation FDA, to issue regulations that provide for the destruction of articles and for other measures that are judged by the Secretary to be necessary to carry out and enforce communicable disease regulations. FDA tentatively concludes that the shell egg refrigeration regulation can be most efficiently and effectively enforced through administrative procedures. Accordingly, FDA is proposing procedures in § 115.50(f) under which FDA may order the diversion or destruction of shell eggs that have been held in violation of the regulations. Under proposed § 115.50(f), FDA may issue to the person holding the shell eggs a written order that the product be diverted or destroyed. The proposed regulations would provide for diversion for processing in accordance with the EPIA because FDA tentatively concludes that it may be possible to produce safe egg products from shell eggs that have been held in violation of the regulation. Because the EPIA requires pasteurization of egg products, any *Salmonella* present would be eliminated. The written order would identify the shell eggs that are affected, and the grounds for issuing the order and would provide that, unless the order is appealed, either by filing a written appeal or by requesting a hearing, the shell eggs must be diverted or destroyed within 10-working days of receipt of the order.

In addition, authority for the enforcement of section 361 of the PHS Act is provided for in part under section 368 of the PHS Act. Under section 368(a) of the PHS Act any person who violates a regulation prescribed under section 361 of the PHS Act may be punished by imprisonment for up to 1 year. Individuals may also be punished for violating such a regulation by a fine of up to $100,000 if death has not resulted from the violation or up to $250,000 if death has resulted (18 U.S.C. 3559 and 3571(b)). Organizations may be fined up to $200,000 per violation not resulting in death and $500,000 per violation resulting in death (18 U.S.C. 3559 and 3571(c)). In addition, Federal district courts have jurisdiction to enjoin individuals and organizations from violating regulations implementing section 361 of the PHS Act.

III. The Proposal for Shell Egg Labeling

A. Rationale for Shell Egg Labeling Proposal

As discussed in section I.D of this document, data from SE outbreaks show that outbreaks commonly occur when contaminated eggs are mishandled by consumers or other food preparers. Furthermore, consumption data

establish that some consumers eat raw or undercooked eggs.

The CSPI petition contends that the increase in the incidence of foodborne illness has likely occurred, at least in part, because consumers do not realize that partial cooking of raw eggs (e.g., soft-boiled, sunny-side-up) or egg-containing foods will not prevent illnesses. In addition, the petition from Rose Acres Farm, Inc., contends that practically all SE outbreaks and deaths associated with eggs occurred because of mishandling of the eggs.

As discussed previously, FDA believes that it will be difficult for the industry to rapidly design and implement a program that will produce *Salmonella*-free eggs. However, as discussed in section I.F of this document, in the meantime, there are measures that can reduce risks to consumers: Refrigeration, which lengthens the effectiveness of the eggs' natural defenses against SE and slows the growth rate of SE, and thorough cooking, which kills viable SE that may be present. Many comments to the 1998 ANPRM maintained that proper handling of shell eggs is an important measure that could reduce the incidence of foodborne illness. According to a few of the comments, the majority of outbreaks occur because of improper handling of eggs, e.g., pooling and incomplete cooking by food preparers. Most comments to the 1998 ANPRM that addressed labeling supported labeling cartons of eggs with instructions for proper handling. Although some comments supported the use of short messages, such as ''keep refrigerated,'' others supported safe handling instructions that also included instructions on proper cooking of eggs.

The agency is concerned that unless consumers and food preparers are advised about both the risks presented by eggs contaminated with SE and the ways they can reduce these risks, consumers, particularly those at greatest risk, could suffer serious illness or death from the consumption of raw or undercooked eggs and egg-containing foods. Accordingly, FDA tentatively concludes that there is an immediate need to require label statements that inform consumers of the public health risks associated with consumption of raw or improperly cooked shell eggs and provide safe handling instructions.

B. Legal Authority for FDA to Require Label Statements

FDA is proposing these regulations under both the act and the PHS Act. FDA's legal authority under the act to require label statements on food products derives from sections 201(n), 403(a)(1), and 701(a) of the act (21 U.S.C. 321(n), 343(a)(1), and 371(a)). FDA's legal basis to require safe handling instructions on shell eggs also derives from the provisions of sections 311, 361, and 368 of the PHS Act that relate to communicable disease. Under section 403(a)(1) of the act, a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the act 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. Section 701(a) of the act authorizes FDA to issue regulations for the efficient enforcement of the act. FDA previously has relied on these authorities when it required label warning statements to alert consumers to the potential hazards of certain ingredients of foods and dietary supplements, e.g., protein products (49 FR 13679, April 6, 1984) and iron-containing dietary supplements (62 FR 2218, January 15, 1997). Likewise, the agency is relying on these authorities in proposing to require label statements on shell eggs not processed to destroy all viable *Salmonella*.

As discussed previously, it is well documented that shell eggs may contain *Salmonella*, especially transovarian transmitted SE, which can result in serious, life-threatening illness. The risk is greatest for children, the elderly, and persons who are immune compromised (Ref. 18). Therefore, the agency tentatively concludes that information disclosing the risk of foodborne illness associated with consumption of raw or undercooked shell eggs is material information that must be given to consumers at the point of purchase.

However, the consequences that may result from consumption of SE-contaminated eggs may be reduced or eliminated by proper handling techniques that first limit the number of SE microorganisms and then kill those microorganisms. Thus, consumers have effective ways, other than avoidance of shell eggs, to reduce the risk of illness from consumption of SE-contaminated shell eggs. In light of this, the agency tentatively concludes that information on safe handling practices that consumers can use to protect themselves from illness is material information about the product that must be included in its labeling to ensure that the product is not misbranded.

As discussed in section II.B of this document, the PHS Act authorizes the Secretary of DHHS to make and enforce regulations that prevent the introduction, transmission, or spread of communicable disease from State to State. As discussed in that section, temperature abuse of shell eggs 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 agency tentatively concludes that, in addition to a refrigeration requirement, a regulation requiring safe handling instructions that inform consumers to properly refrigerate and cook shell eggs (as fully discussed in section III.D of this document) is also necessary to prevent the spread of communicable disease.

FDA tentatively concludes that a regulation to require label statements that provide safe handling instructions on shell eggs (proposed § 101.17(h)(1)) also should apply to eggs that are not shipped across State lines by producers or retailers (proposed § 101.17(h)(6)). As noted in section II.B of this document, there have been outbreaks of salmonellosis associated with such eggs. Therefore, FDA is concerned that if it does not require safe handling instructions on shell eggs that are laid, processed, and sold in one State, consumers will not have material information that would inform them of ways to handle and cook eggs to prevent illness. Thus, without the inclusion of all eggs in the scope of this proposed regulation, FDA could not ensure that consumers who purchase eggs laid, processed, and sold in one State would have information that would help protect them from the risk of salmonellosis. In addition, as discussed in section II.B of this document, the agency believes that consumers who shop across State borders may purchase SE-contaminated shell eggs from one State and carry them across State lines. Therefore, without the inclusion of all eggs in the scope of this proposed regulation, the agency would be hampered in preventing the spread of salmonellosis from one State to another. The agency tentatively concludes that safe handling instructions should be required on all shell eggs to prevent the interstate spread of a communicable disease from one State to another. FDA requests comment on its tentative conclusion.

Failure to comply with the requirements of proposed § 101.17(h) would render the food misbranded under section 403(a)(1) of the act and would violate regulations issued under

section 361 of the PHS Act. As discussed in section II.C of this document, enforcement of regulations is conducted under sections 301 to 304 of the act. Section 361 of the PHS Act authorizes FDA to issue those regulations that are necessary to enforce communicable disease provisions of the statute. Thus, the agency is proposing procedures in § 101.17(h)(8) that it may use to order the relabeling, diversion, or destruction of shell eggs that do not comply with the regulation. Under proposed § 101.17(h)(8)(i)(A), FDA may issue to the person holding the shell eggs a written order that the product must be relabeled, diverted, or destroyed. As also discussed in section II.C of this document, violations of the PHS Act are subject to injunctions and criminal prosecutions.

As discussed in section II.B of this document, FDA has examined several options on how the agency could accept assistance from the States and localities in enforcement of the refrigeration provision of this proposed regulation. The agency has considered similar options on how it could accept State and local enforcement assistance of the labeling provision. Because this proposed labeling requirement would affect shell eggs that laid, processed, and sold in one State, the agency believes that it would be an efficient use of resources for State and local agencies to assist in enforcing the labeling regulations. Moreover, FDA believes that sections 311 and 361 of the PHS Act authorize the agency to issue a regulation that would allow States and localities to enforce the labeling regulation themselves. Therefore, the agency has tentatively concluded that it should allow State and local regulators that are able and willing under section 311 of the PHS Act, and are authorized to regulate the labeling of shell eggs within their States or localities, to enforce the requirement for safe handling instructions. Accordingly, proposed § 101.17(h)(7) provides that those States and localities that are able and willing are authorized under sections 311 and 361 of the PHS Act to enforce proposed § 101.17(h)(1) as set out in proposed § 101.17(h)(7). With respect to the hearing procedures, the proposed regulation recognizes that many States and localities already have administrative procedures in place for hearings allowing them to use a similar hearing process as long as that process satisfies basic due process requirements.

C. Covered Products

As discussed in section II.C of this document, technology to process shell eggs in a manner to destroy SE in the egg would significantly reduce or eliminate the risk of transovarian transmitted SE, and would thereby render the label statements unnecessary. Accordingly, FDA is proposing in § 101.17(h)(4) that shell eggs that have been, before distribution to consumers, specifically processed to destroy all viable *Salmonella* be exempt from the labeling requirements.

The standards of identity for liquid, dried, and frozen egg white, egg yolk, and whole egg products (21 CFR part 160) require that these products be pasteurized or otherwise treated to destroy all viable *Salmonella* microorganisms. Further, the agency expects that the standardized egg product ingredients in any nonstandardized egg product, such as scrambled egg mixes, would also be pasteurized or otherwise treated to destroy all viable *Salmonella* microorganisms. FDA has no information about the existence of egg products that have not been pasteurized or otherwise treated to destroy all viable SE and other *Salmonella*. However, the agency specifically requests data or other information that suggests that such products are commercially available. Should such products exist, FDA tentatively concludes that any final label statement required for shell eggs also be applicable to these products as well.

The safe handling statement is intended to inform consumers of ways that they may safely handle eggs to reduce their risk of foodborne illness. Likewise, the use of the safe handling statement on cartons of shell eggs that are not for direct sale to consumers, e.g., shell eggs that are to be labeled or repacked at a site other than originally processed or are shipped for use in food service establishments such as schools, hospitals, and restaurants also serves to inform repackers and food preparers of the safe handling procedures. However, FDA tentatively concludes that the same goal of conveying the safe handling labeling to repackers and food preparers could also be accomplished by customary trade practices. For example, the safe handling statement could be included on an invoice or product specifications sheet. Accordingly, FDA is proposing in § 101.17(h)(5) that the safe handling statement for shell eggs that are not for direct sale to consumers, e.g., those that are to be repacked or labeled at a site other than where originally processed or are sold for use in food service establishments may be provided on cartons or in labeling, e.g., invoices or bills of lading in accordance with the practice of the trade. FDA requests comment on whether allowing this practice will accomplish its intended goal.

D. Essential Elements of Specific Label Statements

Consumer research available to the agency indicates that when consumers generally believe that a product is safe, messages that note that the product is unsafe without providing information on the nature of the hazard are likely to confuse or frighten them (Ref. 25). This research also indicates that certain elements may be essential in label statements to effectively inform consumers of a potential hazard (Ref. 25). Recently, the agency has used such consumer research to develop effective warning labels. For example, the agency used such information to craft a warning statement for iron-containing supplements in § 101.17(e). As discussed in the final rule requiring that iron-containing supplements bear a warning statement (62 FR 2218), the agency found that elements essential for an effective warning statement for these products included an informational statement that describes the nature and magnitude of the hazard and a handling instruction on how to avoid the hazard. In addition, because the hazard associated with iron-containing products was associated with accidental overdose rather than ordinary conditions of use, essential elements for this warning statement also included a provisional statement that describes situations that require mitigation and an instructional statement that describes what action to take under those circumstances.

In determining what information is essential in the proposed statement, FDA tentatively concluded, based on the continued predominance of SE in foodborne outbreaks, that consumers may not know that there is a food safety hazard associated with shell eggs. Consumption data indicating that some consumers eat raw or undercooked eggs reinforce this tentative conclusion (Refs. 22 to 24). Therefore, FDA tentatively concludes that it is essential that the label statement describe the potential hazard, i.e., that eggs may contain pathogens known to cause serious, life-threatening illness.

In addition, the young, elderly, and persons with immune deficiencies are more susceptible to foodborne illness than others (Ref. 18) but may not realize that they are particularly at risk for serious illness from a food long recognized to be a safe and inexpensive source of good nutrition. These people, especially, along with their caregivers, need the information necessary to make informed decisions about avoiding,

reducing, or eliminating the risk of salmonellosis from eggs and egg-containing foods. Therefore, FDA tentatively concludes that the information needed by consumers about the potential hazard should also include information about the at-risk groups, so that they or their caregivers are aware of their greater risk.

In some circumstances in which the agency has required a label statement to inform consumers of consequences that could result from consumption of a product, FDA has presumed that consumers' reaction to a label statement would be a decision whether to avoid the product. For example, in its recent rulemaking to require a label statement on juice products that have not been processed to control pathogenic microorganisms, FDA stated its belief that it was implicit in its description of the hazard that at-risk groups could avoid the hazard by not consuming the product (63 FR 20486 at 20489, April 24, 1998). Consistent with this belief, one comment to the 1998 ANPRM opposed ''warning labels'' stating that eggs are potentially harmful because the statement would alarm consumers and would reduce egg consumption. However, as previously discussed, the consequences that may result from consumption of SE-contaminated eggs may be reduced or eliminated by proper handling techniques. Failure to make clear that there is a way other than avoidance to reduce this risk could imply to consumers that, similar to their options when faced with other label statements, their only available option is to avoid the product. Therefore, FDA tentatively concludes that an instructional statement that describes measures (i.e., safe handling practices) that consumers can take to reduce or eliminate the risk associated with consumption of SE-contaminated eggs should be an essential element of the label statement. Because temperature has been reported to play a role in suppressing the growth of *Salmonella* microorganisms (see discussion in section I.F of this document), and because thorough cooking kills SE (see discussion in section I.F of this document), FDA also tentatively concludes that the safe handling instructional statement should advise that eggs be refrigerated until they are ready to be cooked and that eggs be thoroughly cooked before they are eaten.

Because the more likely option for consumers who are presented with a label statement that describes a hazard is avoidance, FDA believes that a linking statement that clarifies that the recommended safe handling practices are measures that consumers can take to reduce or eliminate the risk is important to alleviate a potential misperception that avoidance is their only option. Therefore, FDA tentatively concludes that a linking statement that relates the informational statement to the instructional statement is an essential element of the label statement. These essential elements are similar to those contained in other required label statements in § 101.17.

FDA's consumer research on label statements for iron-containing products also shows that the first sentence of a label statement is likely to influence a consumer's decision to continue reading the remainder of the statement (Ref. 25). Moreover, as a result of the safe handling instructions that appear on raw meat and poultry under rulemaking conducted by FSIS (59 FR 14528, March 28, 1994), consumers are already accustomed to reading information about the risk before reading the safe handling practices that can reduce or eliminate the risk. Accordingly, FDA tentatively concludes that the first sentence of the label statement should be an informational statement about the potential hazard to consumers.

Applying the essential elements described previously, FDA crafted examples of label statements. The agency notes that some of the examples of acceptable label statements incorporate language suggested by Rose Acres Farms, Inc., and CSPI. These examples illustrate some of the variations in label statements developed by applying the essential elements. Four such examples are provided as follows:

SAFE HANDLING INSTRUCTIONS: Shell eggs may contain harmful bacteria known to cause serious illness, especially in children, the elderly, and persons with weakened immune systems. For your protection, keep eggs refrigerated and cook eggs and foods containing eggs thoroughly before eating.

SAFE HANDLING INSTRUCTIONS: Shell eggs may contain harmful bacteria known to cause serious illness, especially in children, the elderly, and persons with weakened immune systems. For your protection, keep eggs refrigerated and cook eggs until yolks are firm.

SAFE HANDLING INSTRUCTIONS: Eggs may contain illness-causing bacteria. The risk of life-threatening illness is greatest for children, the elderly, and persons with weakened immune systems. For your protection, keep eggs refrigerated until cooked, and cook eggs thoroughly until yolks are firm.

SAFE HANDLING INSTRUCTIONS: Some shell eggs have been found to contain harmful bacteria known to cause life-threatening illness, especially in children, the elderly, and persons with weakened immune systems. Consumers may protect themselves by keeping eggs refrigerated until cooked, by cooking eggs until the yolk is firm, and by cooking foods containing eggs thoroughly.

In order to evaluate the label statements developed through use of the essential elements and to test the effectiveness of such examples in informing consumers of the risks associated with shell eggs and of the safe handling practices that may be used to mitigate the risks, FDA conducted focus group research to evaluate consumer understanding of several possible safe handling instructions.

Six focus groups were conducted to test possible safe handling statements (Ref. 39). All participants examined and discussed five safe handling statements, including the four examples presented previously. The participants had some awareness of the potential dangers associated with eating eggs, and most were concerned about the safety of the eggs that they were purchasing. They were aware that the main food safety hazard posed by eggs was *Salmonella* contamination. Most of the participants kept their eggs refrigerated. However, many of them reported that they ate foods containing raw eggs, e.g., cookie batter, cake batter, homemade ice cream, and Caesar salad. The participants stated that most of the time they were aware when the foods they ate contained raw eggs, although some were surprised that Caesar salad could contain raw eggs. Generally, the participants were aware that they should thoroughly cook eggs, although they often cooked eggs according to their personal tastes, e.g., sunny-side up.

The participants were generally positive toward the idea of handling instructions on egg packages. Although many of them were already aware of the information presented in the handling statements, they saw the handling statements as useful reminders. To some of the participants, however, some of the information in the handling statements was new. Further, the participants appreciated the fact that with relatively simple steps they could be confident that their eggs were likely to be safe to eat. In addition, many participants thought that egg producers would not object to placing information presented in the example statements on the labels of egg cartons if all egg producers had to do so.

There were some discussions about certain words in the messages that the

groups thought were unnecessary, e.g., ''shell'' eggs, and ''refrigerated until cooked.'' However, participants generally understood the messages and found them to be informative and not misleading. Further, they liked messages that were clear and easy to read.

While the label statements that were tested effectively informed the consumers of the potential hazard associated with the consumption of eggs, the agency did not test all conceivable variations of label statements incorporating the required information. Previous focus group research (i.e., for juice warning labels) indicated that minor wording differences may lead to confusion among consumers. The results of that research led the agency to prescribe the language of the label statement on juice products to ensure that consumers would not be misled (63 FR 37030, July 8, 1998). Similarly, the agency believes that it is also appropriate to prescribe the language of the safe handling statement on eggs. Therefore, the agency tentatively concludes that prescribing the language of each of the essential elements will be the most effective way to ensure that consumers are not misled and will correctly understand the safe handling instructions. This will ensure that consumers know of the risks of consuming raw or undercooked eggs and that they know the measures they can take to protect themselves. In addition, a prescriptive label statement is consistent with label statements for other food products.

FDA believes that a regulation requiring a label statement on cartons of shell eggs must be sufficiently clear to allow the regulated industry to determine that its labeling complies with that regulation. Furthermore, the regulation should establish a so-called ''level playing field'' for all products covered by the regulation by requiring that each product's labeling provide the same information. FDA tentatively concludes that prescribing the specific language for a label statement for shell eggs would accomplish these two goals, as well as ensure a message to consumers that is not confusing, misleading, or otherwise ineffective.

Accordingly, based on information from the focus groups, FDA is proposing in § 101.17(h)(1) to require that the label of shell eggs bear the following statement:

SAFE HANDLING INSTRUCTIONS: Eggs may contain harmful bacteria known to cause serious illness, especially in children, the elderly, and persons with weakened immune systems. For your protection: keep eggs refrigerated; cook eggs until yolks are firm; and cook foods containing eggs thoroughly before eating.

The agency notes that the language in the first sentence of this prescribed label statement for eggs is similar to the label statement that FDA recently required for some juice products. As discussed in the final rule requiring warning statements on juice products that have not been processed to control pathogenic microorganisms (63 FR 37030 at 37045), FDA concluded that the term ''serious illness'' is an accurate description of the hazard caused by foodborne microorganisms that may be present in juice. The agency based its conclusion on results of focus group research which indicated that the term ''serious illness'' was understood and conveyed a strong message without being too extreme. Participants of the focus group research viewed such terms as ''life threatening'' or ''death'' less credible.

Also in that final rule, FDA recognized that the terms children and elderly are not precise. Rather, they are terms chosen by the Council for Agricultural Science and Technology to reflect groups that, in general, have incompletely developed or declining immune systems. Because the exact ages at which a child's immune systems is fully developed and at which an elderly person's immune system has declined are not precisely defined, FDA concluded that it had no basis to specify particular ages for these at-risk groups nor to use terms other than ''children'' or ''elderly.''

Several comments to the 1998 ANPRM expressed concerns about the suggested language that would appear in a proposed label statement. The issues raised in these comments were among those issues considered when FDA developed this proposed rule.

The agency requests comments on other aspects of the proposed safe handling statement and whether it effectively conveys information necessary to adequately inform consumers of measures that they can take to ensure the safety of the food. The agency tentatively concluded that the cooking instructions in the safe handling statement, i.e., ''cook eggs until yolks are firm and cook foods containing eggs thoroughly'' is adequate to inform consumers of ways to prepare eggs in order to reduce the risk of illness. The agency notes that part of the cooking instruction, i.e., ''cook eggs until yolks are firm,'' is one way to describe proper cooking of an egg when consumed as an egg dish. For example, it is expected that when an egg, e.g. fried egg, is cooked until the yolk is firm, then the white would be sufficiently cooked.

For other foods that contain eggs, the safe handling statement must convey to consumers that the food should be cooked thoroughly. Focus group research showed that although many consumers are aware that foods that contain raw or undercooked egg whites only, e.g., meringue, can be a potential health hazard, many did not. However, the reason some consumers were unaware of the potential health risk was that they were unaware that foods like meringue may contain raw egg whites. When informed that such foods may contain raw egg whites, consumers understood the health risk. Thus, the agency tentatively concludes that there is no reason to believe that, when informed of the risk of illness associated with raw or undercooked eggs, consumers would differentiate the potential health risk based on what part of the egg is consumed. Therefore, FDA tentatively concluded that the part of the statement that instructs consumers to cook foods containing eggs thoroughly, would address foods that include any component of the egg, e.g., whole egg, egg white, or egg yolk. The agency requests comments on its tentative conclusion that this statement adequately instructs consumers on the safe handling instruction for foods containing eggs. Comments should include data or a rationale to provide a basis for the agency to adopt alternate phrasing.

As previously discussed, certain subpopulations are at greatest risk of serious illness and death caused by SE. For example, many deaths have occurred in nursing homes (Ref. 3). Because certain consumers, especially those at greatest risk, may want to avoid the risk altogether by avoiding the product, the agency requests comment on whether it should require a statement that the product should not be used for certain purposes, e.g., ''use pasteurized eggs for recipes requiring raw or partially cooked eggs.'' The agency also requests comment on whether it should require an explicit instruction to avoid the product for at-risk consumers or for individuals (e.g., parents, nursing home staff) who are responsible for preparing foods for at-risk consumers.

As discussed in section II.A of this document, FSIS amended its regulations to require that shell eggs packed for consumer use be stored and transported at an ambient temperature that does not exceed 7.2 °C (45 °F) and that the containers of such eggs be labeled to indicate that refrigeration is required. The labeling statement proposed in this document, if finalized, will permit

uniform label statements with the FSIS rule. Consequently, this safe-handling statement would replace the label currently required by FSIS.

In the **Federal Register** of February 24, 1997 (62 FR 8248), FDA published a notice, entitled ''Guidance on Labeling of Foods That Need Refrigeration by Consumers'' (''the Refrigeration Guidance''). In that document, FDA noted that refrigeration is only one of many barriers (e.g., acidification, preservatives, and reduced water activity) that can be used to control microbial risks. However, for many foods (classified as ''Group A foods''[6]), refrigeration is the only practicable barrier to reduce or retard pathogenic growth. The agency also noted that Group A foods, including shell eggs, are potentially hazardous foods, that, if subject to temperature abuse, will support the growth of infectious or toxigenic microorganisms that may be present. Growth of these microorganisms would render the food unsafe (62 FR 8248). As stated in that document, FDA concluded that the appropriate label statement for Group A foods is ''IMPORTANT Must be kept refrigerated to maintain safety.''

In the Refrigeration Guidance document, FDA stated that most consumers seem to understand that foods displayed only in the refrigerated sections of grocery stores such as dairy products, eggs, cold cuts, fresh meats, poultry and seafood, must be refrigerated to maintain quality. Further, the agency stated that, although it is unlikely that consumers are aware of the hazards that temperature abuse can present, it is likely that consumers will refrigerate these products in the absence of labeling. Therefore, the agency did not specifically address these products in the document. However, the agency concluded that the fact that the foods are refrigerated provides no evidence of the effectiveness of the ''keep refrigerated'' label. Although the guidance provided in that document was specifically directed toward products that appeared to be shelf stable or ones for which consumers seemed to not understand the importance of a ''keep refrigerated'' statement, the agency did not specifically exclude any foods from the guidance.

In light of information regarding outbreaks of SE associated with the temperature abuse of eggs and egg-containing products, FDA tentatively concludes that it is important that consumers be informed of the need for refrigeration of shell eggs. Further, the agency believes that the ''keep refrigerated'' statement in the suggested safe handling instructions in the proposed label statement conveys the same message as the label statement in the Refrigeration Guidance. Because the proposed linking statement, i.e., ''for your protection,'' shows that there are measures that consumers can take to reduce or eliminate the risk of foodborne illness, the agency believes that it is implicit in the proposed safe handling instructions that refrigeration helps to maintain the safety of shell eggs. Thus, FDA tentatively concludes that there is no need for both statements in labeling of shell eggs.

Focus group participants responded favorably to a graphic format that used bullets for the safe handling instructions. FDA encourages the use of such a presentation. However, the agency recognizes that all egg cartons may not be able to accommodate this format and, therefore, FDA is not proposing to require it. The agency requests comment on this tentative decision. The agency also requests comments on whether graphics would enhance the visibility of the statement.

The agency notes that, under FSIS regulations (7 CFR 317.2 and 381.125), the safe handling statements that are currently required on raw meats and poultry include graphic illustrations. As discussed in the FSIS final rule (59 FR 14528), participants in consumer research indicated that safe handling instructions accompanied with graphics were preferred to those without graphics. As previously discussed in this section, FDA conducted its own consumer focus group research to evaluate consumer understanding of several safe handling labeling statements for shell eggs. Based on its focus group research, the agency tentatively concluded that the safe handling statement that it is proposing is adequate and effectively informs consumers of the risks associated with the consumption of shell eggs and of measures they can take to reduce their risk of foodborne illness. Therefore, the agency tentatively concludes that additional information, including graphic illustrations, is not necessary to convey the safe handling instructions to consumers. However, although FDA is not proposing to require graphic illustrations in the safe handling statement for shell eggs, the agency encourages use of illustrations similar to those used on raw meat and poultry on the cartons of shell eggs. While the agency did not specifically test the graphic illustrations with the consumer focus groups, the agency believes that, because graphic illustrations have been on meat and poultry product labels for some time, consumers have become familiar with these kinds of symbols. The agency requests comment on whether graphics should be required as part of the safe handling statement for shell eggs.

The agency has solicited specific comments on various aspects of this proposal as well as additional requirements. Any comments supporting additional requirements should include data, information, or a rationale in support of the position advocated. FDA will consider such comments and depending on the administrative record that is developed through the rulemaking process, may adopt as part of a final rule additional requirements. The agency notes, however, that it does not intend that this proposed regulation would, if finalized, preempt any State or local requirements for additional safe handling labeling, e.g., graphics, as long as it does not conflict with Federal requirements.

The agency notes that current regulations in § 101.17 use the terms ''warning'' or ''notice.'' As previously discussed, FDA has presumed that consumers' reaction to a warning statement about the possible presence of harmful bacteria in eggs would be a decision whether to avoid the product. The term ''notice'' could be used, but does not draw attention to the important fact that there are ways to reduce or eliminate the risks of foodborne illness other than avoidance of the product. The agency tentatively concludes, therefore, that the required elements of the label statement are best described as ''safe handling instructions.'' In light of this fact, the agency is proposing in this rulemaking to amend the title of § 101.17 to include the use of the term ''safe handling statements.''

E. Placement and Prominence of Label Statements

Section 403(f) of the act requires mandatory label information to be prominently placed on the label with such conspicuousness (compared with other words, statements, designs, or devices, in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of use. Two comments to the

[6] Group A foods as defined in the Refrigeration Guidance are potentially hazardous foods, which if subjected to temperature abuse, will support the growth of infectious or toxigenic microorganisms that may be present. They have the following characteristics: (1) A pH of >4.6, (2) a water activity of >0.85, (3) do not receive a thermal or other process in the final package that is adequate to destroy foodborne pathogens that can grow under conditions of temperature abuse, and (4) have no barriers built into the product formulation that would prevent the growth of foodborne pathogens that can grow under abuse conditions.

1998 ANPRM requested that FDA provide flexibility in any food labeling statement, e.g., placement of the statement could occur on the inside of the carton, or elsewhere on the package, as long as it is conspicuous. The comments argued that existing federal regulations already require certain label information, such as grading information and nutrition labeling. In addition, the comments maintained that many States also require additional information on egg cartons such as product codes and sell-by dates. Moreover, one comment contended that some States may require certain information in type sizes of 10-point type or 3/8 inch. Thus, the comment argued, there is limited label space for additional information. One comment requested that FDA consider allowing the use of a modified format for small packages (packages of less than a dozen eggs) similar to that permitted for nutrition labeling. The comment questioned whether federal requirements would duplicate or preempt State requirements. One comment stated that some States require the phrase ''Keep refrigerated at or below 45 °F.'' Another comment estimated that approximately 40 percent of egg cartons on the market carry some form of ''warning label.'' The comment pointed out that prior to the beginning of 1998, only 10 percent of the cartons on the market bore safe handling instructions. The comment requested that if existing safe handling instructions meet or exceed federal requirements, FDA should allow manufacturers to retain such labels. The issues raised in these comments were among those considered by FDA as it developed this proposed rule.

In the past, FDA has generally determined that the information panel is the appropriate location for label statements that are required by § 101.17. As discussed in the agency's rulemaking requiring label statements on iron-containing dietary supplements (62 FR 2218), consumer focus group studies indicated that the label statement need not be placed on the principal display panel (PDP) to be effective in informing consumers of the hazard. Participants in the focus group reasoned that the front of the product was used for marketing purposes, and consumers were used to looking at the ''back of products'' for nutrition and factual information including label statements such as warning messages. Thus, the agency required that the warning statement for iron-containing supplements appear on the information panel, the portion of the label where most mandatory information is located. The agency tentatively concludes that for label statements on shell eggs, the requirement for prominence and conspicuousness would similarly be met if the statements appeared on the information panel. However, the agency would not object to firms placing the label statement on the PDP, since the PDP would provide even more prominence. Accordingly, FDA is proposing to require in § 101.17(h)(2) that the label statement appear either on the information panel or on the PDP.

The requirement in the act for prominent display means that the label statement must appear in a manner that makes the statement readily observable and likely to be read. The agency notes that 21 CFR 101.2(c) requires that mandatory information appearing on the PDP and information panel, including information required by § 101.17, appear prominently and conspicuously in a type size no less than 1/16 inch. The agency also notes that 21 CFR 101.15(a) provides that information required on the label appear uncrowded and with sufficient contrast to background material. The agency has concluded that it is not necessary to repeat these requirements for prominence and conspicuousness in the proposed regulation and, therefore, is not including them in this proposal.

Current agency regulations that require a label ''warning'' statement (e.g., the statement required by § 101.17(e) on iron-containing dietary supplements in solid oral dosage form) or a label ''notice'' statement (e.g., the statement required by § 101.17(d)(3) on protein products that are not covered by the requirements of § 101.17(d)(1) and (d)(2)) require that the identifying term ''WARNING'' or ''NOTICE'' be capitalized and immediately precede the language of the applicable label statement. Likewise, consistent with these examples, the agency is proposing in § 101.17(h)(1) to require that the capitalized words ''SAFE HANDLING INSTRUCTIONS'' immediately precede the message of the label statement.

Previous agency regulations that require cautionary information on labels, e.g., on products containing aspartame (39 FR 27317, July 26, 1974), utilized bold type to make the information more prominent. In addition, FDA regulations on nutrition labeling (21 CFR 101.9(d)(1)(iv)) require that certain nutrient information in the Nutrition Facts panel be in bold type to provide more prominence. Therefore, consistent with these examples, the agency is proposing in § 101.17(h)(2) to require that the words ''SAFE HANDLING INSTRUCTIONS'' be in bold type to help alert the consumer that there is new and critically important information about the egg product.

The agency notes that experience has shown that the prominence of some labeling information may be enhanced by the use of a box around the information. The agency's experience with the new nutrition label has been that the box surrounding the nutrition information greatly increases the prominence of the information. In addition, consumer focus group research has shown that boxes around important messages help consumers to distinguish the message from other information (Ref. 25). Therefore, the agency tentatively concludes that the use of a box around the label statement for shell eggs will similarly increase the prominence of the message by setting it off, thereby enhancing the likelihood that consumers will notice and read the message. Accordingly, FDA is including in the proposal a requirement (proposed § 101.17(h)(3)) that the label statement be set off in a box by use of hairlines.

The agency requests comments on the prominence and placement of the proposed label statement and whether the proposal provides sufficient flexibility to accomodate the many types of egg cartons in the marketplace. FDA is particularly interested in comments on whether other measures, e.g., color enhancement, are necessary to focus the consumer's attention on the label statement.

IV. Analysis of Impacts

A. Benefit/Cost Analysis

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866. 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, safety, distributive, and equity effects). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million; adversely affecting some sector of the economy in a material way; or adversely affecting jobs or competition. A regulation is also considered a significant regulatory action under Executive Order 12866 if it raises novel, legal, or policy issues. Under the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requiring cost-benefit and other analyses, a significant rule is defined in section

1531 (a) as ''a 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 (adjusted annually for inflation) in any 1 year * * *.'' Finally, the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S. based enterprises to compete with foreign-based enterprises in domestic or export markets.

FDA tentatively finds that this proposed rule is economically significant under Executive Order 12866. FDA has determined that this proposed rule, based on the median estimate of cost contained in the economic analysis, does not constitute a significant rule under the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Furthermore, in accordance with the Small Business Regulatory Enforcement Fairness Act of 1995 (Pub. L. 104–121) it has been determined that this proposed rule would be a major rule for the purpose of congressional review.

This section summarizes the preliminary regulatory impact analysis of the proposed rule. The full analysis and a list of references is available in a separate document entitled ''Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rule to Require Refrigeration of Shell Eggs at Retail and Safe Handling Labels'' (PRIA/IRFA) published elsewhere in this issue of the **Federal Register.**

One comment to the 1998 ANPRM suggested that FDA consider mandatory sell-by dates, prohibition of re-packaging, and mandatory pasteurization of shell eggs intended for at-risk consumers (such as residents of nursing homes). Several comments stated that in-shell pasteurization was costly; according to one comment, pasteurization equipment would cost $1.5 million. Several comments stressed the cost and difficulty of placing the safe handling statement on egg cartons, which are already crowded with printing. In one comment, a carton manufacturer estimated that designing and producing new plates for all of its egg cartons would cost about $2 million.

1. Regulatory Options

FDA considered several regulatory options for dealing with SE in shell eggs. The options considered include: (1) No new regulatory action, (2) labeling only, (3) refrigeration at 7.2 °C (45 °F) only, (4) refrigeration at 5 °C (41 °F), (5) Hazard Analysis Critical Control Point (HACCP) for shell eggs, (6) in-shell pasteurization, (7) longer compliance periods, and (8) limited retail sell-by period.

FDA believes that relying on current safeguards (option 1) would not greatly reduce the number of illnesses from SE in shell eggs. Even though the benefits from either labeling alone or refrigeration alone (options 2 and 3) exceed the costs, the combined benefits of refrigeration and labeling (the proposed rule) are much greater than either taken separately. FDA found that option 4 (refrigerate shell eggs at 5 °C (41 °F) in retail establishments and institutions) would not have a significant additional effect on SE in shell eggs, but would increase costs substantially. FDA believes that a HACCP-like program (option 5) is currently not feasible. However, FDA is evaluating whether in the future, a HACCP-like program including possibly in-shell pasteurization, may be necessary to further ensure the safety of shell eggs. In-shell pasteurization (option 6) would greatly reduce SE, but FDA believes other interventions between farm and table could reduce SE at lower cost. The main disadvantage of longer compliance periods for the labeling provision (option 7) is that the option would delay the realization of the benefits of the rule. Finally, FDA finds that limiting the retail sell-by period to 30 days (option 8) would have small public health benefits but could impose substantial costs.

2. Benefits

Benefits from the proposed rule to require a safe handling label and the refrigeration of shell eggs at 7.2 °C (45 °F) come from reducing SE-related illness. The basic model for estimating benefits is: ''marginal health benefits = baseline risk (number of SE illnesses related to shell eggs) x expected reduction in the number of illnesses brought about by the proposed rule x health cost per illness''.

FDA used the results of the USDA SE risk assessment for one estimate of the baseline risk and the CDC *Salmonella* surveillance data for another estimate of the baseline. FDA also used the risk assessment model to estimate the expected reduction in illnesses attributed to the proposed rule. The design of the USDA SE risk assessment model allowed FDA to estimate the number of illnesses prevented by comparing the baseline number of illnesses with the number of illnesses under the provisions of the proposed rule. The range (5th to 95th percentile) of estimated annual illnesses prevented for the USDA SE risk assessment baseline was 12,000 to 407,000, with a median of 66,000. The range (5th to 95th percentile) of estimated illnesses prevented for the CDC surveillance baseline was 7,000 to 107,000, with a median of 25,000.

FDA calculated the health cost per illness prevented by classifying SE illnesses into the following outcomes based on severity: Mild, moderate, and severe acute gastrointestinal illnesses; resolved and chronic reactive arthritis; and death. FDA then multiplied the estimated monetary health cost per type of illnesses by the number of illnesses prevented of each type. Total health benefits from the proposed rule were calculated as follows:

total health benefits = (number of mild cases prevented x $ per case) + (number of moderate cases prevented x $ per case) + (number of severe-acute cases prevented x $ per case) + (number of resolved cases of arthritis prevented x $ per case) + (number of chronic cases of arthritis prevented x $ per case) + (number of deaths x $ per death)

The baseline risk, the expected reduction in risk, and the health costs per illness are all uncertain. FDA therefore estimated a distribution of possible health benefits for the proposed rule, with the distribution based on the probability distributions associated with the main uncertainties. The range (5th to 95th percentile) of estimated annual benefits for the USDA SE risk assessment baseline was $87 million to $6.6 billion, with a median of $700 million. The range (5th to 95th percentile) of estimated annual benefits for the CDC surveillance baseline was $50 million to $1.7 billion, with a median of $300 million. The benefits are large, although FDA estimates that 95 percent of shell eggs are already held at ambient temperatures of 7.2 °C (45 °F) or less.

3. Costs

The costs of the proposed rule are the sum of the costs of changes in manufacturing practices—labeling and refrigeration and changes in consumer practices—egg preparation and consumption.

a. *Labeling.* The costs of labeling are the sum of administrative compliance, inventory disposal, and label redesign costs. FDA calculated labeling costs with the following model: ''labeling cost = ($ administrative costs per firm x

number of affected firms) + ($ value of cartons manufactured x disposal percentage of carton inventory) + (number of affected labels x $ redesign cost per label)''.

FDA estimated the total labeling cost for a 6-month compliance period to be a one-time cost of approximately $18 million. The total cost included administrative costs of $280,000, inventory disposal costs of $3 million, and label redesign costs of $15 million.

b. *Refrigeration*. FDA estimated the refrigeration costs to be the cost of the additional equipment required for all establishments to maintain an ambient temperature of 7.2 °C (45 °F). FDA calculated the cost by multiplying the estimated number of establishments that would require new (or upgraded) equipment by the cost of equipment. Both the number of establishments affected and the cost of equipment are uncertain. FDA estimated the number of establishments that would require new equipment by assuming that no establishments in States that had adopted the Food Code and an uncertain fraction—with one-third the most likely value—of establishments in States that had not adopted the Food Code would require new equipment. FDA used industry sources to obtain estimates of the range of costs of new or additional equipment necessary to meet the refrigeration provision of the proposed rule. The estimated costs per establishment ranged from close to zero for small equipment upgrades to $6,000 for a large new refrigerator.

FDA estimated a distribution of possible refrigeration costs for the proposed rule. The range (5th to 95th percentile) of estimated one-time refrigeration costs was $7 million to $228 million, with a median of $31 million.

c. *Changes in consumer practices*. FDA estimated the annual costs to consumers of changing the way eggs are prepared and consumed as follows:

cost of changes in consumer practices = annual number of eggs consumed x baseline fraction of eggs consumed undercooked x fractional reduction in undercooked eggs in response to safe handling label x $ value of undercooking one egg

The cost to consumers is uncertain. The range (5th to 95th percentile) of annual costs was $2 million to $20 million, with a median of $10 million. The cost of changes in consumer practices is an annual recurring cost of the proposed rule.

4. Summary of Benefits/Cost Analysis

Table 1 of this document shows the median estimated benefits and costs of the proposed rule.

TABLE 1.—MEDIAN ANNUAL ESTIMATED BENEFITS AND COSTS OF THE PROPOSED RULE (IN MILLIONS OF DOLLARS)

Incidents of Benefit and Cost Analysis	First Year	All Other Years
Median estimated benefits (USDA SE risk assessment baseline)	$700	$700
Median estimated benefits (CDC surveillance baseline)	$300	$300
Median estimated costs	$60	$10

B. Small Entity Analysis

1. Introduction

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities.

2. Economic Effects on Small Entities

a. *Number of small entities affected*. The proposed rule would affect many small entities, including egg processors, grocery stores and other stores including roadside stands, restaurants and other food service establishments. FDA has not been able to determine how many of the 669 egg processors registered with the USDA are small businesses (Ref. 40). Egg processors generally fall into two industrial classifications: Poultry slaughtering and processing (standard industrial classification (SIC code 2015)) and whole poultry and poultry products (SIC code 5144). The two classifications roughly correspond to in-line and off-line processors. In-line processors package the eggs at the egg laying facility. Off-line processors ship the eggs to packers.

The Small Business Administration (SBA) defines in-line egg processors (SIC code 2015–03) to be small businesses if they employ 500 or fewer people. According to a search in Dun's Market Identifiers (Ref. 41), 25 in-line egg processing firms would be defined as small. SBA defines off-line processors (SIC code 5144) to be small if they employ 100 or fewer people. Dun's Market Identifiers did not have a subcategory for egg processors. For the entire category of poultry and poultry products (SIC code 5144), 80 percent of establishments employ fewer than 100 workers. If the same proportion holds for the subcategory composed of egg processors, then 470 firms would be classified as small.[7] FDA estimated the total number of small egg processors to be 495 (= 25 + 470).

The refrigeration provision would affect small establishments that are not currently refrigerating at 7.2 °C (45 °F). The SBA defines grocery stores (SIC code 5411) to be small if annual gross revenue is less than $20 million. Other food stores (SIC codes 5431, 5451, and 5499), which include fruit and vegetable markets, dairy product stores, and miscellaneous food stores, are small if annual sales are less than $5 million. Restaurants are small if annual sales are less than $5 million; institutions are small if sales are less than $15 million.

As set out in Table 2 of this document, FDA estimates that the number of small establishments affected by the proposed refrigeration provision would be 25,400. The number of establishments (small and large) currently not keeping eggs at an ambient temperature of 7.2 °C (45 °F) is approximately 44,400, which includes 10,700 grocery and other food stores, 24,000 restaurants, and 9,700 institutions (see the PRIA/IRFA document elsewhere in this issue of the **Federal Register**). FDA assumed that the proportion of small establishments affected by the refrigeration provision would be the same as the fraction of institutions for the entire industry in that category. According to SBA size standards for small entities, 71 percent of grocery and other food stores and 54 percent of restaurants are small. Institutions are more complicated, because they cut across SIC codes. FDA assumed that 50 percent of institutions serving eggs are small. The agency asks for comments on this assumption. FDA estimated the number of small establishments affected by the

[7] The estimated total number of in-line establishments is 134, but 52 are branches of firms. If the total number of in-line firms is 82 (= 134 - 52), and the number of processors is 669, then 587 firms are off-line processors. If 80 percent are small, then 470 off-line (= 0.8 x 587) processors are small.

refrigeration provision by multiplying the fraction in each category defined to be small by the total number of establishments affected. Table 2 of this document shows the number of small entities likely to be affected by the refrigeration provision of the proposed rule.

TABLE 2.—NUMBER OF SMALL ENTITIES LIKELY TO BE AFFECTED BY THE REFRIGERATION PROVISION OF THE PROPOSED RULE

Category	Number of Small Establishments Currently Storing Eggs Above 45 °F (7 °C)
Grocery and other stores	7,600
Restaurants	13,000
Institutions	4,800
Total	25,400

b. *Costs to small entities*. Redesigning the label accounts for most of the estimated additional labeling costs for small processors. For a 6-month compliance period, redesign costs would be $1,000 per stockkeeping unit (SKU) for pulp cartons and $500 per SKU for foam cartons. The cost of the labeling provision borne by small processors will vary with the number of SKU's. The average number of SKU's per processor for the industry is 30; FDA assumes that the output of small processors falls in the range of 2 to 20 SKU's. Additional redesign costs could therefore be as high as $20,000 per processor (= 20 x $1,000).

Refrigeration costs vary across establishments, depending on the age of current refrigerators, the planned replacement cycle, and whether the small establishments is currently keeping eggs at or below 7.2 °C (45 °F). Additional refrigeration costs for small retailers would average $633, with $700 the most likely value. FDA assumed that the proportion of additional refrigeration costs borne by small entities would be the same as the proportion of small entities in each category of establishments. The cost of the refrigeration provision to small entities is shown in Table 3 of this document. The agency requests comments on the effect of the refrigeration provision on roadside stands and the practices they follow in marketing eggs.

TABLE 3.—COSTS TO SMALL ENTITIES OF THE REFRIGERATION PROVISION OF THE PROPOSED RULE

Category	Total Costs to Small Entities	Mean Cost per Small Entity
Grocery and other stores	$4.8 million	$633
Restaurants	$8.2 million	$633
Institutions	$3.1 million	$633

3. Regulatory Options

a. *Exemption for small entities*. The burden on small entities would be lifted if they were exempt from the provisions of the proposed rule. Most of the entities affected by this proposed rule, however, are small. Thus, exempting small entities from its provisions would effectively negate the rule.

b. *Longer compliance periods*. Lengthening the labeling compliance period from 6 months to 18 months and lengthening the refrigeration compliance period from the proposed rule's effective date to 12 months after the effective date would provide regulatory relief (cost reduction) to small entities. In order to estimate the regulatory relief from lengthening the refrigeration compliance period, the agency assumed that the cost reduction would equal the interest (discounted at 7 percent per year) on the cost of refrigeration equipment over the extension of the compliance period. If the compliance period were extended by 12 months, the interest on the cost of equipment would be over $1 million (= $16.1 x 0.07). For the most likely equipment cost of $700 per small establishment, the interest saving would be about $50 (=0.07 x $700).

In order to estimate the regulatory relief to small retail entities from a longer labeling compliance period, FDA estimated that total industry costs would fall by $11 million if the compliance period were extended from 6 months to 18 months (see the PRIA/IRFA document elsewhere in this issue of the **Federal Register**). Most of the relief to small businesses would come from the reduced costs of redesigning the carton label. For pulp cartons, extending the compliance period to 18 months would reduce redesign costs from $1,000 (for a 6-month compliance period) to $500 per SKU. For foam cartons, extending the compliance period to 18 months would reduce redesign costs from $500 (for a 6-month compliance period) to $100 per SKU.

Although lengthening the compliance periods would provide some regulatory relief to small entities, they make up such a large part of the affected industries that longer compliance periods would significantly delay the full public health benefits of the proposed rule.

4. Description of Recordkeeping and Recording Requirements

The Regulatory Flexibility Act requires a description of the recordkeeping and recording required for compliance with this rule. This rule does not require the preparation of a report or a record.

5. Worst Case to Small Entities

The greatest impact to a small retail establishment as a consequence of the refrigeration provision would be to cause the entity to bear the entire cost for the purchase of a new refrigerator. The agency estimates that the cost of a new refrigerator is between $2,500 and $6,000 (see the PRIA/IRFA document published elsewhere in this issue of the **Federal Register**). In order to estimate the worst possible outcome for a small entity, FDA assumed that some small retail establishment would purchase a new refrigerator at the maximum estimated cost of $6,000. If the latter

cost were amortized over a 10-year period (using a discount rate of 7 percent) then the approximate annual expense would be $850 per year for 10 years. According to Dun and Bradstreet, 85 percent of all grocery stores have annual sales of less than $20 million, and 71 percent of all restaurants have annual sales of less than $5 million (Ref. 41). Among the smallest 10 percent of these establishments, the average sales volume is $100,000 per year for a grocery store and $50,000 per year for a restaurant. Therefore, the additional expense of $850 per year amounts to approximately 1 to 2 percent of average sales volume per year. Grocery stores and restaurants typically have profit margins on sales of 1 to 5 percent, so a reduction of the profit margin by 40 to 100 percent would be the worst-case outcome for the smallest entities in retail.

The worst case to a small entity attributable to the labeling provision would occur if a small packer were unable to pass along any of the cost to its customers. As shown previously, FDA estimated that the redesign cost to a small processor could be as high as $20,000. If the one-time cost could be amortized over a 10-year period at an annual discount rate of 7 percent, the small packer would incur an additional annual expense of approximately $3,000. FDA has not estimated the annual sales revenues of the smallest egg packers and is therefore unable to compare the estimated amortized cost to annual profits. FDA requests comments on this relationship.

6. Summary of Small Entity Analysis

FDA estimated that the labeling provisions could impose costs of up to $20,000 on 495 small processing establishments. The refrigeration provision would impose estimated costs of $633 per small entity on approximately 25,400 small establishments. FDA finds that, under the Regulatory Flexibility Act, this proposed rule would have a significant economic impact on a substantial number of small entities.

V. Executive Order 12612: Federalism

FDA has examined the effects of the two requirements in this proposal, i.e., refrigeration of shell eggs at retail and safe handling labeling of shell eggs, on the relationship between the Federal Government and the States, as required by Executive Order 12612 on ''Federalism.'' The agency concludes that preemption of State or local rules that establish requirements for refrigeration of shell eggs that would be less stringent than Federal law is consistent with this Executive Order. The agency also concludes that the preemption of State or local rules that establish requirements for safe handling instructions on shell eggs that would not include, at a minimum, the language required by the Federal law is also consistent with this Executive Order.

Section 3(b) of Executive Order 12612 recognizes that Federal action limiting the discretion of State and local governments is appropriate ''where constitutional authority for the action is clear and certain and the national activity is necessitated by the presence of a problem of national scope.'' The constitutional basis for FDA's authority to regulate the safety and labeling of foods is well established.

Section 4(a) of Executive Order 12612 expressly contemplates preemption when there is a conflict between the exercise of State and Federal authority under Federal statute. Moreover, section 4(b) of the Executive Order authorizes preemption of State law in the Federal rulemaking context when there is ''firm and palpable evidence compelling the conclusion that the Congress intended to delegate to the * * * agency the authority to issue regulations preempting State law.'' State and local laws and regulations that would impose less stringent requirements for refrigeration of shell eggs held for retail distribution would undermine the agency's goal of ensuring that shell eggs are properly refrigerated to prevent the growth of SE, and, thus, reduce the risk of foodborne illness. Similarly, State and local requirements for safe handling labeling that do not include, at a minimum, the language required by Federal law would undermine the agency's effort to provide consumers with material information that would inform them how to properly handle and cook eggs so as to reduce their risk of foodborne illness. FDA believes that a single temperature requirement will ensure that all shell eggs for retail distribution would meet minimal standards to ensure safety. The agency also believes that consistent safe handling instructions are necessary so consumers can find essential information in a message that is not confusing or misleading.

The proposed rule would establish national minimum standards with respect to refrigeration and labeling of shell eggs. However, the refrigeration requirements of this proposed rule do not preempt State and local laws, regulations, and ordinances that establish more stringent requirements with respect to the refrigeration requirements, e.g., lower storage temperature requirements. In addition, the labeling provisions of this proposed rule do not preempt State and local laws, regulations, and ordinances that require additional safe handling instructions, e.g., graphics, on shell eggs that do not conflict with the proposed Federal requirements.

As required by the Executive Order, States and local governments will be given, through this notice of proposed rulemaking, an opportunity to participate in the proceedings to preempt State and local laws (section 4(e) of Executive Order 12612). In addition, under the Order, appropriate officials and organizations will be consulted before this proposed action is implemented (section 3(a) of Executive Order 12612).

The agency concludes that the policy proposed in this document has been assessed in light of the principles, criteria, and requirements in Executive Order 12612; that this policy is not inconsistent with that Order; that this policy will not impose additional costs and burdens on the States; and that this policy will not affect the ability of the States to discharge traditional State governmental functions.

VI. Environmental Impact

The agency has determined under 21 CFR 25.30(j) and (k) 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.

VII. Effective Date

FDA is proposing that any final rule that may be issued based upon this proposal become effective 180 days after its publication in the Federal Register. However, because FDA believes that it is in the best interest of all consumers for manufacturers to label shell eggs as soon as possible, the agency urges manufacturers and packers of shell eggs to label their products with safe handling statements consistent with this proposal immediately. FDA recognizes that it is possible that the requirements for the label statements in the final rule may be different from those in the proposal. However, to encourage manufacturers to use the label statements as soon as possible, the agency advises that it intends to allow the continued use of any label that complies with the proposed regulation and is printed prior to date of publication of any final rule resulting from this proposal until that inventory is depleted.

VIII. Paperwork Reduction Act of 1995

FDA tentatively concludes that the labeling requirements proposed in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather the proposed safe handling instructions would be a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

IX. Comments

Interested persons may, on or before September 20, 1999, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

X. References

The following references have been placed on display at the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Centers for Disease Control and Prevention Memorandum from Chief, Foodborne Diseases Epidemiology Section, February 8, 1996.

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16. Snoeyenbos, G. H., C. F. Smyser, and H. Van Roekel, ''Research Note: *Salmonella* Infections of the Ovary and Peritoneum of Chickens,'' *Avian Diseases*, 13:668–670, 1969.

17. *Salmonella Enteritidis* Pilot Project Progress Report, May 22, 1995.

18. Council for Agricultural Science and Technology, *Foodborne Pathogens: Risks and Consequences*, Ames, Iowa: Council for Agricultural Science and Technology, Task Force Report No. 122, ch. 3, 1994.

19. Hennessey, T. W., C. W. Hedberg, L. Slutsker, K. E. White, J. M. Besser-Wiek, M. E. Moen, J. Feldman, W. W. Colemen, L. M. Edmonson, K. L. MacDonald, and M. T. Osterholm, ''A National Outbreak of *Salmonella enteritidis* Infections from Ice Cream,'' *The New England Journal of Medicine*, 334:1281–1286, 1996.

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33. U.S. Public Health Service, ''Food Code: 1999, Recommendations of the United States Public Health Service, Food and Drug Administration,'' Sections 3–401.11 and 3–501.16.

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35. *Salmonella Enteritidis* Review Team Report, January 18, 1997.

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States,'' *Morbidity and Mortality Weekly Report*, 37:490, 495–496, 1988.

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38. Miyamoto, T., T. Horie, E. Baba, K. Susai, T. Fukata, and A. Arakawa, ''*Salmonella* Penetration Through Eggshell Associated With Freshness of Laid Eggs and Refrigeration,'' *Journal of Food Protection*, 61:350–353, 1998.

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40. FDA memorandum, Peter Vardon to the Record, October 7, 1998.

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List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 101

Administrative practice and procedure, Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 115

Administrative practice and procedure, Eggs, Refrigeration.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Services Act, and under the authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR chapter I be amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

2. Section 16.5 is amended by adding paragraph (a)(4) to read as follows:

§ 16.5 Inapplicability and limited applicability.

(a) * * *

(4) A hearing on an order for relabeling, diversion, or destruction of shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264), §§ 101.17(h) and 115.50 of this chapter.

* * * * *

PART 101—FOOD LABELING

3. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

4. Section 101.17 is amended by revising the section heading and by adding paragraph (h) to read as follows:

§ 101.17 Food labeling warning, notice, and safe handling statements.

* * * * *

(h) *Shell eggs.* (1) The label of shell eggs shall bear the following statement:

SAFE HANDLING INSTRUCTIONS: Eggs may contain harmful bacteria known to cause serious illness, especially in children, the elderly, and persons with weakened immune systems. For your protection: keep eggs refrigerated; cook eggs until yolks are firm; and cook foods containing eggs thoroughly.

(2) The label statement required by paragraph (h)(1) of this section shall appear prominently and conspicuously, with the words ''SAFE HANDLING INSTRUCTIONS'' in bold type, on the information panel or the principal display panel of the container.

(3) The label statement required by paragraph (h)(1) of this section shall be set off in a box by use of hairlines.

(4) Shell eggs that have been, before distribution to consumers, specifically processed to destroy all viable *Salmonella* shall be exempt from the requirements of this paragraph (h).

(5) The safe handling statement for shell eggs that are not for direct sale to consumers, e.g., those that are to be repacked or labeled at a site other than where originally processed, or are sold for use in food service establishments, may be provided on cartons or in labeling, e.g., invoices or bills of lading in accordance with the practice of the trade.

(6) The requirements of this section are applicable to all shell eggs.

(7) Under sections 311 and 361 of the Public Health Service Act (PHS Act), any State or locality that is willing and able to assist the agency in the enforcement of paragraphs (h)(1) through (h)(5) of this section, and is authorized to inspect or regulate establishments handling packed shell eggs, may in its own jurisdiction, enforce paragraphs (h)(1) through (h)(5) of this section through inspections under paragraph (h)(9) of this section and through administrative enforcement remedies identified in paragraph (h)(8) of this section until FDA notifies the State or locality in writing that such assistance is no longer needed. When providing such assistance, a State or locality may follow the hearing procedures set out in paragraphs (h)(8)(ii)(C) through (h)(8)(ii)(D) of this section, substituting, where necessary, appropriate State or local officials for designated FDA officials or may utilize comparable State or local hearing procedures if such procedures satisfy due process.

(8) This paragraph (h) is established under authority of both the Federal Food, Drug, and Cosmetic Act (the act) and the PHS Act. Under the act, the agency can enforce the food misbranding provisions under 21 U.S.C. 331, 332, 333, and 334. However, 42 U.S.C. 264 provides for the issuance of implementing enforcement regulations; therefore, FDA has established the following administrative enforcement procedures for the relabeling, diversion, or destruction of shell eggs and informal hearings under the PHS Act:

(i) Upon finding that any shell eggs are in violation of this section, an authorized FDA representative or State or local representative in accordance with paragraph (h)(7) of this section may order such eggs to be relabeled under the supervision of said representative, diverted, under the supervision of said representative for processing in accordance with the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), or destroyed by or under the supervision of an officer or employee of the FDA, or, if applicable, of the State or locality, in accordance with the following procedures:

(A) *Order for relabeling, diversion, or destruction under the PHS Act.* Any district office of the FDA or any State or locality acting under paragraph (h)(7) of this section, upon finding shell eggs held in violation of this regulation, may serve upon the person in whose possession such eggs are found a written order that such eggs be relabeled with the required statement in paragraph (h)(1) of this section before further distribution. If the person chooses not to relabel, the district office of the FDA or, if applicable, the appropriate State or local agency may serve upon the person a written order that such eggs be diverted (from direct consumer sale, e.g., to food service) under the supervision of an officer or employee of the issuing entity, for processing in accordance with the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*)) or destroyed by or under the supervision of the issuing entity, within 10-working days from the date of receipt of the order.

(B) *Issuance of order.* The order shall include the following information:

(*1*) A statement that the shell eggs identified in the order are subject to relabeling, diversion for processing in

accordance with the Egg Products Inspection Act, or destruction;

(*2*) A detailed description of the facts that justify the issuance of the order;

(*3*) The location of the eggs;

(*4*) A statement that these eggs shall not be sold, distributed, or otherwise disposed of or moved except as provided in paragraph (h)(8)(i)(E) of this section;

(*5*) Identification or description of the eggs;

(*6*) The order number;

(*7*) The date of the order;

(*8*) The text of this entire section;

(*9*) A statement that the order may be appealed by written appeal or by requesting an informal hearing;

(*10*) The name and phone number of the person issuing the order; and

(*11*) The location and telephone number of the responsible office or agency and the name of its director.

(C) *Approval of director.* An order, before issuance, shall be approved by the director of the office or agency issuing the order. If prior written approval is not feasible, prior oral approval shall be obtained and confirmed by written memorandum as soon as possible.

(D) *Labeling or marking of shell eggs under order.* An FDA, State, or local representative issuing an order under paragraph (h)(8)(i)(A) of this section shall label or mark the shell eggs with official tags that include the following information:

(*1*) 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)).

(*2*) A statement that the shell eggs shall not be sold, distributed or otherwise disposed of or moved except, after notifying the issuing entity in writing, to:

(*i*) Relabel, divert them for processing in accordance with the Egg Products Inspection Act, or destroy them; or

(*ii*) Move them to another location for holding pending appeal.

(*3*) 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).

(*4*) The order number and the date of the order, and the name of the government representative who issued the order.

(E) *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 shall not sell, distribute, or otherwise dispose of or move any eggs subject to the order unless and until the notice is withdrawn after an appeal except, after notifying FDA's district office or, if applicable, the State or local agency in writing, to:

(*1*) Relabel, divert, or destroy them as specified in paragraph (h)(8)(iv) of this section; or

(*2*) Move them to another location for holding pending appeal.

(ii) The person on whom the order for relabeling, diversion, or destruction is served may either comply with the order or appeal the order to the regional food and drug director.

(A) *Appeal of a detention order.* Any appeal shall be submitted in writing to the FDA 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 shall be held within 5-working days after the appeal is filed or, if requested by the appellant, at a later date, which shall 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 shall state the ownership or proprietary interest the appellant has in the shell eggs.

(B) *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.

(C) *Informal hearing.* Appearance by any appellant at the hearing may be by mail or in person, with or without counsel. The informal hearing shall be conducted by the regional food and drug director or his designee, and a written summary of the proceedings shall be prepared by the regional food and drug director.

(*1*) The regional food and drug director may direct that the hearing be conducted in any suitable manner permitted by law and 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.

(*2*) Employees of FDA will first give a full and complete statement of the action which 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.

(*3*) 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.

(*4*) 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.

(*5*) The regional food and drug director shall 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.

(*6*) The regional food and drug director shall 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 shall include a recommended decision, with a statement of reasons.

(D) *Written appeal.* If the appellant appeals the detention order but does not request a hearing, the regional food and drug director shall render a decision on the appeal affirming or revoking the detention within 5-working days after the receipt of the appeal.

(E) *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 held in violation of this section, he shall affirm the order that they be relabeled, diverted under the supervision of an officer or employee of the FDA for processing under the Egg Products Inspection Act, or destroyed by or under the supervision of an officer or employee of the FDA; otherwise, the regional food and drug director shall issue a written notice that the prior order is withdrawn. If the regional food and drug director affirms the order he shall order that the

relabeling, 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 shall be accompanied by a statement of the reasons for the decision. The decision of the regional food and drug director shall constitute final agency action, reviewable in the courts.

(F) *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 relabel, 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 relabel, divert, or destroy them within 10-working days, the FDA district office, or, if applicable, the State or local agency 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.

(9) Persons engaged in handling or storing packed shell eggs for retail distribution shall permit authorized representatives of FDA to make at any reasonable time such inspection of the establishment in which shell eggs are being held, including inspection and sampling of the labeling of such 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.

5. New part 115 is added to read as follows:

PART 115—SHELL EGGS

Subpart A—General Provisions

Sec.
115.50 Refrigeration of shell eggs held for retail distribution.

Authority: 21 U.S.C. 342, 371; 42 U.S.C. 243, 264, 271.

Subpart A—General Provisions

§ 115.50 Refrigeration of shell eggs held for retail distribution.

(a) For purposes of this section a ''retail establishment'' is an operation that stores, prepares, packages, serves, vends, or otherwise provides food for human consumption directly to consumers.

(b) Except as provided in paragraph (c) of this section, shell eggs held for retail distribution:

(1) Shall promptly be placed under refrigeration as specified in paragraph (b)(2) of this section upon receipt at a retail establishment; and

(2) Shall be stored and displayed under refrigeration at an ambient temperature not greater than 7.2 °C (45 °F) while held at a retail establishment.

(c) Shell eggs that have been specifically processed to destroy all viable *Salmonella* shall be exempt from the requirements of paragraph (b) of this section.

(d) The requirements of this section are applicable to all shell eggs.

(e) Under sections 311 and 361 of the Public Health Service Act (PHS Act), any State or locality that is willing and able to assist the agency in the enforcement of paragraph (b) of this section, and is authorized to inspect or regulate retail establishments, may, in its own jurisdiction, enforce paragraph (b) of this section through inspections under paragraph (g) of this section and through administrative enforcement remedies identified in paragraph (f) of this section until FDA notifies the State or locality in writing that such assistance is no longer needed. When providing assistance under paragraph (f) of this section, a State or locality may follow the hearing procedures set out in paragraphs (f)(2)(iii) through (f)(2)(v) of this section, substituting, where necessary, appropriate State or local officials for designated FDA officials or may utilize comparable State or local hearing procedures if such procedures satisfy due process.

(f) This section is established under authority of both the Federal Food, Drug, and Cosmetic Act (the act) and the PHS Act. Under the act, the agency can enforce the food adulteration provisions under 21 U.S.C. 331, 332, 333, and 334. However, 42 U.S.C. 264 provides for the issuance of implementing enforcement regulations; therefore, 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 finding that any shell eggs have been held in violation of this section, an authorized FDA representative or a State or local representative in accordance with paragraph (e) 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 (21 U.S.C. 1031 *et seq.*) or destroyed by or under the supervision of an officer or employee of the FDA, or, if applicable, of the state or locality in accordance with the following procedures:

(i) *Order for diversion or destruction.* Any district office of FDA or any State or local agency acting under paragraph (e) of this section, upon finding shell eggs held in violation of this regulation, may serve upon the person in whose possession such eggs are found a written order that such eggs be diverted, under the supervision of an officer or employee of the issuing entity, for processing in accordance with the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*) or destroyed by or under the supervision of said district office, within 10-working days from the date of receipt of the order.

(ii) *Issuance of order.* The order shall 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 Egg Products Inspection Act 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 shall not be sold, distributed, or otherwise disposed of or moved except as provided in paragraph (g)(4) 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 and the name of its director.

(iii) *Approval of District Director.* An order, before issuance, shall be approved by the Food and Drug Administration (FDA) District Director in whose district the shell eggs are located. If prior written approval is not feasible, prior oral approval shall be obtained and confirmed by written memorandum as soon as possible.

(iv) *Labeling or marking of shell eggs under order.* An FDA, State or local agency representative issuing an order under paragraph (g)(1) of this section shall 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 shall 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 Egg Products Inspection Act or destroy them; or

(2) Move them to an another location for holding pending appeal.

(C) A statement that the violation of the order or the removal or alteration of the tag is punishable by fine or imprisonment or both (section 368 of the PHS Act, 42 U.S.C. 271).

(D) The order number and the date of the order, and the name of the government representative who issued the order.

(v) *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 shall not sell, distribute, or otherwise dispose of or move any eggs subject to the order unless and until the notice is withdrawn after an appeal except, after notifying FDA's district office or, if applicable, the State or local agency in writing, to:

(A) Divert or destroy them as specified in paragraph (f)(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 shall 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 shall be held within 5-working days after the appeal is filed or, if requested by the appellant, at a later date, which shall 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 shall 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 shall be conducted by the regional food and drug director or his designee, and a written summary of the proceedings shall 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 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 which 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 shall 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 shall 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 shall 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 shall render a decision on the appeal affirming or revoking the detention 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 held in violation of this section, he shall affirm the order that they be diverted, under the supervision of an officer or employee of the FDA for processing under the Egg Products Inspection Act or destroyed by or under the supervision of an officer or employee of the FDA; otherwise, the regional food and drug director shall issue a written notice that the prior order is withdrawn. If the regional food and drug director affirms the order he shall 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 shall be accompanied by a statement of the reasons for the decision. The decision of the regional food and drug director shall constitute final agency action, reviewable in the courts.

(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 appropriate State or local agency 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.

(g) *Inspection.* Persons engaged in retail distribution of shell eggs shall permit authorized representatives of FDA to make at any reasonable time such inspection of the retail establishment in which shell eggs are being held, including inspection and sampling of such eggs and the equipment in which shell eggs are held and any records relating to such equipment or eggs, as may be necessary in the judgement 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.

Dated: June 10, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 99–17122 Filed 7–1–99; 11:12 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 101, and 115

[Docket No. 99N–1307]

RIN 0910–AB30

Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rule to Require Refrigeration of Shell Eggs at Retail and Safe Handling Labels

AGENCY: Food and Drug Administration, HHS.

ACTION: Preliminary regulatory impact analysis and initial regulatory flexibility analysis.

SUMMARY: The Food and Drug Administration (FDA) is publishing both the preliminary regulatory impact analysis prepared under Executive Order 12866 and the initial regulatory flexibility analysis prepared under the Regulatory Flexibility Act on the proposed rule (published elsewhere in this issue of the **Federal Register**) to require shell eggs to contain safe handling statements and to be stored and displayed under refrigeration at 7.2 °C when held by retail establishments. FDA is issuing the proposed rule because of the large number of illnesses and deaths caused by *Salmonella enteritidis* (SE) associated with shell eggs that have not been treated to destroy the pathogen. The proposed rule is intended to ensure that consumers will have the information necessary to protect themselves from eggs contaminated with SE and to ensure that eggs will be held at retail at temperatures that discourage pathogen growth.

DATES: Submit written comments on the analysis of the proposed rule by September 20, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket numbers found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Clark Nardinelli, Center for Food Safety and Applied Nutrition (HFS–726), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–8702.

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I. Preliminary Regulatory Impact Analysis

A. Introduction

FDA has examined the economic implications of the proposed rule as required by Executive Order 12866. 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 effects; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: (1) Having an annual effect on the economy of $100 million, (2) adversely affecting a sector of the economy in a material way, (3) adversely affecting competition, or (4) adversely affecting jobs. A regulation is also considered a significant regulatory action under Executive Order 12866 if it raises novel legal or policy issues.

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), requiring cost-benefit and other analyses, in section 1531(a) defines a significant rule as ''a Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) in any 1 year.'' The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 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: (1) An annual effect on the economy of $100 million; (2) a major increase in costs or prices; (3) significant effects on competition, employment, productivity, or innovation; or (4) significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In the **Federal Register** of May 19, 1998 (63 FR 27502), USDA and FDA published an advance notice of proposed rulemaking (ANPRM) entitled ''*Salmonella* Enteritidis in Eggs.'' Among other things, this ANPRM solicited public comment on what regulations might be required to reduce the public health risk of SE in shell eggs. USDA received approximately 73 responses to this ANPRM, each containing one or more comments. Responses were received from egg farmers, egg packers, associations for the egg industry, other trade associations, consumers, consumer interest groups, animal interest groups, academia, State