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.

SUPPLEMENTARY INFORMATION:

Table of Contents:

I. Preliminary Regulatory Impact Analysis
A. Introduction
B. Failure of the Existing Regime
C. Regulatory Options
1. No New Regulatory Action
2. Labeling Provision Only
3. Refrigeration Provision Only
4. Refrigerate at 5 °C (41 °F)
5. Implement a HACCP-Style System for Shell Eggs
6. In-Shell Pasteurization
7. Longer Compliance Periods
8. Limit the ''Sell By'' Period
D. Coverage
1. Establishments
2. Products
E. Benefits
1. The Shell Eggs and Egg Products Risk Assessment Model
2. Cases of Salmonellosis Prevented
3. Health Benefits from Preventing Salmonellosis
4. Total Health Benefits
5. Additional Benefits
a. Reduced Risk From Other Pathogens
b. Fewer Recalls
6. Uncertainty of Estimated Benefits
F. Costs
1. Types of Establishments Covered
a. Labeling Provision Coverage
b. Refrigeration Provision Coverage
2. Cost Estimates by Requirement and Type
a. Egg Container Labels
i. Administrative Costs
ii. Inventory Disposal Costs
iii. Label Redesign Costs
iv. Summary of Costs to Incorporate Safe Handling Labeling
b. Refrigeration Costs
i. Equipment Costs to Refrigerate at *7.2 °C (45 °F)*
ii. Energy Costs
iii. Shares of Refrigeration Equipment Costs by Type of Establishment
iv. Comparison with Other Studies of Estimated Refrigeration Costs
c. Changes in Consumer Practices
G. Summary of Benefits and Costs
II. Initial Regulatory Flexibility Analysis
A. Introduction
B. Economic Effects on Small Entities
1. Number of Small Entities Affected
2. Costs to Small Entities
C. Regulatory Options
1. Exemption for Small Entities
2. Longer Compliance Periods
D. Description of Recordkeeping and Reporting Requirements
E. Worst Case to Small Entities
F. Summary
III. References
IV. Request for Comments

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

government agencies, and foreign government agencies. Included in these responses were several comments concerning the economic implications raised by the approaches discussed in the ANPRM. One comment 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. One comment suggested allowing existing safe handling labels. Several comments advocated some form of HACCP for shell eggs. Comments regarding the regulatory impact of the proposed rule are addressed below.

B. Failure of the Existing Regime

The proposed rule addresses the handling and preparation of shell eggs by retail establishments and consumers, and should reduce the illnesses and deaths that can occur from consumption of eggs contaminated with SE.

Private markets operate within the framework of legal institutions. The tort system of the common law evolved, in part, to provide remedies to injuries suffered in transactions in private markets. Under this system, if a defective product injures someone, then the injured person may recover damages from the producer of the defective product. The recovery of damages requires the injured person to prove that his/her injuries were caused by the producer's product. However, regardless of the legal theory chosen (negligence, warranty, or strict liability), to recover damages the injured person must be able to link his/her injury to the specific product of a specific producer.

In most instances, consumers experiencing illness from food consumption do not recognize the illness as foodborne or are unable to link the illness to consumption of a particular food. This inability to connect illness and food exists because many symptoms do not occur immediately after consumption of the product. The proposed rule addresses the inability of the tort system to address adequately the mishandling of eggs by retailers and the failure to provide consumers with information needed to reduce SE-related illnesses.

The proposed refrigeration provision addresses the possible market failure (because illnesses are not easily traced to processors) that occurs when eggs are not held at appropriate temperatures at retail and consumers are put at greater risk from SE-contaminated eggs. The increased risk resulting from SE-contaminated eggs that are not held at appropriate temperatures in retail establishments can lead to involuntary health effects for consumers who do not know about the temperature abuse or do not know about the associated increased risk from SE. Indeed, retailers may be as poorly informed as consumers about the SE-related health effects from temperature abused eggs. Because both retailers and consumers may be ignorant or uncertain about the risk, the implicit contract between consumers and retailers does not incorporate the potential harm to consumers caused by the hidden health risk associated with shell eggs. Furthermore, the uncertainty and ignorance may persist about the risk—despite the occurrence of illnesses—because of the long time lapse between the purchase of the SE-contaminated eggs and the onset of SE-related illnesses.

By requiring safe handling statements, the proposed rule will provide information about the potential adverse health effects of SE-contaminated eggs. The information will persuade some consumers to change potentially risky handling practices and thereby reduce the number of illnesses associated with SE in shell eggs. The proposed labeling provision helps correct the failure of the existing regime that occurs when consumers lack relevant information about the safe handling (refrigeration and thorough cooking) of eggs. Because this information is associated with a negative characteristic of the product, and this negative characteristic is not easily differentiated among egg products, processors have little incentive to make this information available to consumers. Without the relevant information, some consumers may not properly refrigerate or may not adequately cook eggs, and some may consume foods containing raw eggs. Information about shell eggs is not complete if people do not know the potential health risks associated with SE-contaminated eggs. The lack of information places consumers, especially the young, the elderly, and persons with immune deficiencies, at a greater health risk.

C. Regulatory Options

1. No New Regulatory Action

Under this option, FDA would rely on current regulations, publicizing risks, voluntary changes in behavior, and current or enhanced State and local enforcement activity to bring about a reduction in illnesses caused by SE in shell eggs. State and local governments that adopt and enforce the 1999 Food Code as issued by FDA will meet the goals of the proposed refrigeration rule. Adopting the Food Code as issued by FDA will also reduce undercooking of eggs in restaurants, which will accomplish part of the goals of the proposed labeling provision. The 1999 Food Code requires raw shell eggs to be cooked 15 seconds at 63 °C (145 °F) if prepared for immediate service in response to a consumer's order. Other raw eggs are required to be cooked 15 seconds at 68 °C (155 °F). Because the 1999 Food Code has not been adopted everywhere and because billions of shell eggs are prepared in the home, the coverage of this option would be less than with the proposed rule.

The threat of litigation might also help bring about the goals of the proposed rule. If victims could sue sellers of SE-contaminated eggs for damages, the incentives to retailers to eliminate SE from shell eggs would increase. Creating incentives for individual retailers to refrigerate eggs, however, may not create incentives for all retailers. Furthermore, the effectiveness of litigation is questionable because the link between the consumption of SE-contaminated eggs and illnesses may be difficult to establish for outbreaks and is nearly impossible to establish for sporadic cases. Moreover, if the link could be established it is not clear whether retailers would be held liable, although new techniques such as deoxyribonucleic acid (DNA) finger printing may someday make it possible to link cases to individual retailers.

2. Labeling Provision Only

The agency could require that egg cartons contain the instructions to food handlers to ''keep refrigerated'', ''cook until yolks are firm'', and ''cook foods containing eggs thoroughly'' described in the context of the microbial hazard and the persons at risk. Requiring the safe handling label alone would place the burden of reducing risk from SE-contaminated eggs solely on food handlers, which includes consumers, restaurants, and institutions. If food handlers follow good sanitation practices and eggs are cooked thoroughly, the risk of salmonellosis

from SE-contaminated shell eggs can be virtually eliminated. FDA believes that the safe handling label will improve cooking practices but will not eliminate SE. The additional safeguard of proper refrigeration is therefore needed to slow the growth of SE and thereby reduce the risk of illness from mishandling. The median estimated annual benefits from labeling only are $261 million for the U.S. Department of Agriculture (USDA) SE risk assessment baseline and $124 million for the Centers for Disease Control and Prevention (CDC) surveillance baseline; the costs from labeling only are $28 million in the first year, with a recurring annual cost of $10 million.[1]

3. Refrigeration Provision Only

The agency could require that retailers refrigerate shell eggs to 7.2 °C (45 °F), without also requiring safe handling labeling. Refrigeration at less than 10 °C (50 °F) slows the growth of SE. Because the level of *Salmonella* that initially contaminates eggs is usually low, refrigeration following laying should keep the numbers of pathogens low until the egg reaches the consumer. Retail refrigeration is particularly important because it occurs later in the flow of eggs from farm to table and, therefore, it can play an important role in postponing yolk membrane breakdown and the consequent rapid growth of SE. Even if SE can be attenuated by refrigeration, some illnesses may still occur because small numbers of SE can cause illness. Moreover, improper storage by consumers after proper retail refrigeration could result in rapid growth of SE. The median estimated benefits from refrigeration alone are $387 million for the USDA SE risk assessment baseline and $211 million for the CDC surveillance baseline; refrigeration alone would impose a one-time cost of $31 million.

4. Refrigerate at 5 °C (41 °F)

Instead of requiring an ambient temperature of 7.2 °C (45 °F) for egg-containing refrigerators at retail, FDA could require an ambient temperature of 5 °C (41 °F), the internal temperature for potentially hazardous foods in the 1999 Food Code. Although current studies show *Salmonella* growth at ambient temperatures under 50 °F is significantly slowed, the advantage of a lower standard is that eggs will cool down slightly faster. FDA could require those establishments to reduce ambient temperatures to 5 °C (41 °F), with a 5-year compliance period. FDA estimated the present value of the total cost of reaching 5 °C (41 °F) in 5 years to be $65 million.[2] Because eggs cool down only slightly faster at 5 °C (41 °F)than at 7.2 °C (45 °F), the lower temperature would not generate additional benefits.

5. Implement a HACCP-Style System for Shell Eggs

The agency could require that a Hazard Analysis and Critical Control Point (HACCP) system be implemented at any or all levels of the shell egg production and distribution chain. In order to match the coverage of the proposed rule, the HACCP-style rule would have to be limited to the same set of establishments covered by the safe handling label. The advantage of a full farm-to-table HACCP is that it could eliminate, reduce, or control SE and other hazards at the source and keep them out throughout the egg processing chain. The disadvantage is that the technological knowledge needed to identify the critical control points and remedial steps to eliminate SE from shell eggs is incomplete. FDA believes that a HACCP-like program, possibly including in-shell pasteurization, is currently not feasible. However, FDA is evaluating whether a HACCP-like program in the future may be necessary to further ensure the safety of eggs.

6. In-Shell Pasteurization

The agency could require that all eggs be pasteurized. Pasteurization of shell eggs should practically eliminate SE. The time and temperatures required to pasteurize shell eggs, however, are close to the combination that will cook the eggs. Successful in-shell pasteurization on a large scale is therefore likely to be quite costly. Currently, pasteurized shell eggs sell for approximately $0.30 more per dozen than regular shell eggs (Ref. 1). Assuming that average cost remained constant with the increased output, to pasteurize all 47 billion shell eggs sold each year (around 4 billion dozen) would cost approximately $1.2 billion per year. In addition to the annual costs, the changeover to pasteurization would require large capital costs. Another potential disadvantage is that pasteurization might lead some consumers to erroneously believe that other safety measures, such as refrigeration and avoiding cross-contamination, might no longer be necessary. Because pasteurization eliminates competing microorganisms, recontamination after pasteurization might lead to rapid growth of SE. Finally, FDA believes that other interventions between farm and table could reduce the risk at lower cost.

7. Longer Compliance Periods

FDA is giving firms 180 days to meet the labeling and refrigeration provisions of this proposed rule. Lengthening the compliance period for labeling to 18 months would reduce labeling costs by allowing some of the changes to be incorporated into planned label changes. Total labeling costs, as shown in Table 14 of this document, fall from $18 million to $7 million if the compliance period is extended to 18 months. Total refrigeration costs fall by about $2 million, which is the difference (at a 7 percent discount rate) in the capital costs of refrigeration in 6 months and refrigeration in 18 months. The total cost savings from extending the compliance period to 18 months, then, are approximately $13 million. One disadvantage would be that a longer compliance period would delay the realization of the public health benefits of the proposed rule. Those benefits substantially exceed $13 million per year. As shown in Table 9 of this document, estimated median annual benefits are $300 million for the CDC surveillance baseline and $700 million for the SE risk assessment baseline.

8. Limit the ''Sell By'' Period

The agency could introduce a ''sell by'' date. Limiting the ''sell by'' period, which is the time within which retailers must sell shell eggs, would limit the SE growth period, thereby reducing the potential dose of SE when it is already in the egg. The disadvantage of this option is that it could not take the place of the proposed refrigeration or labeling provisions. Introducing a ''sell by'' provision without the proposed refrigeration provision would not necessarily prevent the growth of SE in the egg. Moreover, introducing the shortened ''sell by'' provision without the labeling provision would not inform consumers that they should still refrigerate and cook eggs thoroughly. Proper refrigeration is important because it will prevent the rapid growth of SE beyond the ''sell by'' date. The benefit of a ''sell by'' provision is it

[1] The two baselines are explained in section I.E.1 of this document.

[2] FDA estimated that 236,500 retail establishments hold eggs at ambient temperatures greater than 5 °C (41 °F). FDA assumed that the mean and median additional cost per establishment of moving to 5 °C to be $3,500 in current dollars. FDA also assumed that establishments would have 5 years beyond the 7.2 °C compliance period to reach 5 °C, that refrigerators last 20 years, and that additional costs would be zero for those establishments already planning to replace refrigerators within 5 years. The $65 million therefore represents the discounted (at 7 percent) additional costs of refrigeration from 5 to 20 years after the labeling and the 7.2 °C provisions would take effect.

would reduce the likelihood of membrane breakdown and shorten the time for growth should breakdown occur. FDA estimated the benefits from a limited ''sell by'' period by calculating the reduction in average retail storage time if all eggs were sold within 30 days (the USDA period used for pull dating). The benefits of a limited retail storage time are $1.3 million for the USDA SE risk assessment baseline and $600,000 for the CDC surveillance baseline.

The limited shelf life would impose the additional cost of reducing the egg supply, which raises the price of eggs to consumers. If limiting the shelf life were to reduce the egg supply by 5 percent, the additional cost would be approximately $150 million. If limiting the shelf life were to reduce the egg supply by 15 percent, the additional cost would be approximately $450 million.

Other options could reduce the storage time of eggs. A ''use by'' date on the label might lead more people to consume eggs before membrane breakdown occurs. If the storage time in retail establishments, institutions, and homes is reduced by 1 percent, the USDA SE risk assessment model generates about a 0.5 percent decrease in the number of illnesses.

D. Coverage

1. Establishments

Table 1 of this document lists the establishments covered by the proposed rule. FDA expects that the initial costs of labeling will fall on egg processors, until ultimately the costs are passed on to consumers. Refrigeration will affect the entire retail sector, including noncommercial establishments.

TABLE 1.—COVERAGE BY ESTABLISHMENT

Establishment	Affected by Safe Handling Labeling	Affected by Refrigeration at 7.2 °C (45 °F)
Grocery stores	No	Yes
Restaurants	No	Yes
Health food stores	No	Yes
Roadside stands	Yes	Yes
Convenience stores	No	Yes
Prisons	No	Yes
Nursing homes	No	Yes
Schools	No	Yes
Hospitals	No	Yes
Military	No	Yes
Shell egg packers	Yes	No
Transportation	No	No
Farm	No	No

2. Products

Table 2 of this document lists the products covered by the two provisions of the proposed rule.

TABLE 2.—COVERAGE BY PRODUCT

Product	Affected by Safe Handling Labeling	Affected by Refrigeration at 7.2 °C (45 °F)
Shell eggs in cartons	Yes	Yes
Bulk shell eggs in cases	Yes	Yes
Egg products[1]	No	No[1]

[1] Egg products include pasteurized egg products and other eggs treated to remove pathogens. The USDA regulates these products.

E. Benefits

The benefits of the proposal come from reducing the incidence of SE-related illness. FDA will estimate health benefits with the following model of marginal benefits (MB):

$$MB = R \times M \times V$$

where:

R = the baseline risk. In this case, the baseline risk is the estimate of the annual incidence of SE-related illnesses associated with shell egg consumption, proportionally broken down by severity of health effects.

M = the expected marginal reduction in the number of SE-related illnesses attributable to the two provisions of the proposed rule.

V = the cost per type of SE-related illness, including personal utility losses (pain and suffering, productivity) and direct medical expenditures.

The refrigeration and labeling provisions will reduce but not eliminate the consumption of contaminated shell eggs. Requiring refrigeration at all retail outlets and requiring labeling that states that the product should be kept refrigerated, however, should decrease the number of eggs that suffer temperature abuse in retail establishments and in homes. The labeling rule will also generate health benefits by reducing the consumption of raw or undercooked eggs.

In order to estimate the reduction in cases of SE-related illnesses likely to be brought about by the proposed rule, FDA relied mainly on the USDA's *Salmonella Enteritidis* Risk Assessment (Ref. 2). Indeed, FDA could not have carried out the following assessment of benefits without the USDA SE risk assessment. FDA slightly modified the risk assessment in light of data that have become available since the completion of the final version of the model, but the analysis closely followed that of the USDA SE risk assessment team. FDA estimated the benefits of its proposed rule by combining the USDA SE risk assessment's estimated reductions in illnesses with FDA's estimates of the health cost per illness.

1. The Shell Eggs and Egg Products Risk Assessment Model

The USDA's *Salmonella Enteritidis* Risk Assessment uses a farm-to-table model of the production and consumption of eggs. The model consists of five parts: (1) Egg

production, (2) shell egg processing and distribution, (3) egg products processing and distribution, (4) food preparation and consumption, and (5) public health outcomes.

Because the proposed rule will not affect the number of shell eggs contaminated with SE, FDA did not directly use the first three parts of the model. FDA estimated the effects of the proposed rule by introducing the provisions of the proposed rule into the preparation and consumption part of the model and then calculating the changes in public health outcomes.

The presence of SE in the raw egg is not sufficient to ensure that people will become ill from eating contaminated eggs. If the eggs are continuously refrigerated from the time they leave the processor up until the time they are cooked, and if they are thoroughly cooked, then the risk assessment model predicts that the SE will not multiply before cooking and cooking will eliminate the surviving pathogens. The large number of outbreaks and sporadic cases identified—and the larger number thought to occur—suggest that the conditions for pathogen kill-off are not being met. In 1996, the CDC's surveillance found 9,566 confirmed SE isolates, or 25 percent of the 39,000 confirmed cases of salmonellosis (Ref. 3). In 1997, the CDC's surveillance found 7,924 confirmed SE isolates, or 23 percent of the 34,608 confirmed cases of salmonellosis (Ref. 3). From 1988 through 1992, SE accounted for more than 40 percent of all bacterial foodborne outbreaks with known etiology and about 33 percent of all outbreaks with known etiology (Ref. 4).

The two requirements of this proposed rule form part of a farm-to-table approach to shell egg safety. These requirements address the table end of the hazard. Although they will lead to lower pathogen counts, reduced pathogen strength, and reduced pathogen consumption, they will not eliminate SE in shell eggs.

The baseline for the cases of salmonellosis prevented is the number of illnesses attributable to shell eggs before the proposed rule. The USDA SE risk assessment estimated the number of illnesses with a full farm-to-table model. The first stage of the model estimated the number of infected eggs laid with a simulation that incorporated the estimates of the number of infected flocks and the likelihood of frequency of infected eggs in an infected flock. The next stage of the model took the estimated number of infected raw shell eggs and estimated the number of infected eggs likely to be consumed. The model followed the eggs through possible paths from the farm to the table. Depending on how processors, transporters, and cooks treated the infected eggs, the SE could be killed, remain stagnant, multiply, or (if pooled) spread to other eggs. The last stages of the model used a dose-response function to estimate the number and severity of illnesses caused by SE in shell eggs. All stages of the model used computer simulations to generate ranges and distributions rather than point estimates. FDA generated a modified USDA SE risk assessment baseline by substituting more recent data on the proportion of establishments not refrigerating shell eggs at 7.2 °C (45 °F).

The CDC surveillance baseline estimated the distribution of illnesses based on the number of confirmed cases as indicated by SE isolates reported to CDC. The CDC surveillance baseline estimated the number of illnesses as actual reported cases plus estimated unreported cases.

Table 3 of this document shows the results of three Monte Carlo simulations for the baseline estimates of SE-related illnesses caused by shell eggs. All simulations used the Microsoft Excel version of the Palisade@Risk® quantitative risk assessment software. The first simulation, shown in part a of Table 3 of this document, is the baseline result of the SE risk assessment team model. The second simulation is the baseline model with 95 percent rather than 90 percent probability that shell eggs are refrigerated at 7.2 °C (45 °F) in retail establishments and institutions. FDA modified the original model because the agency had more recent information (see the next paragraphs) on the number of establishments not refrigerating shell eggs at 7.2 °C (45 °F). Part b of Table 3 of this document presents the results of the simulation based on the more recent information.

Part c of Table 3 of this document presents the third baseline estimation, which is the result of estimating the number of cases directly from CDC *Salmonella* surveillance data. FDA used the same procedure as the USDA SE risk assessment team to estimate the number of SE cases from surveillance data. The data collected by the CDC *Salmonella* surveillance project show that from 1988 through 1997 the number of SE isolates ranged from a low of 6,578 in 1992 to a high of 10,201 in 1995, with about 8,400 per year on average. The USDA SE risk assessment estimated the probability that an isolate would be reported to be 0.01431. With 8,400 isolates reported and a probability of reporting equal to 0.01434, FDA simulated a distribution for all SE illnesses, including those caused by foods other than shell eggs (not shown in Table 3 of this document).[3] The USDA SE risk assessment assumed that shell eggs accounted for 20 to 100 percent of all illnesses from SE. FDA assumed that shell eggs accounted for approximately 10 to 60 percent of all illnesses from SE.[4] The assumption that 10 to 60 percent of all SE illnesses came from the consumption of shell eggs, combined with the estimated number of illnesses, generated the estimates shown in part c of Table 3 of this document.

All three baselines in Table 3 of this document are estimates of the current incidence of SE from shell eggs. FDA estimated the health benefits of the proposed rule based on the baselines in parts b and c of Table 3 of this document. The baselines, however, could change before the proposed rule takes effect. Other Federal or State regulations, consumer education, and voluntary SE eradication by farms or processors could reduce the baseline number of SE illnesses. If such a reduction were to occur before or at the same time as the proposed rule took effect, then FDA would be using a baseline that was too high and, therefore, would over-estimate health benefits from the proposed rule. FDA recognizes the potential bias, but believes that changes in the baseline number of illnesses are likely to be small or negligible before the proposed rule takes effect.

---

[3] FDA simulated the number of SE illnesses not reported with a negative binomial distribution. The simulation calculated the total number of illnesses (reported and not reported) as: Number reported + Negative binomial (number reported + 1, frequency of reporting) = 8,400 + NEGATIVE BINOMIAL (8,401, 0.01434).

[4] According to the results of outbreak analyses for the years 1988 through 1992, eggs were the food vehicle in 64 percent of the SE outbreaks for which the food vehicle could be identified (Ref. 4). Therefore, FDA assumed that 60 percent represented the maximum fraction of cases attributable to eggs. More than half of the SE outbreaks, however, did not have a known food vehicle. If outbreaks with unknown vehicles are added to the total, then eggs accounted for only 29 percent of all SE outbreaks (including outbreaks with known and unknown vehicle) from 1988 through 1992. Furthermore, the causes of outbreaks may not be the same as the causes of sporadic cases. FDA believes that shell eggs may be less important cause of sporadic SE cases than of SE outbreaks. Many outbreaks have been linked to the pooling of large numbers of eggs in nursing homes and other institutional settings. Because pooling eggs would have little effect on the probability of a sporadic case occurring, eggs are not likely to account for as large a proportion of sporadic cases as of outbreaks. FDA believes it plausible that eggs account for only one-third as high a fraction of all SE cases as of outbreaks. For a lower bound on the fraction of cases caused by eggs, FDA multiplied the fraction of all outbreaks caused by eggs (29 percent) by the relationship between the egg fraction of all cases and the egg fraction of outbreaks (one-third). Therefore, FDA estimated that 10 percent represented the minimum fraction of SE cases attributable to eggs.

TABLE 3.—THREE BASELINE ESTIMATES OF SE FROM SHELL EGGS

	5th percentile	Median	Mean	95th percentile
a. *USDA SE Risk Assessment*				
Illnesses	126,374	504,082	661,633	1,742,592
Arthritis	3,631	14,864	19,994	55,915
Deaths	68	301	391	1,050
b. *USDA SE Risk Assessment as Modified by FDA*				
Illnesses	115,645	416,156	569,231	1,508,814
Arthritis	3,372	12,548	17,175	48,594
Deaths	66	250	354	985
c. *CDC Surveillance Model*				
Illnesses	63,884	189,599	191,511	319,275
Arthritis	1,330	5,533	5,727	12,202
Deaths	37	122	115	197

2. Cases of Salmonellosis Prevented

FDA cannot precisely estimate the number of cases likely to be prevented by the proposed rule; therefore, the agency used a range of cases prevented to estimate the benefits of the proposed rules. For the refrigeration provision, FDA used the USDA SE risk assessment model (as modified by FDA) to determine the effects of eliminating virtually all temperature abuse in retail and institutional establishments. In the simulation of the model, the number of illnesses fell as the proportion of establishments assumed to be holding eggs at 7.2 °C (45 °F) or less increased from 95 percent to virtually 100 percent.

FDA used a study of changes in consumer behavior as a result of the USDA safe handling label for meat to estimate the effects of the safe handling label for shell eggs. The Food Marketing Institute (Ref. 5) found that 59 percent of shoppers were aware of the USDA safe handling labels for meat. Of those aware of the labels, 43 percent changed their behavior as a result of the labels. Of those who changed their behavior, the changes ranged from 1 percent (use of antibacteria soap to wash hands) to 41 percent (washing or disinfecting counters, cooking areas, and utensils after contact with meat). The behavioral changes most similar to what the proposed rules aim to bring about for shell eggs were the 19 percent increase in proper cooking of meats and the 7 percent increase in proper refrigeration. If the meat cooking and refrigeration results indicate the likely effects of the proposed label for eggs, then the likelihood that shell eggs will be undercooked or consumed raw will decline by approximately 5 percent (= 59 percent x 43 percent x 19 percent) and the likelihood that consumers will fail to properly refrigerate eggs will decline by approximately 2 percent (= 59 percent x 43 percent x 7 percent).[5]

The USDA SE risk assessment model treats proper cooking as a kill step for SE. Whatever the baseline, if undercooking falls by 5 percent, so will the number of illnesses, all else the same. The effects of retail refrigeration come early in the life of the egg. The effects of the safe-handling label come later in the life of the egg than refrigeration, so the effects of proper cooking in reducing illnesses will be net of the effects of refrigeration. Safe cooking will reduce the number of illnesses remaining—after the effect of refrigeration—by 5 percent.

In separate simulations, FDA used the USDA SE risk assessment model to estimate the effects of the labeling provision, the refrigeration provision, and the proposed rule combining the provisions. In another simulation, FDA estimated the effects of including a ''sell by'' date on the label or some equivalent policy to reduce retail storage time. If the ''sell by'' date were 30 days after receiving the eggs, the average retail storage time would be reduced by 6 percent (Ref. 2).[6] FDA used 6 percent as the potential shortening of average retail storage time. FDA did not include shortened storage time in the simulations that estimated the effects of the proposed rule.

FDA estimated policy effects for both the modified SE risk assessment and the surveillance baselines. FDA first simulated the possible regulatory approaches in the modified USDA SE risk assessment model. The simulations generated distributions of the number of illnesses prevented by those approaches. The results are shown in part a of Table 9 and part a of Table 10 of this document. The CDC surveillance baseline began with the final result—a distribution of the number and severity of illnesses. No farm-to-table steps entered the model. The CDC surveillance model could not estimate how the illnesses occurred; the model only produced an estimate of the number of illnesses. Because the CDC surveillance baseline was not an outcome of a model, FDA could not directly estimate effects with the surveillance baseline. Instead, FDA assumed that the policy effects would be proportionally the same for both the CDC surveillance and the USDA SE risk assessment baselines. The estimated effects of the proposed rule on the surveillance baseline, then, equaled the percentage effects from the SE risk assessment applied to the CDC baseline.[7] The results are shown in part

[5] The sample size was 1,007. The reduction in undercooked eggs likely to be brought about by safe handling instructions rested on several assumptions. The most important assumptions were that: (1) The 5 percent reduction in unsafe cooking practices and the 2 percent reduction in unsafe refrigeration practices implied by the survey results for the USDA meat handling labels accurately reflected people's practices in their home, (2) the results for home food handlers would hold for restaurant food handlers, (3) the results for the meat label would hold for egg labels, (4) the change in behavior would extend to raw eggs as well as undercooked eggs, and (5) the sample of 1,007 consumers was reasonably representative (Ref. 5). The greatest uncertainty in extrapolating from the meat handling results is in assuming that the effects will hold for those products that contain raw eggs. Cookie dough, cake and brownie batter, egg nog, and other homemade products are major sources of the consumption of raw eggs, but the desire to consume them also appears to be deeply ingrained among consumers.

[6] In the risk assessment, retail storage time for eggs is a truncated exponential distribution, with the unconstrained (that is, nontruncated) expected storage time equal to 7 days, minimum storage equal to 0, and maximum equal to 60. If the maximum is changed to 30, mean storage time falls by 6 percent.

[7] Comparing the illnesses prevented in Tables 9 and 10 of this document with the appropriate baseline in Table 3 of this document can

Continued

b of Table 9 and part b of Table 10 of this document.

3. Health Benefits From Preventing Salmonellosis

The health benefits associated with preventing salmonellosis are: (1) Lessening the loss of productivity, (2) the reduction in pain and suffering, and (3) the reduced expenditures on medical treatment. In order to quantify the losses suffered by victims of salmonellosis, it is first necessary to develop an index to measure the losses associated with pain, suffering, mobility, and other problems associated with becoming ill. FDA estimated the utility losses caused by pain and suffering with a symptom-problem health utility index. Lost productivity was indirectly estimated by measures of body movement, physical location, and functional state. FDA estimated medical costs directly. The symptoms of salmonellosis vary by serotype and the immune status of the victim. Diarrhea, nausea, vomiting, fever, and headache lasting from 1 day to 1 week or more characterize a typical case of salmonellosis. Mild cases last 1 to 3 days, moderate cases last 2 to 12 days, and severe cases last 11 to 21 days (Ref. 6). Some acute cases are followed by post-*Salmonella* reactive arthritis, with symptoms that include pain and possible functional disability (Ref. 7, 31, and 32). Moreover, some acute cases lead to death, especially among elderly victims.

Tables 4 through 7 of this document contain descriptions of the health effects associated with salmonellosis. Table 4 of this document lists the codes associated with salmonellosis of varying levels of severity. Tables 5 and 6 of this document explain the codes.

TABLE 4.—HEALTH EFFECTS AND SYMPTOMS OF ILLNESSES ASSOCIATED WITH SALMONELLOSIS

Severity	Functional Status	Symptom-Problem Complex Code
Mild	MOB(4) + PAC(3) + SAC(3)	9
Moderate	MOB(4) + PAC(3) + SAC(3)	9
Severe—acute	MOB(2) + PAC(1) + SAC(1)	9
Reactive arthritis, resolved in 4 months	MOB(5) + PAC(3) + SAC(3 and 4)	7
Reactive arthritis—chronic, intermittent, waxing and waning, or unremitting	MOB(5) + PAC(3) + SAC(3 and 4)	7

Table 5.—DESCRIPTION OF FUNCTIONAL STATUS CODES (USED TO MEASURE PRODUCTIVITY LOSS)

Function Status Code	Scale	Weight or Utility Loss
Mobility (MOB)		
5	No limitations	0.000
4	Did not drive car; other limitations	0.062
2	In hospital	0.090
Physical Activity (PAC)		
4	No limitations	0.000
3	Walked with physical limitations	0.060
1	In bed or wheelchair	0.077
Social Activity (SAC)		
5	No limitations	0.000
4	Limited in other activities	0.061
3	Limited in primary activity	0.061
2	Performed self-care	0.061
1	Help with self-care	0.106

TABLE 6.—DESCRIPTION OF SYMPTOM-PROBLEM COMPLEX CODES (USED TO MEASURE LOSS FROM PAIN AND SUFFERING)

Symptom-Problem Complex	Description	Utility Weight
9	Sick or upset stomach, vomiting, or diarrhea (watery bowel movements)	0.290
7	Pain, stiffness, numbness, or discomfort of neck, hands, feet, arms, legs, ankles, or several joints together	0.299

FDA estimated the health loss per day for the different levels of illness severity by summing the lost productivity (as measured by functional status) and the loss from pain and suffering (as measured by the symptom-problem index). These losses per day can be interpreted as the difference between 1 day of perfect health and 1 day of suffering the productivity loss and pain and suffering associated with one of the health conditions. The numerical scale is based on the notion of a quality-adjusted life day. The quality-adjusted life day for a day of perfect health equals 1; the quality-adjusted life day for death equals 0. For illnesses, the quality-adjusted life day falls between 0 and 1. A day spent suffering a mild case of salmonellosis has a quality-adjusted life day equal to 0.527 (= 1 – 0.473).

The loss of utility per illness equals the daily loss multiplied by the duration of the illness. For example, mild salmonellosis lasts 1 to 3 days. The total utility losses for a mild case lasting 2 days equal 2 x 0.473 = 0.946, or about 1 quality-adjusted life day. The resolved cases of post-*Salmonella* reactive arthritis may last 1 day to 4 months (Ref. 7). FDA assumed that chronic cases of reactive arthritis last for the rest of the victim's life. FDA used a distribution for the age of onset for salmonellosis, based on FoodNet results for 1996 and 1997 (Ref. 8). FDA also used a distribution for the age of onset for reactive arthritis. FDA combined the two distributions to generate a single distribution for the

approximate the percentage effects. FDA also independently estimated the proportional effects of the proposed rule. In that simulation, the mean fraction of baseline illnesses prevented was 19 percent, the median was 15 percent, the 5th percentile was 6 percent, and the 95th percentile was 49 percent.

length of time that post-*Salmonella* reactive arthritis would be expected to last.

TABLE 7.—UTILITY LOSSES FROM SALMONELLOSIS

Severity	Functional Utility per Day	Symptom-Problem Utility Weight per Day	Total Utility Loss per Day	Duration (days per year)	Utility Losses per Case per Year	Medical Costs per Case per Year
Mild	0.183	0.290	0.473	1 to 3	0.473 to 1.419	0
Moderate	0.183	0.290	0.473	2 to 12	0.946 to 5.676	$800
Severe—acute	0.273	0.290	0.563	11 to 21	6.193 to 11.823	$9,100
Reactive arthritis—resolved	0.121	0.299	0 to 0.42	1 to 121	0 to 50.4	$100
Reactive arthritis—chronic	0.121	0.299	0 to 0.42	365	0 to 153.3	$400

FDA assumed that the most likely value of a quality-adjusted life day was $630, a value derived from the statistical estimate of the benefit for a small reduction in the probability of death, commonly called the value of a statistical life. If the value of a statistical life is $5 million, and the average discounted number of life years (in the studies that generated this estimate) lost is 21.8, then the value of a single quality-adjusted life day is ($5 million ÷ 21.8) ÷ 365 = $630.[8] The value of utility losses for nonfatal cases of acute salmonellosis would therefore equal the losses of quality-adjusted life days multiplied by $630.

The value of a quality-adjusted life day is highly uncertain. Therefore, FDA used a distribution, not a point estimate, to value the utility losses from salmonellosis. FDA based the distribution on a most likely value, a minimum, and a maximum. The most likely value, as shown previously, was $630. FDA based the minimum value of a quality-adjusted life day on the average daily gross domestic product per person, which was approximately $80 per day in 1997 (($8 trillion ÷ 268 million) ÷ 365) (Ref. 9). FDA believes that the gross domestic product per person understates willingness to pay, because most studies of the value of a statistical life indicate that people are willing to pay more than their average earnings to avoid all of the costs associated with illnesses. FDA used gross domestic product per person as a strict lower bound, because it is not plausible that people on average would be willing to pay less than the value of output per person. FDA based the maximum value of a quality-adjusted life day on the literature on the value of a statistical life. In a survey of the literature on the value of a statistical life, the most plausible upper-bound estimate was approximately $8.4 million in 1997 prices (Ref. 10). The upper-bound value of a quality-adjusted life day would, therefore, be about $1,000 (($8.4 million ÷ 21.8) ÷ 365).

In addition to utility losses (lost productivity, pain, and suffering), salmonellosis leads to direct medical expenditures. The medical costs of acute salmonellosis vary from nothing for a mild case to more than $9,000 for severe cases (Ref. 11). The medical costs for chronic cases vary from $100 for resolved cases to $400 per year for long-lasting cases (Ref. 12).

The total health costs per case are the sum of utility losses (which include productivity and pain and suffering) and medical expenditures. The total costs of SE illnesses would be the costs per case of each severity multiplied by the number of illnesses of each severity. For chronic illnesses that are not resolved, the utility losses and medical costs stretch indefinitely into the future. FDA calculated the present value of chronic medical expenditures and utility losses with a discount rate of 7 percent. For example, medical costs for reactive arthritis of $400 per year take a present value of $5,400 for cases that last 44 years. The annual costs of reactive arthritis are the net present value of the costs of new cases.

FDA based the distribution of cases by severity on the FoodNet results for diarrheal illness, which indicate that 92 percent of victims do not seek medical attention (Ref. 8). The FoodNet population survey could not determine the causes of diarrhea for people who did not seek treatment. *Salmonella* accounts for a large portion of isolates of the people who do seek medical treatment for diarrhea and is therefore assumed to account for a large portion of all diarrheal illness. FoodNet used the fraction of all victims who seek medical attention Consistent with the FoodNet approach, FDA assumed that 92 percent of victims of salmonellosis do not seek medical treatement. FDA assumed that these cases were mild. Also, the agency assumed that 15 percent of those who sought medical attention for SE would be hospitalized (Ref. 8).[9] Of those who were hospitalized, about 5 percent would die. The case-fatality rate simulated by the model equaled the probability of hospitalization multiplied by the conditional probability of death given hospitalization. In most simulations it was around 0.05 to 0.06 percent.[10] The proportion of acute cases that lead to post-salmonellosis reactive arthritis has been estimated at 2 to 3 percent (Ref. 13) and 6.4 percent (Ref. 7). The USDA SE risk assessment used a 2 to 4 percent range, with the mean equal to 3 percent. FDA used the same mean, but with a 0 to 6 percent range, reflecting the continued wide uncertainty associated with reactive arthritis after acute

[8] FDA calculated the discounted life expectancy based on 36 years lost, which was approximately the loss in the injury studies used to estimate the value of a statistical life. The workers were around 40 years old. The rate of time preference used to discount the years if life lost was 3 percent, often identified as the pure rate of time preference. If 36 years are continuously discounted at 3 percent per year, the result is 21.8 years.

[9] FDA revised the USDA SE risk assessment's distribution of illnesses by severity in light of FoodNet results (Ref. 8). The FoodNet results were not available at the time the risk assessment was carried out. The revisions to the USDA SE risk assessment, however, were small. FDA used 92 percent as the fraction of illnesses that are mild, compared with 94 percent in the USDA SE risk assessment. The USDA SE risk assessment assumed that 10 percent were hospitalized. FoodNet found that 15 percent of all persons with foodborne pathogens (and sought medical care) were hospitalized. Because the FoodNet data were more recent, FDA assumed that 15 percent of those who consulted physicians for SE illness were subsequently hospitalized.

[10] Many sources (Ref. 13) state that about 0.1 percent of cases of salmonellosis lead to death. The SE risk assessment, however, generated lower case-fatality rates for SE. Because the result was specific to SE, FDA used the lower estimate generated by the SE risk assessment. FoodNet has not generated enough cases to compute a meaningful case-fatality rate for SE illnesses.

salmonellosis. FDA estimated the distribution of cases by severity for reactive arthritis based on an outbreak study (Ref. 7). The lost quality-adjusted life days for post *Salmonella* reactive arthritis are also uncertain. With only one study of severity, FDA did not have sufficient information to justify a point estimate; therefore, the agency used a range of 0 to 0.42 for the daily loss of quality-adjusted life days.

Most of the deaths attributed to SE are elderly persons. Of the 27 deaths linked to foodborne SE disease outbreaks from 1988 through 1992, 23 fatalities (85 percent) occurred in nursing homes (Ref. 4). To estimate benefits from preventing deaths, FDA assumed that the probability that the victim was age 75 or older was 80 percent. The loss of quality-adjusted life years is much less for victims age 75 and older than for victims from rest of the population. The use of the same value for the benefits of preventing fatalities among the general population and preventing fatalities among those age 75 and older (especially the nursing home population) would therefore not be appropriate. FDA assumed that the average loss of discounted quality-adjusted life years would be about 6 for victims age 75 and older and about 26 for other victims.[11]

4. Total Health Benefits

FDA estimated the effects of the proposed rule by combining the distribution of effects on the number of illnesses with the distribution of monetary values associated with the illnesses prevented. The calculations involved two steps. In the first step FDA used the USDA SE risk assessment model to estimate the number of illnesses prevented. In the second step, FDA estimated the health benefits associated with preventing those illnesses. The uncertainties associated with several important parts of the formula led FDA to use Monte Carlo computer simulations to estimate the total health benefits of the proposed rule.[12]

In the Monte Carlo simulation, the computer repeatedly calculated health benefits based on the following formula:

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 prevented x $ per death)

Instead of calculating the total health benefits once, based on single estimates for each value in the formula, the simulation calculated the health benefits over and over again. Each calculation (or iteration) used different values, with the values drawn from probability distributions. The probability distributions used in the simulation are shown in Table 8 of this document.[13]

TABLE 8.—DISTRIBUTIONS USED TO ESTIMATE THE MONETARY VALUE OF CASES OF SALMONELLOSIS PREVENTED

Variable	Distribution	Source
Number of illnesses prevented	Cumulative	Ref. 2
Number of mild illnesses	Binomial (number of illnesses, 0.92)	Ref. 8
Number of moderate illnesses	Binomial (number at least moderate, 0.85)	Ref. 8
Number of severe, acute illnesses	Binomial (number at least severe, 0.95)	Ref. 2
Number of deaths	Residual	Ref. 2
Value of a quality-adjusted life day ($)	Beta-Pert (80, 630, 1,000)	See text
Fraction of illnesses resulting in reactive arthritis	Beta-Pert (0, 0.03, 0.06)	See text
Fraction of reactive arthritis cases resolved	Beta (10, 19)	Ref. 7
Quality-adjusted life day lost per day of reactive arthritis	Uniform (0, 0.42)	Ref. 15
Duration of mild illnesses	Uniform (1,3)	Ref. 6
Duration of moderate illnesses	Uniform (2, 12)	Ref. 6
Duration of severe illnesses	Uniform (11, 21)	Ref. 6
Duration of resolved reactive arthritis	General (1, 121; uniform (2,7), uniform (8,28), uniform (29,120); 0.2222, 0.6666, 0.1111)	Ref. 7
Duration of chronic reactive arthritis	Normal (35, 3.5)	Refs. 8 and 16
Distribution of deaths between elderly and general population of deaths that are old people	Binomial (number of deaths, 0.8)	Ref. 4
Discounted years of life lost per death of elderly victims	6.2	See text
Discounted years of life lost per death of other victims	26.4	See text

Each simulation calculated health benefits 1,000 times. FDA simulated the

[11] FDA divided victims into 2 age groups, those age 75 and over and all others. FDA then assumed that within the 2 categories of those age 75 and over and all other, the age of vitims of fatal SE illnesses was the same as the age of victims of all cases of salmonellosis in the 1996 through 1997 FoodNet data base. The average age of salmonellosis victims under age 75 was about 24, for an estimated average years of life lost of 53. If 53 years of life lost are discounted at 3 percent per year, the result is 26 discounted years lost. The average age of salmonellosis victims age 75 and over was about 82, for an estimated average years of life lost of 7. The discounted years of life lost (at 3 percent per year) is 6.

[12] The simulations all used Latin Hypercube sampling, which first sorts the samples in stratified groups and then samples equally from each group. The one-stage simulations contained 1,000 iterations. The two-stage simulations used 50 uncertainty iterations, then 50 simulations of 500 iterations each.

[13] The agency selected distributions based on the underlying data or common assumptions about the variables being modeled. The main innovations were the use of Beta and Beta-Pert distributions. The Beta distribution is part of the Bernoulli family of distributions and is closely related to the Binomial. The Binomial gives the distribution of the number of successes (s) in n trials if the probability of success in each trial is p. The Beta shows the distribution of the value of p when s successes occur in n trials. The Beta-Pert distribution is a Beta distribution that has been rescaled to run between values other than 0 and 1. The Beta-Pert uses a minimum, maximum, and most likely value to generate a distribution running from the minimum to the maximum, with a mean equal to (minimum + (4 x most likely) + maximum) ÷ 6. In contrast to the Triangular, which has a mean of (minimum + most likely + maximum) ÷ 3, the Beta-Pert is less sensitive to extreme values and generates more outcomes close to the mean. For those reason, the agency used the Beta-Pert rather than the triangular when only the minimum, most likely, and maximum values were given. For discussions of the nature and use of these distributions in Monte Carlo simulation see Ref. 14.

effects of the proposed rule, the separate effects of the refrigeration and labeling components of the proposed rule, and the effects of a decline in retail storage time. Tables 9 and 10 of this document present the 5th percentile, mean, median, and 95th percentile simulated health benefits.

TABLE 9.—TOTAL ANNUAL HEALTH BENEFITS FROM THE REDUCTION IN SALMONELLOSIS ATTRIBUTABLE TO THE PROPOSED SHELL EGG RULES: USDA *Salmonella* ENTERITIDIS RISK ASSESSMENT BASELINE AND CDC SURVEILLANCE BASELINE

Variable	5th Percentile	Median	Mean	95th Percentile
a. Modified USDA SE Risk Assessment Baseline				
Illnesses prevented	12,369	65,801	115,848	407,064
Mild	11,391	60,479	106,580	374,192
Moderate	831	4,484	7,878	27,900
Severe	142	747	1,321	4,685
Arthritis—resolved	147	588	1,171	4,453
Arthritis—chronic	468	1,146	2,313	8,317
Death	6	39	69	246
Health benefits	$86.7 million	$703 million	$1,700 million	$6,610 million
b. *CDC Surveillance Baseline*				
Illnesses prevented	7,032	25,132	36,937	107,230
Mild	6,476	23,092	33,982	98,607
Moderate	475	1,691	2,511	7,286
Severe	80	284	421	1,235
Arthritis—resolved	47	240	382	1,182
Arthritis—chronic	95	488	714	2,073
Death	3	16	22	66
Health benefits	$49.2 million	$303 million	$501 million	$1,679 million

TABLE 10.—TOTAL ANNUAL HEALTH BENEFITS FROM THE REDUCTION IN SALMONELLOSIS ATTRIBUTABLE TO THE VARIOUS REGULATORY APPROACHES: USDA *Salmonella* ENTERITIDIS RISK ASSESSMENT BASELINE AND CDC SURVEILLANCE BASELINE

Variable	5th Percentile	Median	Mean	95th Percentile
Reduced Retail Storage Time				
a. Modified USDA SE Risk Assessment Baseline				
Illnesses prevented	0	162	3,000	13,908
Health benefits (millions)	0	$1.3	$29.8	$169
b. CDC Surveillance Baseline				
Illnesses prevented	0	88	997	4,998
Health benefits (millions)	0	$0.6	$2.1	$71.2
Refrigeration to 7.2 °C (45 °F) Only				
a. Modified SE Risk Assessment Baseline				
Illnesses prevented	997	34,791	86,512	340,387
Health benefits (millions)	$9.6	$387	$1,260	$5,500
b. CDC Surveillance Baseline				
Illnesses prevented	548	15,812	27,447	94,317
Health benefits (millions)	$3.2	$163	$372	$1,476
Labeling only				
a. Modified SE Risk Assessment Baseline				
Illnesses prevented	6,500	23,097	32,191	84,147
Health benefits (millions)	$43.8	$261	$444	$1,460
b. CDC Surveillance Baseline				
Illnesses prevented	3,339	10,008	10,531	17,672

TABLE 10.—TOTAL ANNUAL HEALTH BENEFITS FROM THE REDUCTION IN SALMONELLOSIS ATTRIBUTABLE TO THE VARIOUS REGULATORY APPROACHES: USDA *Salmonella* ENTERITIDIS RISK ASSESSMENT BASELINE AND CDC SURVEILLANCE BASELINE—Continued

Variable	5th Percentile	Median	Mean	95th Percentile
Health benefits (millions)	$20.2	$103	$150	$421

5. Additional Benefits

a. *Reduced risk from other pathogens.* Refrigeration and thorough cooking may reduce the risk from pathogens other than SE in eggs. These other product-pathogen combinations include other serotypes of *Salmonella* in eggs and pathogenic organisms in other foods. Because other foods are often stored in the same refrigerator cases as shell eggs, refrigerating shell eggs at 7.2 °C (45 °F) will reduce the ambient temperature for all foods stored in the same case. If some of these other foods are ready-to-eat potentially hazardous foods, the requirement to refrigerate at 7.2 °C (45 °F) may generate additional health benefits by reducing the illnesses associated with those products.

b. *Fewer recalls.* The rule could lead to fewer recalls. Although FDA had no recalls of shell eggs in the most recent year, recalls that might have occurred in the future could be prevented by the proposed rule.

6. Uncertainty of Estimated Benefits

As Table 9 of this document shows, the range of potential benefits from the proposed rule is wide. With the USDA SE risk assessment baseline, the 95th percentile benefits are 75 times the 5th percentile benefits. With the CDC surveillance baseline, the 95th percentile benefits are 35 times the 5th percentile benefits. However they are calculated, the estimated benefits from the proposed rule are uncertain.

The uncertainty comes from many sources. Some uncertainty comes from the ordinary variation of known factors. For example, the duration and severity of the illnesses associated with acute salmonellosis vary. The age of victims also varies. Many of the estimated factors affecting the size of health costs, such as the division of deaths between the elderly and younger people, the severity of reactive arthritis, and the number of illnesses that progress from mild salmonellosis to more serious illnesses can vary from year to year. Because of this ordinary variability, it is impossible to generate a single number representing the effects of the proposed rule. As the variable factors change, the effects of the proposed rule change.

The wide range of outcomes shown in Table 9 of this document, however, is not generated solely by the variability of known factors such as ages of victims and severity of illness. Much of the range in Table 9 of this document comes from uncertainty about the values of several elements of estimated health benefits. Fundamental uncertainty exists in that the agency does not know and may never know some of those values. The principal fundamental uncertainties associated with the benefit assessment are:

- Uncertainty about the baseline number of illnesses associated with SE in shell eggs,
- Uncertainty about the proportion of cases of salmonellosis that lead to reactive arthritis,
- Uncertainty about the number of illnesses likely to be prevented by the proposed rule, and
- Uncertainty about the monetary value of illnesses caused by SE in shell eggs.

The effects of these uncertainties can be characterized with a series of figures.[14] In Figure 1 of this document, the agency shows how the distribution of estimated health benefits changes when the baseline distribution of estimated SE illnesses associated with shell eggs changes. As the figure shows, there is much overlap, but the USDA SE risk assessment baseline leads to higher estimated benefits than does the CDC surveillance baseline. The figure also shows that even if the agency knew which distribution the USDA SE risk assessment or the CDC surveillance was the appropriate baseline, large uncertainty would remain. The ranges of outcomes for each baseline distribution cover several billion dollars.

As FDA acquires more information, the uncertainties caused by the agency's lack of knowledge of the incidence of reactive arthritis caused by salmonellosis, the effectiveness of the proposed rule, and the monetary value of the illnesses caused by SE may be reduced but will not be eliminated. Better estimates of the incidence of arthritis are likely to become available in the future, but some uncertainty will remain. The agency will never precisely know the effectiveness of the rule or the average monetary value of preventing a case of salmonellosis. The uncertainty about the effects of policy stem from the many other factors that affect the number of illnesses, including other policies, changes in consumer behavior (perhaps because of education), changes in the pathogen itself, and possible technological changes in processing and other sectors of the industry. All of these changes will affect the baseline distribution of estimated illnesses and, therefore, change the distribution of estimated effects of the proposed rule. The other remaining uncertainty, the monetary value of preventing a case, is based on estimates of the average person's willingness to pay to avoid a small increase in the probability of illness, injury, or death. FDA believes that although it is possible to identify a range of plausible values for the willingness to pay, the true average willingness to pay is probably unknowable.

FDA illustrates the effects of the principal uncertainties in Figures 2 and 3 of this document. In Figure 2 of this document, the uncertainties are assumed away. In other words, Figure 2 of this document is constructed on the assumption that FDA knows the correct baseline, knows the incidence of post-*Salmonella* reactive arthritis, knows the effectiveness of the proposed rule, and knows the value of a statistical life year. If FDA knew those values, one possible distribution of health benefits would be that shown in Figure 2 of this document. In this figure, the values of the main uncertain variables are fixed.[15]

The problem with Figure 2 of this document is that FDA does not know if the selected values of the uncertain variables (which were chosen randomly from the distributions of possible values) are correct. Different values for the principal uncertainties would generate different distributions. Ten values for the uncertain variables would generate 10 different distributions, not one as in Figure 2 of this document. Figure 3 of this document contains the distribution illustrated in Figure 2 of

[14] The next several paragraphs and the figures are based on Ref. 14.

[15] The values for the baseline illnesses, incidence of reactive arthritis, effectiveness of the proposed rule, and the monetary value of preventing illnesses were randomly selected and then fixed for the simulation illustrated in Figure 2 of this document.

this document, as well as nine others—four more from the CDC surveillance baseline and five from the USDA SE risk assessment baseline. The agency does not know which of the 10 distributions pictured in Figure 3 of this document is correct. Indeed, the correct distribution could be another one entirely. In Figure 4 of this document, 100 different values of the uncertain variables generate 100 different simulated distributions of health benefits. The best estimate of health benefits is somewhere in the thick mass of Figure 4 of this document, but it is impossible to tell where.

The uncertainty does not mean that nothing can be concluded about the benefits of the proposed rule. The distributions shown in Figures 3 and 4 of this document tend to be of two types: (1) Narrow distributions concentrated in the low end of the benefits scale, and (2) wide distributions encompassing everything from small benefits to enormous benefits. The narrow distributions bunched at the low end of the scale represent large health benefits. For example, the 5th percentile benefits from the CDC surveillance baseline are, as shown in Table 9 of this document, approximately $50 million per year—a large health benefit. The distributions shown in Figures 1 through 4 of this document suggest that although there is some small probability of small benefits, most of the values generated by the simulations represent large public health benefits.

BILLING CODE 4160–01–F

Figure 3. Uncertainty of Health Benefits: 10 Simulations

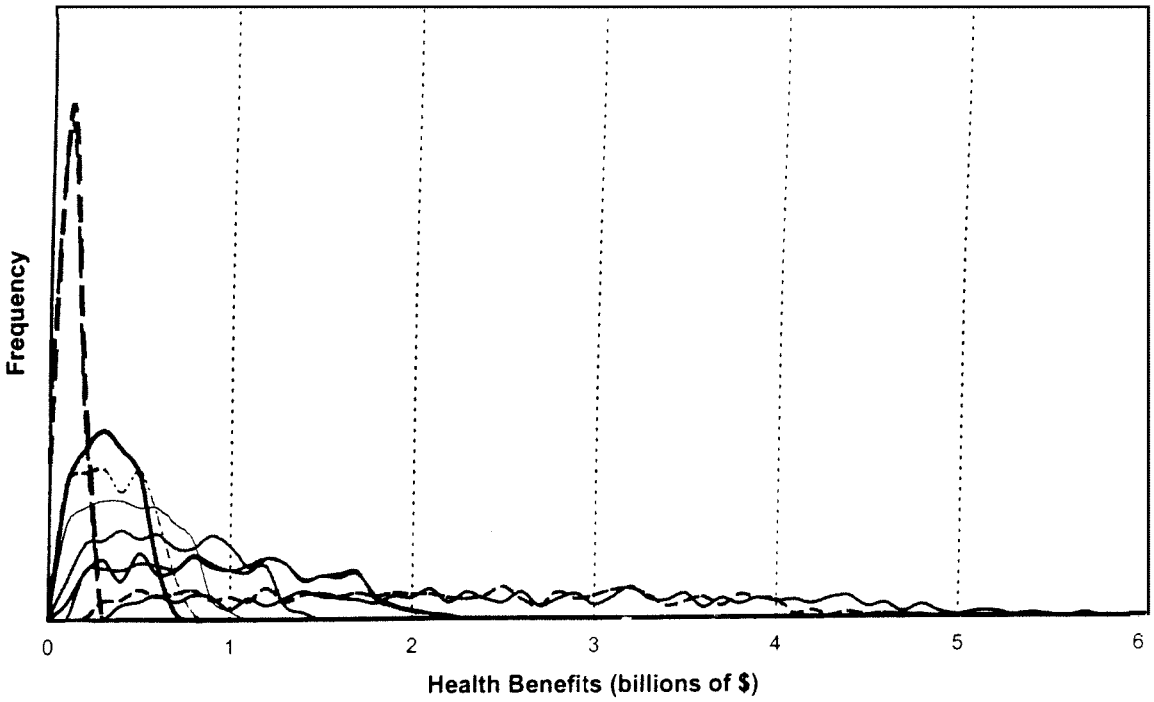
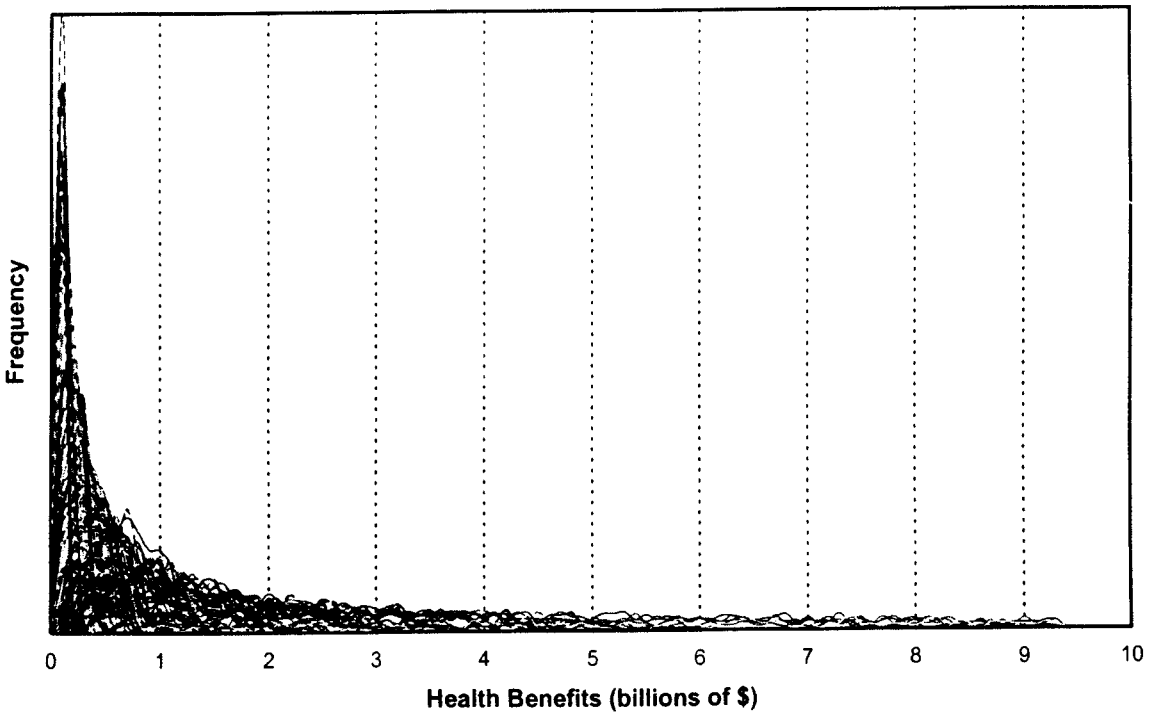


Figure 4. Uncertainty of Health Benefits: 100 Simulations



BILLING CODE 4160–01–C

F. Costs

The costs of the proposed rule include the redesign of egg cartons, the other costs necessary to add the safe handling label to egg cartons, the additional equipment and energy costs to achieve the specified refrigeration temperatures for shell eggs, and the costs of changes in consumer practices resulting from the safe handling label.

1. Types of Establishments Covered

The labeling provision and the refrigeration provision will affect different parts of the food industry.

a. *Labeling provision coverage*. The labeling provision covers shell eggs sold in labeled cartons or in cases for bulk sale. The labeling provision would affect all egg packers, processors, and distributors (hereinafter collectively referred to as ''packers''). There are 669 packers registered with USDA (Ref. 17).

b. *Refrigeration provision coverage*. The refrigeration provision covers all retail establishments that sell or otherwise provide eggs as products to consumers (such as grocery stores selling cartons of eggs) or that use shell eggs in the production of other products sold or provided to consumers (such as hospitals providing prepared eggs to patients). These retail establishments include grocery stores, restaurants, health food stores, convenience stores, other retail establishments, as well as such institutions as prisons, nursing homes, schools, hospitals, and the military establishments.

2. Cost Estimates by Requirement and Type

a. *Egg container labels*. The proposed labeling provision requires shell egg containers to have a safe handling statement. The cost of the proposed provision may be estimated by measuring the additional costs either where they first occur—at the carton manufacturers—or at the segments of the industry that bear the costs of relabeling. Because the egg industry, which includes egg producers, carton manufacturers, egg distributors, and retailers is competitive, the carton manufacturers will likely pass some or all of the costs of relabeling on to packers.[16] The cost of relabeling if measured correctly will be the same no matter where in the carton market they are measured; therefore, the agency used the most readily accessible cost information for its estimates, which came from the carton manufacturers. It is irrelevant for purposes of cost estimation that packers are covered by the rule and carton manufacturers are not, because the costs are the same wherever measured.

The agency assumed that the carton manufacturer's additional costs or relabeling would be for administration, inventory disposal, and label redesign. The one-time costs include the costs of replacing existing printing plates (if the planned useful life of plates expires after the start of the compliance period), the loss of existing carton inventory (if the inventory does not meet label requirements at the start of the compliance period), and an additional administrative expense to interpret and execute the firm's compliance with the rule. The agency does not expect any firms in the industry to shut down as a consequence of the rule, because the increased costs from the rule are one-time costs that are not expected to be large enough to make shutting down the best option.

FDA calculated labeling costs with the following formula:

labeling costs = ($ administrative costs per firm x number of affected firms) + ($ value of cartons manufactured x disposal percentage of carton inventory) + ($ redesign cost per label x number of affected labels)

FDA calculated, separately, each of the three costs: Administrative, inventory disposal, and label redesign.

i. *Administrative costs*. To estimate the administrative costs, the agency used the following formula:

AC = A x F

where:

AC = administrative costs.

A = administrative costs per firm.

F = number of firms in the industry.

Administrative costs include the firm's additional management and other overhead expenses needed to implement the proposed rule. Total administrative cost for the industry will be the administrative cost per firm multiplied by the number of firms that manufacture egg cartons. The Food Serving and Packaging Institute supplied information on the number of carton manufacturers (Ref. 19). Table 11 of this document shows FDA's estimates of the administrative cost per firm for different compliance periods. Administrative costs tend to decrease with the length of the compliance period, because longer compliance periods allow carton producers more time to incorporate the mandated label changes into regularly planned design, equipment, and personnel changes. In addition, fewer overtime hours would be required and possibly a lower level of management would be involved. Industry sources provided the agency with estimates of the cost per firm for a 12 month-compliance period (Refs. 19 through 24). FDA inferred the amounts shown for the 6-month and 18-month compliance periods from the estimate for the 12-month compliance period. The agency assumed that a firm would require more hours with a shorter compliance period, and fewer hours with a longer compliance period.

TABLE 11.—ADMINISTRATIVE COSTS (ESTIMATED FOR CARTON MANUFACTURERS)

Compliance Period	6 Months	12 Months	18 Months
Number of firms	8	8	8
Cost per firm	$35,000	$25,000	$15,000
Total	$280,000	$200,000	$120,000

[16] If both segments of the egg industry are competitive, the measured costs of carton manufactures could equal the costs borne by packers. Competition is a reasonable assumption for the packers because there are at least 669 firms in the industry. Competition may also be assumed for the carton manufacturers because their segment of the industry is contestable, meaning that it is a market with the potential for firm entry and exit. The economic theory of contestable markets suggests that when there is relatively free entry and exit into the market, prices will be set just high enough to cover the additional costs of production caused by the rule. The carton manufacturing industry four-firm concentration ratio is 85 percent, which is high. Despite a high concentration ratio, carton-manufacturing firms will still set carton prices at competitive levels or risk entry from new competitors. Anecdotal evidence exists that a new carton manufacturing firm did attempt to enter the market a few years ago (Ref. 18). It failed to be profitable and left the market shortly after entering, implying that the existing industry structure is competitive. The agency does not expect existing firms in the industry to exit as a consequence of the rule, because the increased costs from the rule are one-time costs. The remaining question is how those one-time costs will be split between carton manufacturers and packers. Although the question is important from the standpoint of the distribution of the burden of labeling costs, it does not affect the size of those costs.

ii. *Inventory disposal costs.* To estimate the inventory disposal costs, the agency used the following formula:

ID = IV x I

where:

ID = inventory disposal costs.

IV = total value of egg cartons manufactured annually.

I = lost carton stock as a percent of industry volume.

Inventory disposal costs are the costs of discarding otherwise useable carton inventory that does not comply with the new rule. The agency estimated inventory disposal costs by multiplying the total dollar value of the cartons produced annually by an estimate of the percentage of stock left over after the proposed rule would take effect.

Many egg packers have carton turnover rates of once or twice a week, while other firms turn over their carton stock once or twice a year. Egg packers, whatever their rate of turnover, never hold a large number of cartons in inventory. Inventory disposal costs tend to decrease with longer compliance periods, because longer compliance periods allow packers to use up their carton inventory. Based on information provided by industry sources, the agency estimated the likely percentage of stock remaining for three compliance periods: 6 months, 12 months, and 18 months (Refs. 19 through 24). Table 12 of this document shows FDA's estimate of the inventory disposal costs.

TABLE 12.—INVENTORY DISPOSAL COSTS

Compliance Period	6 Months	12 Months	18 Months
Total industry volume	$150,000,000	$150,000,000	$150,000,000
Lost stock as percent of industry	2 percent	1 percent	0.5 percent
Total inventory disposal cost	$3,000,000	$1,500,000	$750,000

iii. *Label redesign costs.* To calculate the label redesign costs the agency used the following formula:

LRC = $ per SKU x SKU's

where:

LRC = label redesign cost.

$ per SKU = cost per stock keeping unit.

SKU's = number of stock keeping units.

Label redesign costs are associated with the redesign of the carton's printed label that would be needed to incorporate the proposed safe handling statement. FDA estimated the costs by multiplying the number of affected separable labels on cartons or containers, referred to as stock keeping units (SKU's), by the estimated cost per SKU. The total number of SKU's for the industry is about 20,000 (Refs. 19 through 24). Although the labels affected would only be those without safe handling statements consistent with the proposed rule, the agency assumed that because the proposed rule requires specific language, no existing statements would be acceptable. Therefore, the agency estimated the costs based on the assumption that all labels would be changed.

Label redesign costs decrease with a longer compliance period, partly because the carton's design, printing plates, and other capital investments must be changed periodically regardless of regulatory initiatives. If the compliance period were as long as the useful life of the existing carton design, the label redesign costs of the proposed rule would be greatly reduced.

Redesign costs are lower, the more surface area on the carton, and are higher, the less surface area on the carton. Surface area is a major problem for labeling egg cartons, because of the relative absence of large, flat surfaces suitable for labels. When the surface area is not large enough to accommodate the proposed safe handling statement, the costs of redesign may also include redesigning the carton itself. Surface area is a significant issue for pulp paper carton manufacturers, because virtually all pulp paper cartons are ''view style'' cartons. View style cartons have a significantly reduced printable area. The additional cost of carton redesign to the pulp paper sector of the industry would put it at a competitive disadvantage. The alternative to pulp paper as carton material is foam. Foam cartons can more easily accommodate the proposed safe handling statement than can pulp paper cartons and, therefore, the cost of redesign would be less for foam cartons. The agency estimated the costs to redesign the labels per SKU, for both the pulp paper and foam carton segments of the industry, from information provided by industry sources (Refs. 19 through 24). Table 13 of this document shows a summary of the estimated costs for the foam carton segment of the industry for three compliance periods. Table 13a of this document shows the estimated costs for the pulp paper segment for three compliance periods. Table 13b of this document shows the total cost for both segments of the industry for the three compliance periods.

TABLE 13.—FOAM CARTON LABEL REDESIGN COSTS

Compliance Period	6 Months	12 Months	18 Months
Cost per SKU	$500	$250	$100
SKU's	10,000	10,000	10,000
Subtotal foam carton	$5,000,000	$2,500,000	$1,000,000

TABLE 13a.—PULP PAPER CARTON LABEL REDESIGN COSTS

Compliance Period	6 Months	12 Months	18 Months
Cost per SKU	$1,000	$750	$500
SKU's	10,000	10,000	10,000
Subtotal pulp paper carton label redesign	$10,000,000	$7,500,000	$5,000,000

TABLE 13b.—TOTAL INDUSTRY LABEL REDESIGN COSTS

Compliance Period	6 Months	12 Months	18 Months
Subtotal foam carton label redesign	$5,000,000	$2,500,000	$1,000,000
Subtotal pulp paper carton label redesign	$10,000,000	$7,500,000	$5,000,000
Total label redesign cost	$15,000,000	$10,000,000	$6,000,000

iv. *Summary of costs to incorporate safe handling labeling.* Table 14 of this document summarizes the estimated costs to incorporate safe handling statements on egg cartons.

TABLE 14.—ESTIMATED TOTAL INDUSTRY COSTS TO INCORPORATE SAFE HANDLING STATEMENTS

Compliance Period	6 Months	12 Months	18 Months
Total administrative costs	$280,000	$200,000	$120,000
Total inventory disposal costs	$3,000,000	$1,500,000	$750,000
Total label redesign costs	$15,000,000	$10,000,000	$6,000,000
Total labeling costs	$18,000,000	$12,000,000	$7,000,000

b. *Refrigeration costs.* The refrigeration provision of the proposed rule requires retailers to refrigerate shell eggs at 7.2 °C (45 °F) or less within 6 months from the date of publication of the final rule. The refrigeration provision potentially generates two additional costs to retailers: (1) An additional one-time capital cost to replace existing refrigeration equipment if the existing equipment is unable to cool to the proposed temperature, and (2) the cost of the additional energy needed to achieve and maintain the lower cooling temperature.

i. *Equipment costs to refrigerate at 7.2 °C (45* °F). FDA used the following formula to estimate the additional equipment costs to refrigerate eggs at 7.2 °C (45 °F):

C = R x $ per R

where:

C = cost to refrigerate at 7.2 °C (45 °F).

R = number of retailers that would incur an additional cost.

$ per R = cost per retailer.

The baseline number of establishments affected was the number of retailers that were not already required to refrigerate at 7.2 °C (45 °F) by State or local requirements, and who did not have refrigerators cooling at 7.2 °C (45 °F).

The number of establishments and the additional refrigeration cost per establishment were both uncertain. The agency did not know: (1) How many and which retail establishments sell eggs, (2) the temperature at which the eggs are refrigerated in the establishments that sell eggs, (3) the age and temperature capability of the refrigerators, or (4) the price of refrigerators and components. FDA used ranges for the uncertain values and then estimated costs with Monte Carlo computer simulations similar to those described in section I.E of this document.

To estimate the total number of retail establishments likely to be affected by the refrigeration provision, the agency first determined the number of establishments in each State with data from Dun's Market Identifiers (Ref. 25).[17] If a State had already adopted the 1997 Food Code as issued by FDA or a similar code that required refrigeration to the proposed temperature, FDA assumed that there would be no additional equipment costs attributable to the proposed rule. The agency assumed that retailers in States with a refrigeration rule that met or exceeded the Federal requirement would incur no additional equipment costs.

Table 15 of this document illustrates how the agency estimated the number of establishments likely to be affected by the requirement to refrigerate eggs at 7.2 °C (45 °F). Column A of Table 15 of this document lists each State. Column B shows the maximum allowable refrigeration temperature for each State, where there is a State requirement.[18] Column C shows the total number of grocery or similar stores per State. Using Standard Industrial Classification (SIC) categories, the retail establishments included in this column are grocery stores (SIC 5411), poultry stands (SIC 5144), fruit and vegetable markets (SIC 5431), and dairy products stores (SIC 5451). Column D shows the number of grocery or similar stores that would be required to lower their refrigeration temperatures because of the proposed Federal provision. The agency assumed that between 0 and 100 percent of all establishments without a 7.2 °C or lower refregeration requirement, with 33 percent the most likely value, would be required to reduce their refrigeration temperatures.[19] FDA combined the estimated number of establishments refrigerating at 7.2 °C in States without a requirement with the number of establishments in the 37 States (and the District of Columbia) with such a requirement, the result was that 95 percent of all establishments were estimated to refrigerate shell eggs at 7.2 °C or less. The agency based the assumption on the belief that most establishments in States that did not have a refrigeration rule would nevertheless refrigerate eggs at 7.2 °C (45 °F) or less. FDA assumed that these establishments would either be required to refrigerate by a local rule or would choose to refrigerate at 7.2 °C (45 °F) in order to satisfy consumer demand. The agency seeks comments on this assumption. Column E shows the total number of restaurants (eating places) (SIC 5812) per State. Column F shows the number of restaurants that would be required to lower their refrigeration temperatures because of the proposed rule. The agency assumed that the most likely fraction of restaurants that would be required to lower their temperature would also be 33 percent of the total restaurants in those States without a State requirement. Column G shows the total number of institutions that serve eggs to consumers in each State. Institutions include prisons, military establishments, hospitals, nursing homes, public and private schools grades kindergarten through 12, colleges, and universities. Column H

[17] See Table 15 of this document.

[18] If a State has no temperature requirement, FDA used 100 as the default value.

[19] In the calculations shown in Table 15 of this document, FDA used a Beta-pert distribution (0,33,1). For an explanation (see Ref. 14).

shows the number of institutions that would be required to lower refrigeration temperatures because of the proposed rule. Column I shows the total number of retailers, including grocery stores, restaurants, and institutions in each State. Column J shows the total number of retailers that would be required to lower their refrigeration temperatures because of the proposed rule.

TABLE 15.—ESTIMATED EFFECTS OF REFRIGERATION PROVISION BY STATE

A	B	C	D	E	F	G	H	I	J
State	State Temp. Requirement	Total Grocery Stores	Affected Grocery Stores	Total Restaurants	Affected Restaurants	Total Institutions	Affected Institutions	Total Retail	Total Affected Retail
AL	45	4,142	0	5,957	0	2,443	0	12,542	0
AK	100	327	126	971	375	664	257	1,962	759
AZ	60	1,990	769	6,970	2,695	1,760	681	10,720	4,145
AR	45	2,341	0	3,702	0	1,883	0	7,926	0
CA	41	16,230	0	57,209	0	14,880	0	88,319	0
CO	45	1,733	0	7,260	0	2,369	0	11,362	0
CT	45	2,192	0	6,317	0	1,870	0	10,379	0
DE	41	467	0	1,340	0	375	0	2,182	0
DC	45	516	0	1,651	0	390	0	2,557	0
FL	41	10,223	0	27,256	0	5,629	0	43,108	0
GA	41	6,287	0	12,229	0	3,454	0	21,970	0
HI	45	596	0	2,187	0	450	0	3,233	0
ID	45	790	0	2,017	0	917	0	3,724	0
IL	41	5,916	0	19,158	0	7,358	0	32,432	0
IN	45	3,023	0	8,692	0	3,740	0	15,455	0
IA	45	2,214	0	4,783	0	2,755	0	9,752	0
KS	60	1,595	617	4,183	1,617	2,637	1,020	8,415	3,254
KY	45	3,550	0	5,806	0	2,449	0	11,805	0
LA	45	4,317	0	6,630	0	2,737	0	13,684	0
ME	100	1,396	540	2,328	900	1,143	442	4,867	1,882
MD	45	2,982	0	8,162	0	2,442	0	13,586	0
MA	45	3,467	0	11,819	0	3,609	0	18,895	0
MI	40	5,716	0	14,321	0	5,632	0	25,669	0
MN	45	2,795	0	6,561	0	3,022	0	12,378	0
MS	41	3,332	0	3,806	0	11,726	0	18,864	0
MO	60	3,440	1,330	7,876	3,045	3,998	1,546	15,314	5,921
MT	41	642	0	1,589	0	1,318	0	3,549	0
NE	45	1,186	0	2,515	0	2,239	0	5,940	0
NV	100	704	272	2,431	940	652	252	3,787	1,464
NH	100	866	335	2,407	931	846	327	4,119	1,593
NJ	60	5,619	2,173	15,234	5,890	4,133	1,598	24,986	9,661
NM	100	1,419	549	2,801	1,083	1,187	459	5,407	2,091
NY	45	14,757	0	35,667	0	8,207	0	58,631	0
NC	45	6,635	0	11,316	0	3,559	0	21,510	0
ND	41	883	0	984	0	894	0	2,761	0
OH	45	5,988	0	17,434	0	6,886	0	30,308	0
OK	60	2,741	1,060	4,877	1,886	3,071	1,187	10,689	4,133
OR	45	2,204	0	6,088	0	1,951	0	10,243	0
PA	45	7,868	0	19,864	0	7,006	0	34,738	0
RI	41	642	0	2,033	0	614	0	3,289	0
SC	45	3,827	0	6,315	0	1,888	0	12,030	0
SD	41	570	0	1,236	0	1,043	0	2,849	0
TN	100	5,264	2,035	8,634	3,338	2,954	1,142	16,852	6,516
TX	41	15,307	0	31,907	0	10,488	0	57,702	0
UT	41	956	0	2,911	0	1,060	0	4,927	0
VT	100	719	278	1,064	411	564	218	2,347	908
VA	45	4,872	0	10,483	0	3,229	0	18,584	0
WA	45	3,467	0	10,438	0	3,085	0	16,990	0
WV	100	1,703	658	2,349	908	1,414	547	5,466	2,114
WI	40	2,635	0	7,688	0	3,931	0	14,254	0
WY	45	309	0	926	0	586	0	1,821	0
Total		183,360	10,743	448,382	24,022	163,137	9,676	794,879	44,440

The agency assumed that each retailer not already in compliance with a State or local refrigeration rule would incur additional equipment costs in order to comply with the proposed rule. The agency also assumed that each retail establishment would have only one refrigerator that would be affected by the proposed rule. The equipment cost would be either the cost to replace old refrigerator components before the end of the component's useful life or the cost to purchase a new refrigerator after deducting the remaining useful value of the old refrigerator. Not all current refrigerators or refrigerator components such as compressors and coils are capable of cooling to the proposed lower temperatures. Older cooling equipment may not be able to achieve lower cooling temperatures, or if able to do so

cannot maintain a uniform temperature. Many older compressors lack sufficient horsepower (compressor power) and many older refrigeration coils lack the surface area for sufficient heat exchange. Attempting to meet the temperature requirements of the proposed rule with under-capacity refrigerators in a multishelf display case can cause both under-cooling and over-cooling of the products (Ref. 26). Excessively cold temperatures for products located at the top of display shelves can occur when the bottom shelves are targeted to meet the temperature requirement; excessively warm temperatures can occur at the bottom if the top shelves are targeted to meet the temperature requirement. Furthermore, products must be cooled to an even lower temperature than the proposed rule to ensure that at the end of the defrost cycle, when there is no cooling, the refrigerator does not exceed the allowable temperature. Maintaining a uniformly cool temperature in display cases, then, is not feasible when refrigerator components lack sufficient capacity. Because attempting to maintain the temperature with insufficient cooling capacity can adversely affect the safety, quality, and shelf life of the food products, some establishments would be forced to purchase new refrigerators or components.

All commercial refrigerators eventually wear out and have to be replaced. The cost of replacement resulting from the proposed rule only occurs if replacement becomes necessary before the planned end of the useful life of the existing equipment. Commercial refrigeration industry sources say that the useful life of a commercial refrigerator can be as long as 20 years, although on average commercial refrigerators last about 10 years (Ref. 27). The life of the refrigerator matters, because the longer the useful life of existing refrigerators, the greater will be the foregone capital cost borne by firms compelled to replace them. It follows that the longer the compliance period, the smaller will be the useful life left at the time of replacement and the smaller will be the cost borne by firms.

Retailers whose equipment could not reach the proposed safe cooling temperature and who were not planning to purchase a refrigerator or components during the compliance period would be forced to make a one-time purchase of refrigerators or components. The difference between the planned capital replacement cost without the proposed rule and the capital cost with the proposed rule would be the equipment cost of the refrigeration provision (the new equipment cost minus the salvage value of the old equipment). It would be a one-time cost, because all future purchases would occur at the end of the useful life of the refrigerator and not in response to the proposed rule.

The agency assumed that only one refrigerator per retailer would be potentially affected by the provision, because even the largest retail outlets (such as supermarkets) rarely have more than one refrigerator or display case exclusively devoted to selling eggs. Some large grocery stores might have more than one refrigerator containing eggs such as when eggs are displayed in island refrigerators for marketing purposes or in display cases in the dairy section. The agency assumed that for every retailer with more than one refrigerator devoted to eggs, there would be one, probably a smaller retailer, who did not sell eggs.

The agency assumed that additional equipment costs per affected establishment varied from close to 0 to approximately $6,000. This range of estimated equipment costs combined two separate ranges, one for small equipment costs and one for large equipment costs. The small equipment costs ranged from 0 to $1,000, with $700 the most likely value. The large equipment costs ranged from $1,000 to $6,000, with $4,000 the most likely value. FDA assumed that equipment expenditures would be highly correlated with the size of establishment, so that small firms would have small equipment costs and large firms would have large equipment costs. With 80 percent of establishments classified as small, the assumption that costs and establishment size were correlated led to the assumption that 80 percent of refrigeration costs would fall in the small range and 20 percent would fall in the large range.[20] FDA recognized, however, that the correlation would likely not be perfect; some small firms could have large equipment costs and some large firms could have small equipment costs.

FDA estimated total equipment costs with a Monte Carlo simulation of 1,000 calculations (or iterations). Each calculation consisted of an estimate of the number of affected establishments multiplied by an estimate of the equipment cost per establishment. The 5th percentile, median, mean, and 95th percentile of simulated total equipment costs are shown in Table 16 of this document.

TABLE 16.—TOTAL ANNUAL EQUIPMENT COSTS TO REFRIGERATE TO 7.2 °C (45 °F)

5th Percentile	Median	Mean	95th Percentile
$7,000,000	$31,000,000	$56,000,000	$228,000,000

ii. *Energy costs.* The additional energy costs likely to be caused by the proposed rule appear to be negligible, because new commercial refrigerators are significantly more energy efficient than older refrigerators. As retailers replace their existing equipment to comply with the rule, the agency expects retailers to adopt energy-efficient technologies, which will reduce their energy consumption by approximately the amount of additional energy used to lower their existing refrigeration temperature to 7.2 °C (45 °F). FDA therefore assumed that the proposed rule would lead to no additional energy costs.

iii. *Shares of estimated refrigeration costs by type of establishment.* The shares of total refrigeration costs by type of establishment are shown in Table 17 of this document. FDA assumed that equipment costs accounted for all refrigeration costs of the proposed rule.

[20] In the simulation used to estimate total equipment costs, the distributions of small and large equipment costs were characterized as Beta-pert distributions with small costs distributed as Beta-Pert (0,700,1000) and large costs distributed as Beta-pert (1000,4000,6000). The two distributions were combined with a discrete distribution that assumed that the probability that costs were small was 0.8 and the probability that costs were large was 0.2. The full distribution for the simulation was: Discrete ((Beta Pert (0,700,1000), Beta-Pert (1000,4000,6000)), (0.8, 0.2)).

TABLE 17.—REFRIGERATION COST SHARES BY TYPE OF ESTABLISHMENT

Type of Establishment	Share of Total Refrigeration Cost (in percent)
Grocery stores	25
Restaurants	54
Institutions	21

iv. *Comparison with other studies of estimated refrigeration costs.* The agency found only two studies, by Dunn and Madison (Ref. 28) and by Madison (Ref. 29), that have estimated the costs of a similar proposed refrigeration rule. Dunn and Madison estimated the statewide impact from lowering the refrigeration requirement from 55 °F to 45 °F. They assumed that the statewide average refrigeration temperature before the proposed rule was 55 °F. They estimated the most likely cost to egg packers to reduce refrigerator temperatures from 55 °F to 45 °F to be $0.05 per dozen eggs, but that the cost could be as low as $0.02 per dozen. The smaller cost held when the eggs were produced from larger flocks and were cooled in refrigerators with larger capacity. The estimates were based on the cost to modify the existing cooling systems to increase cooling capacity. Although egg packers and not retailers incurred the additional costs, the agency believes that the costs to one segment of the industry would be passed on to a downstream segment and would be nearly equal on a per carton basis.[21]

The Dunn and Madison estimates can be compared to the agency's estimate of the cost to refrigerate eggs at 7.2 °C (45 °F). The higher estimate of refrigeration costs (Refs. 28 and 29) of $0.05 per dozen eggs equals $0.08 per dozen eggs in current (1998) dollars. The lower estimate of refrigeration costs (Refs. 28 and 29) of $0.02 per dozen eggs equals $0.032 per dozen eggs in current (1998) dollars. The agency multiplied both the lower and the higher estimates of cost per dozen eggs by the agency's estimate of the total number of eggs sold at retail in States without a current refrigeration rule.

For the comparison with the Dunn and Madison estimates, FDA assumed that there were no regional or State differences in consumption per person of shell eggs across the country. The agency got the number of shell eggs produced and consumed nationwide from the USDA Economics Research Service (Ref. 30). The agency assumed that the national consumption of eggs equaled to the national production of eggs after subtracting for net exports, breakers, and diverted eggs. FDA further assumed that a State's share of the national consumption of eggs equaled the State's share of national population. Table 18 of this document shows the resulting estimate of the number of affected eggs sold in States that do not currently meet the proposed refrigeration provision.

TABLE 18.—STATE EGG CONSUMPTION

State	State Temperature Requirement	Number of Eggs Consumed (Millions)
Alabama	45	
Alaska	None	106
Arizona	60	691
Arkansas	45	
California	41	
Colorado	45	
Connecticut	45	
Delaware	41	
District of Columbia	45	
Florida	41	
Georgia	41	
Hawaii	45	
Idaho	45	
Illinois	41	
Indiana	45	
Iowa	45	
Kansas	60	455
Kentucky	45	
Louisiana	45	
Maine	None	223
Maryland	45	
Massachusetts	45	
Michigan	40	
Minnesota	45	
Mississippi	41	
Missouri	60	936
Montana	41	
Nebraska	45	
Nevada	None	239
New Hampshire	None	200
New Jersey	60	1,405

[21] The costs could be passed on if all segments of the industry were competitive.

TABLE 18.—STATE EGG CONSUMPTION—Continued

State	State Temperature Requirement	Number of Eggs Consumed (Millions)
New Mexico	None	285
New York	45	
North Carolina	45	
North Dakota	41	
Ohio	45	
Oklahoma	60	579
Oregon	45	
Pennsylvania	45	
Rhode Island	41	
South Carolina	45	
South Dakota	41	
Tennessee	None	906
Texas	41	
Utah	41	
Vermont	None	103
Virginia	45	
Washington	45	
West Virginia	None	327
Wisconsin	40	
Wyoming	45	
Total[1]		6,500

[1] Rounded

The agency used the following formula to calculate the cost to refrigerate at 7.2 °C (45 °F) using Dunn and Madison's estimated average cost per dozen eggs:

RC = DE x $ per D

where:

RC = cost to refrigerate to 7.2 °C (45 °F).

DE = total number of eggs (in dozens) in States where eggs not currently refrigerated to 7.2 °C (45 °F).

$ per D = cost per dozen eggs to refrigerate to 7.2 °C (45 °F).

The agency estimated that 6.5 billion eggs were not refrigerated at 7.2 °C (45 °F) (see Table 18 of this document). The number of dozens not refrigerated at 7.2 °C (45 °F) would therefore be 540 million (= 6.5 billion ÷ 12). The high estimated cost of refrigeration would be about $43 million (= 540 million dozen eggs x $0.08 per dozen). The low estimated cost of refrigeration would be about $17 million (= 540 million dozen eggs x $0.032 per dozen).

Table 19 of this document compares FDA's estimate of the costs of refrigeration with estimates based on Dunn and Madison's high and low average refrigeration cost per dozen eggs. As the table shows, FDA's median estimate of total refrigeration costs fall between Dunn and Madison's high and low estimates.

TABLE 19.—COMPARATIVE SUMMARY OF COSTS FROM THE REFRIGERATION PROVISION (MILLIONS)

Method	FDA (Median)	Dunn and Madison (High)	Dunn and Madison (Low)
7.2 °C (45 °F)	$31	$43	$17

c. *Changes in consumer practices.* A safe handling label will not by itself lead to safer eggs. The changes people make in response to the label lead to safer eggs. In the calculation of benefits from the safe handling label, FDA assumed that some people would respond to the proposed safe handling label by cooking eggs more thoroughly or by switching away from foods that require raw or undercooked eggs. FDA recognizes that if people for reasons of safety reduce their consumption of foods they would have otherwise preferred, they bear the costs of changing their preparation and consumption practices. If it were possible to do so, many people would be willing to pay more to continue to be able to eat the unsafe food, supposing it could be made safe. The extra willingness to pay is the measure of the cost of changing consumer practices when consumers are unable to purchase or prepare a safe version of the preferred food.

The agency calculated the cost of changing consumer practices with the following formula:

CS = E x UP x ΔUP x $ per U

where:

CS = annual cost of changing consumer practices.

E = total eggs consumed per year.

UP = baseline percentage of total eggs that were not cooked thoroughly before the rule.

ΔUP = percentage reduction in eggs that are not cooked thoroughly because of the rule.

$ per U = value of undercooking one egg.

The estimated number of eggs consumed was 46.8 billion. Based on results of the Food Consumption and Preparation Survey, the USDA SE risk assessment used a distribution with a most likely value of 33 percent to estimate the baseline percentage of eggs that were not cooked thoroughly before the proposed rule.[22] FDA estimated the percentage reduction of consumption of undercooked eggs as a distribution, with a most likely value of about 5 percent.[23] The agency assumed that $0.025 (= $0.30 ÷ 12), the cost per egg for in-shell pasteurization, would be the upper bound that consumers would be willing to pay for safe handling. The agency assumed that the lower bound cost would be 1/25th of the upper bound

[22] The minimum was 27 percent and the maximum was 46 percent. The distribution used in the simulation was Beta-Pert (0.27, 0.33, 0.46).

[23] FDA used a Beta distribution to characterize the reduction in undercooking. The Beta distribution (50,959) was based on survey results for the USDA safe handling label for meat (Ref. 5). FDA used the same survey to estimate the benefits of the proposed safe handling label.

cost, or $0.001. The agency further assumed that the value to consumers of one undercooked egg would vary uniformly between the lower bound ($0.001) and the upper bound ($0.025)[24]

Because of the uncertainty associated with the calculation, the agency estimated the costs of changing consumer practices with a Monte Carlo simulation. Table 20 of this document shows the results of the 1,000 calculations of the annual cost of changes in consumer practices brought about by the proposed rule.

TABLE 20.—ESTIMATED ANNUAL COST OF CHANGES IN CONSUMER PRACTICES ATTRIBUTABLE TO THE PROPOSED SAFE HANDLING LABEL

Variable	5th Percentile	Median	Mean	95th Percentile
Annual cost to consumers	$2,000,000	$10,000,000	$10,000,000	$20,000,000

G. Summary of Benefits and Costs

The agency estimated the median annual benefits of this proposed rule to be about $300 million for the CDC surveillance baseline model and about $700 million for the USDA SE risk assessment baseline model. The estimated median costs to refrigerate shell eggs at 7.2 °C (45 °F) were $31 million in the first year. The agency estimated the cost to incorporate safe handling statements as $18 million for a 6-month compliance period. The median estimated cost of changing consumer practices was $10 million per year. Therefore, the agency estimated the total cost of the proposed rule in the first year to be about $60 million. After the first year, the only continuing cost would be reduced consumer satisfaction, which recurs year after year as long as consumers have a preference for undercooked eggs. FDA concludes that the effects of the proposed rule would be economically significant under Executive Order 12866. The proposed rule, based on the median estimate of cost contained in the economic analysis, would not be significant under the Unfunded Mandates Reform Act.

TABLE 21.—MEDIAN ANNUAL ESTIMATED BENEFITS AND COSTS OF THE PROPOSED RULE (IN MILLIONS OF $)

	First year	All other years
Median estimated benefits (USDA SE risk assessment baseline)	$700	$700[1]
Median estimated benefits (CDC surveillance baseline)	$300	$300[1]
Median estimated costs	$60	$10

[1] The benefits remain high after the first year if no other interventions affect SE in shell eggs. If other Federal or State regulations, consumer education, and producer initiatives reduce the baseline incidence of SE illness from shell eggs, then the benefits from the proposed rule will decline over time. The decline will be roughly proportional to the decline in baseline incidence of SE illness from shell eggs.

II. Initial Regulatory Flexibility Analysis

A. Introduction

FDA has examined the economic implications of these proposed rules 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.

B. Economic Effects on Small Entities

1. Number of Small Entities Affected

The proposed rule would affect many small entities, including egg processors, grocery stores, restaurants, and other food service establishments. Of the 669 egg processors registered with the USDA, FDA has not been able to determine how many are small businesses (Ref. 17). Egg processors generally fall into two industrial classifications: Poultry slaughtering and processing (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. 25), 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.[25] 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 22 of this document, FDA estimated 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] In the simulation, the value of an undercooked egg was characterized as a uniform distribution: Uniform ($0.001, $0.025).

[25] 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.

24,000 restaurants, and 9,700 institutions (see Table 15 of this document). 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 refrigeration provision by multiplying the fraction in each category defined to be small by the total number of establishments affected. Table 22 of this document shows the number of small entities likely to be affected by the refrigeration provision of the proposed rule.

TABLE 22.—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 7.2 °C (45 °F)
Grocery and other stores	7,600
Restaurants	13,000
Institutions	4,800
Total	25,400

2. 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 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. 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 costs of refrigeration for small retailers would average $633 per establishment, with $700 the most likely cost. 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. Table 23 of this document shows the estimated total cost of the refrigeration provision to small entities. The agency requests comments on the effect of the refrigeration provision on roadside stands.

TABLE 23.—COSTS TO SMALL ENTITIES OF THE REFRIGERATION PROVISION OF THE PROPOSED RULE

Category	Total Costs to Small Entities	Mean Cost per Small Entity
Grocery	$4.8 million	$633
Restaurants	$8.2 million	$633
Institutions	$3.1 million	$633
Total	$16.1 million	$633

C. Regulatory Options

1. 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.

2. 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 first estimated the decline in total industry costs and then multiplied it by the small business share of total costs. Total industry costs would fall by $11 million if the compliance period for labeling were extended from 6 months to 18 months (see Table 14 of this document). 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.

D. 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.

E. 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. 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. 25). 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 would be 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 did not estimate the annual sales revenues of the smallest egg packers and, therefore, it was unable to compare the estimated amortized cost to annual profits. FDA requests comments on this relationship.

F. Summary

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 average costs of $633 per small entity (and up to $6,000) 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.

III. References

The following references have been placed on display in 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. Memorandum of telephone conversation between Marilyn Balmer, FDA, and Peter Vardon, FDA, September 4, 1998.
2. Baker Jr., A. R., E. D. Ebel, R. M. McDowell, R. A. Morales, W. D. Schlosser, and R. Whiting, *Salmonella* Enteritidis Risk Assessment Team, *Salmonella* Enteritidis Risk Assessment: Shell Eggs and Egg Products, Washington, DC: United States Department of Agriculture, Food Safety and Inspection Service, June 12, 1998.
3. Centers for Disease Control and Prevention (CDC), *Salmonella* Surveillance, Atlanta, GA: Centers for Disease Control and Prevention, 1997.
4. Bean, N. H., J. S. Goulding, M. T. Daniels, and F. J. Angulo, ''Surveillance for Foodborne Disease Outbreaks—United Sates, 1988–1992,'' *Journal of Food Protection*, vol. 60, pp. 1265–1286, 1997.
5. Food Marketing Institute (conducted by Abt Associates, Inc.), ''Trends in the United States: Consumer Attitudes & the Supermarket,'' Washington, DC: Food Marketing Institute, 1996.
6. Mauskopf, J. A., M. T. French, A. S. Ross, D. M. Maguire, R. W. Leukrith, Jr., and K. D. Fisher, ''Estimating the Value of Consumers' Loss from Foods Violating the Federal Food, Drug, and Cosmetic Act,'' Research Triangle Report to the Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, September 1988.
7. Thompson, G. T. D., Debra A. De Rubeis, M. A. Hodge, C. Rajanayagam, and R. D. Inman, ''Post-Salmonella Reactive Arthritis: Late Clinical Sequelae in a Point Source Cohort,'' *The American Journal of Medicine*, vol. 98, pp. 13–21, January 1995.
8. CDC/USDA/FDA Foodborne Diseases Active Surveillance Network (FoodNet), 1997, Surveillance Results, U.S. Department of Health and Human Services, U.S. Public Health Service, Centers for Disease Control and Prevention, April 1998.
9. Economic Report of the President, Washington: United States Government Printing Office, February 1998.
10. Viscusi, W. K., ''The Value of Risks to Life and Health,'' *Journal of Economic Literature* vol. 31, pp. 1912–1946, December 1993.
11. Buzby, J. C., T. Roberts, C.-T. Jordan Lin, and J. M. MacDonald, Bacterial Foodborne Disease: Medical Costs and Productivity Losses, Washington, DC: United States Department of Agriculture, Economic Research Service, Agricultural Economic Report No. 741, August 1996.
12. Zorn, D. J., and K. Klontz, Appendix: The Value of Consumer Loss to Foodborne Reactive Arthritis, Federal Register 63, May 1, 1998.
13. Council for Agricultural Science and Technology (CAST), Food-Borne Pathogens: Risks and Consequences. Ames, Iowa: Council for Agricultural Science and Technology, Task Force Report No. 122, September 1994.
14. Vose, D., Quantitative Risk Analysis: A Guide to Monte Carlo Simulation Modeling, New York: Wiley, 1996.
15. Kaplan, R. M., J. P. Anderson, and T. G. Ganiats, ''The Quality of Well-being Scale: Rationale for a Single Quality of Life Index,'' In Quality of Life Assessment: Key Issues in the 1990's, edited by Stuart R. Walker and Rachel M. Rosser, pp. 65–94 and 442–444, The Netherlands: Kluwar Academic Publishers, 1993.
16. Adams, P. F., and M. A. Marano, Current Estimates from the National Health Interview Survey, 1994, Series 10: Data from the National Health Survey No. 193, Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, December 1995.
17. Memorandum of facsimile transmission from Gale Mason, USDA, to Peter Vardon, FDA, February 25, 1998.
18. Memorandum of conversation between Carlton Lofgren, McAnally Enterprises, and Peter Vardon, FDA, January 21, 1998.
19. Letter from Richard B. Norment, Food Serving and Packaging Institute, to Peter Vardon, FDA, February 23, 1998.
20. Memorandum of telephone conversation between Norman Patterson, Dalco Packaging Corp., and Peter Vardon, FDA, January 28, 1998.
21. Memorandum of telephone conversation between Norman Patterson, Dalco Packaging Corp., and Peter Vardon, FDA, February 4, 1998.
22. Memorandum of telephone conversation between Barbara Walters and Alan Andrews, Tenneco Packaging Co., and Peter Vardon, FDA, January 15, 1998.
23. Memorandum of telephone conversation between Alan Andrews, Tenneco Packaging Co., and Peter Vardon, FDA January 30, 1998.
24. Memorandum of telephone conversation between Dale Gerber, Cascade Diamond Corp., and Peter Vardon, FDA, February 9, 1998.
25. Dun and Bradstreet, Dun's Market Identifiers, The Dialog Corp. Mountain View, California, March 19, 1998.
26. Faramarzi, R., and M. Woodworth, ''Colder Temperatures in Display Cases,'' *ASREA Journal*, vol. 39, No. 12, December 1997.
27. Memorandum of telephone conversation between Scatter Satterfield, Commercial Refrigerators Manufacturers Association, and Peter Vardon, FDA, January 26, 1998.
28. Dunn, J. W., and M. E. Madison, ''Interregional Competition for Eggs,'' *Journal of Applied Poultry Research*, vol. I, No. 1, March 1992.
29. Madison, M., ''Salmonella and Egg Handling Regulations,'' Farm Management Reports, Pennsylvania State University, February 1990.
30. Putnam, J. Jones, and J. E. Allshouse, Food Consumption, Prices, and

1970–1995. Washington, DC: U.S. Department of Agriculture, Economic Research Service, Statistical Bulletin No. 939, August 1997.

31. Smith, J. L., S. A. Palumbo, and I. Walls, ''Relationship Between Foodborne Bacterial Pathogens and the Reactive Arthritides,'' *Journal of Food Safety*, vol. 13, 1993.

32. Granfors, K., S. Jalkanen, A. A. Lindberg, O. Maki-Ikola, R. V. Essen, R. Lahesmaa-Rantala, H. Isomaki, R. Saario, W. J. Arnold, and A. Toivanen, ''Salmonella Lipopolysaccharide in Synovial Cells from Patients with Reactive Arthritis,'' *Lancet*, vol. 335, March 24, 1990.

IV. Request for Comments

Interested persons may, on or before September 20, 1999, submit to the Dockets Management Branch (address above) written comments regarding this preliminary regulatory impact analysis and initial regulatory flexibility analysis. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket numbers 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.

Dated: June 10, 1999.

Jane E. Henney

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 99–17121 Filed 7–1–99; 11:12 am]

BILLING CODE 4160–01–F