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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

7 CFR Part 59

[Docket No. 97–069F]

RIN 0583–AC04

Refrigeration and Labeling Requirements for Shell Eggs

AGENCY: Food Safety and Inspection Service.

ACTION: Final rule and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is revising its regulations governing the inspection of eggs and egg products to implement 1991 amendments to the Egg Products Inspection Act (EPIA). These amendments require that shell eggs packed for consumer use be stored and transported under refrigeration at an ambient temperature not to exceed 45°F (7.2°C). In addition, the amendments require that these packed shell eggs be labeled to state that refrigeration is required. Finally, the amendments require that any shell eggs imported into the United States packed for consumer use include a certification that the eggs, at all times after packing, have been stored and transported at an ambient temperature of no greater than 45°F (7.2°C).

DATES: *Effective Date:* The effective date of the final rule is August 27, 1999.

Comment Date: As noted below, the proposed rule concerning refrigeration and labeling requirements for shell eggs was published on October 27, 1992. Because the proposed rule was published approximately six years ago, FSIS is requesting comments on this final rule. FSIS requests comments on the economic impact analysis in these regulations and on options for monitoring compliance with the refrigeration and labeling requirements. Comments must be received on or before October 26, 1998.

ADDRESSES: Send an original and two copies of comments to: FSIS Docket Clerk, Docket #97–069F, Room 102, Cotton Annex, 300 12th Street, SW, Washington, DC 20250–3700. Reference material cited in the document and any comments received will be available for public inspection in the FSIS Docket Room from 8:30 a.m. to 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Ms. Patricia F. Stolfa, Assistant Deputy Administrator, Regulations and Inspection Methods, Food Safety and Inspection Service, U.S. Department of Agriculture (202) 205–0699.

SUPPLEMENTARY INFORMATION:

Background

In 1991, as part of the Food, Agriculture, Conservation and Trade Act Amendments of 1991 (Pub.L. 102–237) (hereafter referred to as ''the 1991 EPIA amendments''), Congress amended the EPIA to require that egg handlers store and transport shell eggs destined for the ultimate consumer under refrigeration at an ambient temperature of no greater than 45°F (7.2°C) (21 U.S.C 1034(e)(1)(A)). (See also 21 U.S.C. 1037(c)). The 1991 EPIA amendments specify that these refrigeration requirements apply to shell eggs after they have been packed into a container destined for the ultimate consumer. The 1991 EPIA amendments also require that egg handlers label the shell egg containers to indicate that refrigeration is required (21 U.S.C. 1034(e)(1)(B)). In addition, these amendments require that any eggs packed into a container destined for the ultimate consumer and imported into the United States include a certification that the eggs have, at all times after packaging, been stored and transported at an ambient temperature that is no greater than 45°F (7.2°C) (21 U.S.C. 1046(a)). The 1991 EPIA amendments specify that these requirements become effective 12 months after promulgation of final regulations implementing the EPIA amendments (21 U.S.C. 1034 note).

The Agricultural Marketing Service (AMS) proposed a rule in 1992 to implement the 1991 EPIA amendments (57 FR 48569, October 27, 1992); however, AMS never published a final rule incorporating these amendments into the regulations governing the inspection of eggs and egg products. Following enactment of the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 (Pub.L. 103–354; 7 U.S.C. 2204e), food safety issues were consolidated in FSIS. Because these statutorily mandated requirements are intended to improve food safety, FSIS, rather than AMS, is promulgating this final rule to revise the regulations governing the inspection of eggs and egg products to implement the 1991 EPIA amendments. By January 1, 1999, FSIS and AMS will publish revisions to the regulations transferring the provisions concerning refrigeration and labeling of shell eggs from 7 CFR, Chapter I, to 9 CFR, Chapter III, so that these provisions will be in the same title as the Federal meat and poultry products inspection regulations.

The 1998 Appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies (1998 Appropriations) (Pub.L. 105–86) provides that $5 million of FSIS' annual appropriation will be available for obligation only after the Agency promulgates a final rule to implement the refrigeration and labeling requirements included in the 1991 EPIA amendments. The Agency is thus revising its regulations to implement these requirements. FSIS is adopting the proposed regulations published in 1992 concerning refrigeration and labeling of shell eggs with some technical changes based on its review of the proposed rule and the comments on that proposal.

In addition to the refrigeration and labeling requirements, AMS's proposed rule included revisions to 7 CFR Part 56, Grading of Shell Eggs and U.S. Standards, Grades, and Weight Classes for shell eggs. FSIS is publishing this final rule on the refrigeration and labeling requirements but is not revising part 56.

Under the 1991 EPIA amendments, USDA is responsible for enforcing the refrigeration and labeling requirements at storage facilities and transport vehicles of shell egg packers (21 U.S.C. 1034(e)(1) and (2)). The Secretary of Health and Human Services is responsible for enforcing the labeling and refrigeration requirements at food manufacturing establishments, institutions, and restaurants, other than plants packing eggs (21 U.S.C. 1034(e)(3)).

On May 19, 1998 (63 FR 27502), FSIS and the Food and Drug Administration (FDA) published an advance notice of proposed rulemaking (ANPR) concerning *Salmonella* enteritidis (SE) in eggs. Through this notice, the Agencies are seeking to identify farm-to-table actions that will decrease the food safety risks associated with shell eggs. The ANPR may result in additional Agency actions concerning shell eggs. Although this final rule may bring about a small reduction in SE risk, it does not address many of the underlying food safety problems posed by eggs. These problems can only be dealt with in the context of a broader process that examines a variety of food safety issues in addition to ambient air temperatures. Through the ANPR, FSIS and FDA are looking at how best to address the food safety concerns of shell eggs as part of their mutual farm-to-table HACCP strategy. Any additional actions that may result from this process will be considered in light of identified public health risks and available alternatives.

On June 12, 1998, FSIS completed a risk assessment concerning SE in shell eggs and egg products in response to an increasing number of human illnesses associated with consumption of shell eggs (FSIS, *Salmonella Enteritidis Risk Assessment*, Washington, DC, June 12, 1998). The objectives of this risk assessment are to: establish the unmitigated risk of foodborne illness from SE, identify and evaluate potential risk reduction strategies, identify data needs, and prioritize future data collection efforts. This risk assessment developed a model to assess risk throughout the egg and egg products continuum. The risk assessment model was used to estimate the possible benefits of this rule, as discussed below.

Comments

One hundred and fifty-nine comments were submitted in response to the proposed rule. Thirty-one commenters, including private citizens, State departments of agriculture, several trade associations, and several members of the egg industry, supported the proposal. The remainder of commenters opposed the proposed rule or suggested alternatives to it. Commenters opposed to the rule included private citizens, trade associations, and members of the egg industry. The majority of comments from the egg industry opposed the rule and suggested alternatives to it. Six comments were received after the close of the comment period. All of these comments were generally opposed to the proposed rule.

Size of Establishments Required to Comply With the Rule

Several small producers recommended exempting from the refrigeration and labeling requirements producers with flocks of 5,000, 10,000, or 50,000 hens, or exempting producers that marketed a specified number of cases of eggs or a specified number of eggs per week, such as 500 cases per week or 1,200 eggs per week. These producers wanted an exemption from the refrigeration requirements because, they stated, the high costs of complying with the refrigeration requirements would effectively force them out of business. In contrast to these comments from small producers, several other producers and several associations stated that all egg industry members should be treated equally, and that no producers should be exempt from the refrigeration and labeling requirements.

Several commenters stated that they had flocks of less than 3,000 layers but packed eggs from other producers. These commenters asked whether the refrigeration and labeling requirements would apply to them.

Consistent with current regulations that exempt from inspection egg handlers with flocks of 3,000 or fewer birds (see § 59.100), the 1991 EPIA amendments specify that any egg handler with a flock of 3,000 layers or less is not subject to inspection for purposes of verifying compliance with the refrigeration and labeling requirements (21 U.S.C. 1034(e)(4)). Given this consistency, FSIS is responding to Congress's clear intent and limiting the exemption from the refrigeration and labeling requirements in § 59.50 to egg handlers with flocks of 3,000 or fewer layers (§ 59.50(c)).

In response to the comments suggesting that the refrigeration and labeling requirements should apply to all producers, the Agency points out that the statute provides that the refrigeration and labeling requirements in the 1991 EPIA amendments are not applicable to any egg handler with a flock of 3,000 or fewer layers. FSIS concludes that, for clarity, it is appropriate to reflect this fact in its regulations with an exemption.

Egg packers who obtain eggs from other producers will not be exempt from the refrigeration and labeling requirements. The exemption will only apply to egg handlers with a flock of 3,000 or fewer layers who pack eggs from their own flock. This exemption is consistent with the exemption from registration requirements for producer-packers with an annual egg production from a flock of 3,000 hens or less (see § 59.690).

Costs of the Rule

Approximately half the commenters stated that the rule would impose major costs on the industry. Many small businesses stated that the compliance costs associated with this rule could force them out of business.

Several commenters stated that they believed that the cost estimates in the 1992 proposed rule were too low and provided their own cost projections. For example, one small producer stated that it would cost its family-owned business approximately $200,000 to comply with the requirements. One association that represents the poultry, egg, and allied industry received information from its members on the price of refrigerated trucks: One member estimated that a new 26 foot refrigerated tractor trailer would cost $92,000, and another producer stated that a used refrigerated trailer portion costs $25,000. The association stated that, on the basis of this information, the cost of replacing and modifying the industry's fleet might exceed the estimates made by the Department.

In addition, several commenters stated that costs would be particularly high because at the time the proposed rule was published, the Environmental Protection Agency (EPA) was revising laws concerning refrigerants. These commenters believed that, subsequent to purchasing new refrigeration equipment to comply with the 45°F refrigeration requirements, they would again be required to replace refrigeration equipment once the new EPA laws regarding refrigerants went into effect.

Five members of the industry stated that the proposed rule would be extremely costly to the entire shell egg industry. These commenters stated that the cost analysis included in the 1992 proposed rule ignored major costs, such as new higher powered refrigeration units for both warehouses and vehicles, greater insulation requirements for warehouses and vehicles, ongoing depreciation expenses per year on the new refrigeration equipment, replacement costs of new equipment after its useful life, yearly maintenance costs, much higher ongoing yearly energy costs required for higher powered refrigeration units, and the effects of inflation. These commenters stated that compliance costs would outweigh any benefits of reducing cases of salmonellosis. In addition, these commenters stated that the increased compliance costs would force smaller producers and smaller distributers out of business, resulting in layoffs and

higher rates of unemployment. In addition, they stated that the higher cost of compliance would result in higher consumer prices for eggs.

The same five commenters discussed in the preceding paragraph stated that the requirements for imported eggs could also have a negative impact on international trade. These commenters stated that food products prepared with shell eggs abroad may not meet the U.S. refrigeration requirements for shell egg production. Thus, they maintained, the refrigeration requirements would lead to restrictions on imports of foreign food items prepared with shell eggs if refrigeration requirements in a particular country did not meet U.S. standards.

Finally, one association suggested costs to the industry might increase because of increased taxes on energy consumption.

Although the Agency agrees this rule is likely to result in an increase in costs to the industry, the 1991 EPIA amendments and the 1998 Appropriations require that FSIS promulgate this final rule. The Agency's current cost impact analysis is discussed below, under the heading, ''Incremental Social Costs.'' The original analysis of the costs of the regulation was conducted in 1992. The current analysis updates the 1992 cost estimates for inflation and changes in the State regulatory environment. The comments submitted in response to the analysis in the proposed rule were based on 1992 costs. For these reasons, the Agency is providing opportunity for comment on the updated economic impact analysis.

In the discussion of the cost to the industry, the Agency notes that many States already have enacted laws that require ambient temperatures of 45°F for shell egg storage and transportation. As explained below, producers in these States may not incur any significant costs as a result of this rule. In the other States, there is likely to be some increase in costs to the industry.

In regard to EPA laws concerning refrigerants, FSIS notes that those laws are in effect. At this time, the industry will have met these EPA requirements. Therefore, these regulations will not affect industry compliance with EPA requirements.

In response to the comments on international trade, it should be noted that the requirements in these regulations apply to imported shell eggs that are not imported under disease restriction and are destined for the ultimate consumer. The requirements do not apply to other imported processed food products containing eggs.

Finally, with regard to costs that may be imposed due to taxes on energy consumed, no significant new taxes have been imposed based on energy consumed.

Transportation

Many comments from members of the egg industry concerned problems with complying with the proposed transportation requirements. Some commenters stated that the cost of complying with the transportation requirements would be extremely high for them. Others stated that maintaining 45°F during transportation would not be possible. For example, one company stated that its trucks average sixteen deliveries per load, and, in certain situations, the truck doors remain open for ten to fifteen minutes during delivery. Therefore, the company explained, on a warm day, it is impossible to maintain the 45°F temperature in the truck. Another commenter stated that producers servicing family-owned markets and restaurants use a truck with less than one ton capacity, and that a truck of this size is not made with a refrigeration unit with enough cooling capacity to maintain 45°F. One association explained that many of its members believed that the constant opening and closing of the truck's storage compartment during local deliveries would prevent the truck from reaching an ambient temperature of 45°F.

About 20 commenters offered a variety of alternative options for exempting small producers from the requirement that shell eggs remain refrigerated during transportation. These alternative options included exempting from refrigeration requirements eggs delivered within a certain radius of the packing facility, eggs delivered in a certain size truck, and eggs delivered within a certain specified delivery time.

The specific requirement of the 1991 EPIA amendments is that shell eggs be refrigerated at 45°F during transportation. Other than the exemption for egg handlers with 3,000 or fewer layers, the statute does not provide any exemptions from the requirement that shell eggs be refrigerated during transportation. Therefore, the Agency has no discretion concerning this requirement and is not making the changes in the regulations that were requested by the commenters.

Alternative Temperature Requirements

About 15 commenters suggested that eggs should be held at temperatures above 45°F, such as 50°F, 55°F, or 60°F. One commenter noted that the current voluntary grading program regulations require that eggs be kept at 60°F, and that a change to 45°F would be a significant change. Several commenters stated that refrigerating eggs at 45°F would cause them to ''sweat'' when they are exposed to non-refrigerated conditions. These commenters stated that wet eggs can allow the passage of waterborne bacteria into the egg.

Several commenters offered suggestions for additional refrigeration requirements. One member of the industry suggested that the rule might be enhanced if it specified the time allowed for the shell eggs to reach an internal temperature of 45°F. Several other commenters recommended establishing refrigeration requirements that would apply to eggs prior to packing. For example, one State department of agriculture suggested that shell eggs should be refrigerated at 55°F or lower, within 24 hours of being laid, until the egg is washed and packed.

The statute specifically requires that eggs packed for consumer use be stored and transported at 45 °F. Therefore, the Agency has no discretion concerning the required temperature.

In response to the suggestions concerning additional refrigeration requirements, the 1991 EPIA amendments do not specify requirements concerning the internal temperature of eggs or an ambient temperature requirement for eggs that are not yet packed. However, these actions may be considered as part of the review that flows from the joint FSIS/FDA ANPR. FSIS or FDA may take further action in response to these comments at a later time.

Benefits of the Regulation

Approximately 50 commenters questioned whether this regulation would result in any health benefits. Commenters stated that safety problems related to eggs are caused by inadequate food preparation in restaurants and hotels, and that refrigeration by the producer will not remedy this problem. Similarly, several commenters noted that problems often arise because of mishandling by the consumer. Other commenters stated that the Agency should focus efforts on specific egg production establishments or particular regions where *Salmonella* has been detected.

Five comments from members of the shell egg industry stated that there was inadequate scientific evidence to justify the proposal, and that available studies show that relatively few salmonellosis cases can be attributed directly to shell eggs. Therefore, these commenters asserted, there is a need for more complete epidemiological studies and

documentation of actual salmonellosis cases that are directly linked to inadequate refrigeration of shell eggs held by producers and distributors. These commenters noted that studies show no growth of SE in eggs with an *internal* temperature of 45 °F; however, the commenters explained that the internal temperature of eggs will not reach 45 °F as soon as they are stored under refrigeration. They also argued that packed eggs may never reach this temperature throughout the distribution process. Similarly, another commenter stated that commercial processing plants will be unable to bring eggs to 45 °F before they are transported, especially when they are packed in cartons, cased, and stacked on pallets. This commenter also questioned whether the ambient temperature refrigeration requirements would improve the safety of shell eggs.

In contrast, several commenters stated that they believed that these regulations would improve the safety of shell eggs. For example, one medical association stated that existing scientific evidence provides a sufficient basis for requiring that shell eggs be stored and transported in refrigerated trucks at an ambient temperature of 45 °F, and that this refrigeration requirement would control the replication of SE. This commenter stated that, once the rule is effective, reported cases of SE in humans will be markedly reduced. An epidemiologist employed by a Federal agency stated that most human outbreaks of SE in which shell eggs were the probable source could have been prevented if time and temperature abuse had not taken place.

Although there is no consensus concerning the level of health benefits these regulations may achieve, the 1991 EPIA amendments and the 1998 Appropriations require that FSIS promulgate this final rule.

In response to concerns regarding food safety problems because of mishandling of eggs at retail establishments, FDA may propose a rule addressing refrigeration of eggs at retail, as discussed in the ANPR.

With regard to public education efforts, the Food Safety Education and Communications Staff within FSIS provides information to the public concerning numerous food safety issues, including egg-related food safety issues. This office provides food safety education information through USDA's Toll-Free Meat and Poultry Hotline (1–800–535–4555), through public service announcements, printed materials, and a variety of communication channels. In addition, FSIS makes this information available over the Internet (URL: http://www.fsis.usda.gov/).

Finally, as noted under the heading, ''Incremental Social Benefits,'' the Agency has estimated that these regulations would result in a mean reduction of 1.54 percent in salmonellosis cases related to SE in shell eggs. To estimate the reduction of the number of salmonellosis cases that would result from the implementation of these regulations, FSIS's risk assessment model, discussed below, was adjusted so that all eggs were exposed to ambient temperatures of 45 °F or lower after packing. The risk assessment predicts that additional measures would result in greater benefits than would result from the ambient temperature requirements in this rule. For example, the risk assessment predicts that maintaining ambient temperatures of 45 °F throughout processing and distribution (that is, from processing through retail) will result in an eight percent average reduction in human SE illnesses. In addition, the risk assessment model predicts that maintaining internal temperatures of eggs at 45 °F would result in a twelve percent decrease in human SE illnesses (FSIS, *Salmonella Enteritidis Risk Assessment*, Washington, DC, June 12, 1998: 26–27). The Agency recognizes that requiring an internal shell egg temperature of 45 °F (7.2 °C) would result in greater benefits than an ambient temperature requirement; however, the statute provides for an ambient temperature requirement only, and any such additional requirement will have to be considered in response to the ANPR.

Labeling Requirements

Approximately 30 commenters were opposed to the labeling requirements. Some of the commenters mistakenly believed ''warning labels'' would be required. Others stated that the labeling provisions were unnecessary because they believed consumers know that eggs should be refrigerated. Finally, many of these commenters believed the labeling requirements would be costly for producers, and that increased costs would be incurred by consumers.

Several commenters who supported the labeling requirements suggested requiring additional information on egg containers, such as a ''pull date'' or expiration date; a statement identifying the flock that produced the eggs in the container; the phrase, ''keep refrigerated at 45°F or below''; and the packing date and the packing plant number.

Three comments were from companies promoting time/temperature indicators. The companies explained that these indicators are labels that act as temperature recording devices and change color to indicate the temperature at which the carton is held and the length of time the carton is held at a particular temperature. These commenters suggested that time/temperature indicators should be affixed to egg cartons.

Establishments can meet the labeling requirements adopted in this rule (see §§ 59.50(b), 59.410(a), 59.950(a)(4), and 59.955(a)(6)) simply by including the phrase, ''Keep Refrigerated,'' or words of similar meaning, on the egg containers. Therefore, the labeling provisions do not require a warning statement. The Agency has determined that adding this phrase to shell egg labeling will result in only minimal costs for producers that do not currently include this labeling on egg cartons. Furthermore, many producers are currently labeling egg cartons to indicate that the product should be kept refrigerated.

With regard to the recommendations for additional labeling requirements, the statute does not specify any additional labeling provisions, and the Agency is not including additional labeling requirements in these regulations.

Implementation Details

Several commenters questioned how the rule would be implemented and provided suggestions concerning methods for measuring the temperature in transportation vehicles and storage facilities. For example, several commenters questioned the particular location an inspector would use inside a cooler or a truck to obtain the ambient temperature. One commenter recommended that the temperature should be checked at least 10 minutes after all doors are closed. One commenter asked what would happen during a mechanical breakdown, and whether producers should use recording thermometers both in cooler rooms and trucks. One association suggested that inspection of coolers be handled on a case-by-case basis because, the association explained, no two coolers are alike, and their configurations and holding capacities differ. The association also recommended that cooler doors be closed for at least five minutes before temperature readings are taken, and that readings be taken in at least three locations. This same commenter recommended that truck inspections be limited to trucks on property not being loaded, and that inspection of trucks occur before loading, with the door closed for at least five minutes and refrigeration equipment operating. Finally, this same commenter stated that when plants are

found to be out of compliance with the temperature regulations, consideration should be given for re-inspection within the annual quarter before a citation is issued.

Several commenters questioned the intent of proposed § 59.134(b). They were concerned that the provision stating that ''the perimeter of each cooler room * * * shall be made accessible'' would require that they create a walking aisle around the cooler room, or that the entire perimeter would need to be accessible for inspection. The commenters explained that to make the entire perimeter accessible to an inspector would result in reduced storage capacity and increased costs.

In response to the concerns about accessibility of the perimeter of the cooler room, the Agency advises that it does not intend that producers would be required to reduce storage space or create a walking aisle. The Agency is specifying that the perimeter must be accessible because it may often be the warmest area in the cooler, and because the center of the cooler room is typically accessible. An establishment could comply with the requirement that the perimeter of the cooler room be made accessible to inspectors by locating thermometers along the perimeter or allowing inspectors to use extension devices with attached thermometers to obtain the temperature along the perimeter.

The rule will not be effective until a year after the publication date. The Agency is currently considering various policy options for monitoring industry compliance with the rule. In response to the question concerning whether producers should use recording devices in cooler rooms and trucks, producers may install thermometric equipment and temperature recording devices; however, these regulations do not require that producers do so. FSIS requests comments on implementation of this rule.

Longer Phase-In Period

Several commenters recommended that the Department implement the rule over a phase-in period (two commenters suggested a three-year phase-in period), explaining that a phase-in period would provide producers adequate time to bring their equipment into compliance. Similarly, a small producer that expressed general support for the rule argued that the effective date for the final rule should be extended beyond a year from publication to allow the industry more time to meet the refrigeration requirements.

The EPIA specifies that the refrigeration and labeling requirements become effective 12 months after promulgation of final regulations implementing the amendments (21 U.S.C. 1034 note). Therefore, the Agency does not have the authority to provide for an extended phase-in period.

Technical Suggestions

A State department of agriculture commented that the proposed definition of ''immediate container'' is confusing and recommended changing the phrase ''not consumer packaged,'' as used in the proposed definition, to ''not packaged by the consumer.''

In response to the comment concerning the definition of ''immediate container,'' the Agency points out that the phrase, ''not consumer packaged'' refers to eggs packed for a buyer, such as a restaurant or hotel, that buys containers of eggs larger than those for household consumers. This definition simply provides that an immediate container could be a carton for household consumers or a larger container for a restaurant or other institution. To clarify the definition, FSIS has revised it to read, ''Immediate container means any package or other container in which egg products or shell eggs are packed for household or other ultimate consumers.''

One commenter questioned the intent of the provision in proposed § 59.132, which stated that ''access shall not be refused at any reasonable time to any representative of the Secretary to any plant, place of business, or transport vehicle subject to inspection.'' This commenter suggested wording that would provide that access be provided to any representative of the Secretary at any time business operations are being conducted.

In § 59.132, as well as in § 59.760, FSIS has removed the phrase ''at any reasonable time,'' which the commenter questioned, for greater consistency with the EPIA, which does not limit Agency access to establishments (see 21 U.S.C. 1034). FSIS is also making these changes for greater consistency with the Federal meat and poultry inspection regulations (see 9 CFR 381.32 and 9 CFR 306.2), which do not restrict Agency access to establishments.

The Final Rule

When these regulations become effective, egg handlers with flocks of more than 3,000 layers will be required to comply with the new refrigeration and labeling provisions. Consistent with current regulations that exempt from inspection egg handlers with flocks of 3,000 or fewer birds (see § 59.100), the 1991 EPIA amendments specify that any egg handler with a flock of 3,000 layers or less is not subject to inspection for purposes of verifying compliance with the refrigeration and labeling requirements (21 U.S.C. 1034(e)(4)).

To monitor temperatures in storage rooms and transport vehicles, egg handlers with flocks of more than 3,000 layers may choose to install thermometric equipment and temperature recording devices; however, these regulations do not prescribe the means by which egg handlers are to comply with these provisions or to monitor their compliance. These regulations allow establishments the flexibility to determine how to meet the statutory requirements and how to monitor and ensure their compliance. U.S. Department of Agriculture (USDA) inspectors will verify that storage facilities and transport vehicles are refrigerated at or below 45°F (7.2°C).

In § 59.5, FSIS is adding new definitions to the regulations to reflect the terminology in the 1991 EPIA amendments. AMS proposed adding all of these definitions in the 1992 proposed rule. FSIS has added the term ''ambient temperature,'' as used in the 1991 amendments, to clarify that the 45°F (7.2°C) refrigeration requirement refers to the air temperature maintained in a shell egg storage facility or transport vehicle.

The regulations include a definition for ''ultimate consumer'' that reflects how this term is used in the 1991 amendments. The Agency has defined the ''ultimate consumer'' as any household consumer, restaurant, institution or any other party who has purchased or received shell eggs or egg products for consumption. In 1992, AMS proposed to define this term as a household consumer, retail store, restaurant, institution, food manufacturer or other interested party who has purchased or received shell eggs or egg products for use or resale. After review of the proposed language, FSIS determined that an ultimate consumer should be defined as a party that purchases shell eggs or egg products for *consumption*, rather than for use or resale. Therefore, FSIS determined that a retail store or food manufacturer would not be considered an ultimate consumer and has modified the definition accordingly. The term ''ultimate consumer'' is used in the existing regulations, and each time it is used, examples of ''ultimate consumers'' follow the term. As was proposed, FSIS has revised §§ 59.28(a)(1) and 59.690 to remove these examples, because the term will now be included in the definitions section.

The 1991 EPIA amendments specifically refer to eggs that have been packed into a ''container'' and establish refrigeration requirements for shell eggs after packing (21 U.S.C 1037(c)). To implement these amendments, this final rule adds new language to the definition of ''container or package'' to refer to shell eggs in containers destined for the ultimate consumer. The current definition for ''container or package'' does not provide specific examples of a container or package for shell eggs. Therefore, as was proposed, FSIS has revised the definition of ''container or package'' to distinguish between containers for egg products and containers for shell eggs. In the definition of ''immediate container'', FSIS has modified the language proposed in 1992 to clarify that an immediate container means any package or other container in which egg products or shell eggs are packed for household or other ultimate consumers. The labeling requirements would apply to all types of containers (that is, both immediate containers and shipping containers).

As was proposed, FSIS has revised the definition of the term ''egg handler'' to clarify that the ultimate consumer is not considered an egg handler.

As was proposed in 1992, FSIS is incorporating the refrigeration and labeling requirements prescribed by the 1991 EPIA amendments for domestic shell eggs into its regulations by adding §§ 59.50 and 59.410(a). In these sections, FSIS has made only minor revisions to the provisions proposed in 1992. Section 59.410(a) provides that all shell eggs packed into containers destined for the ultimate consumer be labeled to indicate that refrigeration is required and includes an example of labeling that would meet this requirement, ''Keep Refrigerated.'' The provision also allows establishments to use other words of similar meaning.

To reflect the fact that the 1991 amendments specify that egg handlers with flocks of 3,000 or fewer layers are not subject to inspection for purposes of verifying compliance with refrigeration and labeling requirements, § 59.50(c) includes new language that clarifies that producers-packers with a flock of this size are exempt from these refrigeration and labeling requirements.

As was proposed in 1992, FSIS is amending §§ 59.132, 59.134, and 59.760 to clarify that inspectors must be granted access to transport vehicles and cooler rooms to verify that any shell eggs packed into containers for the ultimate consumer are stored and transported at an ambient temperature of no greater than 45°F (7.2°C). Transport vehicles that would be subject to inspection would include containers holding eggs that are attached to railroad cars or semi-trailer chassis.

As discussed above, FSIS has revised the provisions proposed in 1992 under §§ 59.132 and 59.760 to remove the phrase ''at any reasonable time'' for greater consistency with the EPIA and for greater consistency with the Federal meat and poultry inspection regulations.

FSIS has also revised the provision proposed in 1992 under § 59.760 to refer to representatives of the ''Secretary'' rather than representatives of the ''Administrator.'' In the near future, FSIS intends to revise the current definition of ''Administrator'' in this part, which refers to the Administrator of AMS, to refer to the Administrator of FSIS. Because AMS retains surveillance activities under § 59.760, FSIS has revised this section to refer to representatives of the ''Secretary'' rather than representatives of the ''Administrator.'' This revision reflects a change in Agency organization made in response to the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994.

As was proposed in 1992, FSIS has revised § 59.915 to incorporate the statutory amendment that imported shell eggs packed into containers destined for the ultimate consumer include a certification stating that the eggs have, at all times after packing, been stored and transported under refrigeration at an ambient temperature of no greater than 45°F (7.2°C). In addition, §§ 59.950 and 59.955 require that imported shell egg containers and imported egg shipping containers be labeled to indicate that refrigeration is required. In each of these sections, FSIS has made only minor changes to the language AMS proposed in 1992.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Has no retroactive effect; and (2) does not require administrative proceedings before parties may file suit in court challenging this rule. Public Law 102–237 provides that with respect to the temperature requirements contained therein, no State or local jurisdiction may impose temperature requirements pertaining to eggs packaged for the ultimate consumer which are in addition to, or different from, Federal requirements.

Executive Order 12866

FSIS is required to publish these regulations to comply with the 1991 EPIA amendments and the 1998 Appropriations. This rule has been designated significant and was reviewed by the Office of Management and Budget under Executive Order 12866. Executive Order 12866 requires USDA to identify and, to the extent possible, quantify and monetize benefits and costs associated with the rule. This section estimates these benefits and costs. As discussed below, because of changes in State laws concerning the refrigeration of shell eggs, FSIS has changed the baseline that was used for determining costs in the 1992 proposed rule. If the Agency had used the original baseline, the estimated costs would have been higher than the estimates in this rule. In addition, the benefits in this rule are based on the recently completed SE risk assessment and data that were not available in 1992. The estimated annual benefits of this rule are lower than those estimated in 1992 (see 57 FR 48572).

Incremental Social Benefits

The incremental social benefits of the rule are the avoidance of illnesses and deaths associated with consumption of eggs contaminated with SE. SE is a serotype of the family of pathogen *Salmonella.* When the disease affects humans, it causes salmonellosis, which usually appears 6 to 72 hours after eating contaminated eggs and egg products and lasts up to 7 days. Symptoms of this disease include diarrhea, abdominal cramps, fever, nausea, and vomiting (nausea and vomiting develop in less than 50 percent of cases). Children, the elderly, and people with compromised immune systems are particularly vulnerable to SE infection. Deaths from SE disease occur in these vulnerable groups. Statistics of outbreaks reported to the Centers for Disease Control and Prevention (CDC) on foodborne diseases reveal that an increasing number of salmonellosis cases are associated with SE; however, it should be noted that the CDC actively contacts each State to obtain information concerning SE but does not actively contact the States for information on the other *Salmonella* serotypes.

From 1985 to 1993, consumption of eggs was associated with 83 percent of SE-related outbreaks where a food vehicle was identified (CDC, ''Outbreak of *Salmonella enteritidis* Associated with Homemade Ice Cream—Florida, 1993,'' *Morbidity and Mortality Weekly Report* 43(36) (September 16, 1994): 669–671). The proportion of cases of salmonellosis reported to CDC attributable to SE increased from 5 percent in 1976 to 26 percent in 1994 (CDC, ''Outbreaks of Salmonella

Serotype Enteritidis Infection Associated with Consumption of Raw Shell Eggs—United States 1994–1995,'' *Morbidity and Mortality Weekly Report* 45(34) (August 30, 1996): 737–742). In 1995 and 1996, salmonellosis cases attributable to SE represented about 25 percent of salmonellosis cases reported to the CDC. Preliminary data from the Foodborne Diseases Active Surveillance Network (FoodNet) indicate that SE represented 17% of all cases of *Salmonella* in 1996 (*FSIS, FSIS/CDC/FDA Sentinel Site Study: The Establishment and Implementation of an Active Surveillance System for Bacterial Foodborne Diseases in the United States*, February 1997).

In the discussion below, FSIS assumes that SE cases associated with the consumption of eggs represent 25 percent of all human salmonellosis cases. This assumption is based on the percentage of SE cases reported to the CDC in recent years. FSIS is using this percentage rather than the 17 percent based on FoodNet data because the FoodNet database is still being implemented and covers only Minnesota, Oregon, and counties in Connecticut, Georgia, and California. In addition, only the first year of data is available from the Foodnet. The CDC surveillance system has been active for approximately 30 years, all States contribute to the CDC surveillance data, and States receive incentives for submissions to the CDC surveillance system.

In 1996, 39,027 confirmed cases of human salmonellosis were reported to the CDC by State, local, and Federal departments of health. From 1985 through 1996, there have been 508,673 reported cases of salmonellosis (Centers for Disease Control and Prevention, Laboratory Confirmed *Salmonella*, Surveillance Annual Summary, 1993–1995 and 1996). Based on CDC outbreak data, the three illness-causing serotypes most frequently reported—*Salmonella* typhimurium, *Salmonella* heidelberg, and *Salmonella* enteritidis—are most often traced to poultry and eggs when a food vehicle is found. A food vehicle is found in only about 25 to 30 percent of cases.

Since the reporting of outbreak statistics to CDC is voluntary, it is estimated that there are an additional 20 to 100 cases of salmonellosis for every reported case, or some 800,000 to 4 million cases per year (R. Chalker and M. Blaser, ''A Review of Human Salmonellosis: III. Magnitude of *Salmonella* Infection in the United States,'' *Review of Infectious Diseases* 10(1) (1988): 111–124). The severity of the underreported cases as well as their statistical distribution is unknown and hence this analysis could not adjust for such probabilities. The estimate of 800,000 to 4 million is based on the number of cases reported to the CDC surveillance system through 1996 and is confirmed by the data for the 1988–92 period.

TABLE 1.—HEALTH AND ECONOMIC BENEFITS OF REFRIGERATING EGGS AT 45°F RULE: LOW BENEFITS ESTIMATES

Annual number of egg-related human SE cases	Lower bound of health costs associated with column 1 in $ (1996) [1]	Upper bound of health costs associated with column 1 in $ (1996) [2]
661,633 [3]	$225 million	$900 million.
Estimated Reduction in Egg-Related SE Cases due to 45°F Refrigeration [4]		
Health benefits (number of cases avoided)	Lower bound of economic benefits associated with column (1) $ (1996)	Upper bound of economic benefits associated with column (1) in $ (1996)
10,189	$3.47 million	$13.86 million.

[1] Jean C. Buzby and Tanya Roberts, ''Guillain-Barré Syndrome Increases Foodborne Disease Costs,'' *Food Review* (September-December 1997): 36–42. This report provides an estimate of costs of total human Salmonella cases from all food sources. The costs estimated in this table assume that egg-related SE cases represent 25% of total human salmonellosis cases. The report estimates the lower bound of the low estimate of health care costs at $900 million.

[2] Ibid. The report estimates the upper bound of the low estimate of health care costs at $3.6 billion.

[3] FSIS, *Salmonella Enteritidis Risk Assessment*, Washington, DC, June 12, 1998. The number shown in the chart is the estimated mean number of salmonellosis cases resulting from the consumption of SE-contaminated eggs. The estimated number of cases per year in the *Risk Assessment* ranges from 126,374 to 1.7 million.

[4] FSIS, *Salmonella Enteritidis Risk Assessment*, Washington, DC, June 12, 1998. The risk assessment model estimates that refrigeration of eggs at 45°F during storage and transportation will result in a mean reduction of 1.54% in human SE cases.

TABLE 2.—HEALTH AND ECONOMIC BENEFITS OF REFRIGERATING EGGS AT 45° F RULE: HIGH BENEFITS ESTIMATES

Annual number of egg-related human SE cases	Lower bound of health costs associated with column 1 in $ (1996) [5]	Upper bound of health costs associated with column 1 in $ (1996) [6]
661,633 [7]	$1.2 billion	$3.075 billion.

TABLE 2.—HEALTH AND ECONOMIC BENEFITS OF REFRIGERATING EGGS AT 45° F RULE: HIGH BENEFITS ESTIMATES—Continued

Annual number of egg-related human SE cases	Lower bound of health costs associated with column 1 in $ (1996) [5]	Upper bound of health costs associated with column 1 in $ (1996) [6]
Estimated Reduction in Egg-Related SE Cases due to 45°F Refrigeration [8]		
Health benefits (number of cases avoided)	Lower bound of economic benefits associated with column (1) $ (1996)	Upper bound of economic benefits associated with column (1) in $ (1996)
10,189	$18.48 million	$47.355 million.

[5] Jean C. Buzby and Tanya Roberts, ''Guillain-Barré Syndrome Increases Foodborne Disease Costs,'' *Food Review* (September–December 1997): 36–42. This report provides an estimate of costs of total human Salmonella from all food sources. The costs estimated in this table assume that egg related SE cases represent 25% of all human salmonellosis cases. The report estimates the lower bound of the high estimate of health care costs at $4.8 billion.

[6] Ibid. The report estimates the upper bound of the high estimate of health care costs at $12.3 billion.

[7] FSIS, *Salmonella Enteritidis Risk Assessment*, Washington, DC, June 12, 1998. The number shown in the chart is the estimated mean number of salmonellosis cases resulting from the consumption of SE-contaminated eggs. The estimated number of cases per year in the *Risk Assessment* ranges from 126,374 to 1.7 million.

[8] FSIS, *Salmonella Enteritidis Risk Assessment*, Washington, DC, June 12, 1998. The risk assessment model estimates that refrigeration of eggs at 45°F during storage and transportation will result in a mean percent reduction of 1.54% in human SE cases.

Tables 1 and 2 show an estimated number of annual human illnesses resulting from consumption of SE-contaminated eggs. This number is based on the mean estimated annual number of cases in the *Salmonella Enteritidis Risk Assessment* published by FSIS (June 12, 1998). This report estimates that the number of cases of illness resulting from consumption of SE-contaminated eggs ranges from 126,374 to 1.7 million per year. The Agency is using data from the risk assessment rather than the number of reported cases because, as noted above, it is estimated that there are an additional 20 to 100 cases of salmonellosis for every reported case. Tables 1 and 2 display the mean estimate because the mean is not unduly affected by a few moderately small or moderately large values, and this stability increases with the sample size. To estimate the economic value of the health costs of salmonellosis, the USDA's Economic Research Service (ERS) related illnesses and deaths to four types of severity groups of patients. The four severity groups were: (1) those who did not visit a physician, (2) those who visited a physician, (3) those who were hospitalized, and (4) those who died prematurely because of their illness (Jean C. Buzby and Tanya Roberts, ''Guillain-Barré Syndrome Increases Foodborne Disease Costs,'' *Food Review* (September–December 1997): 36–42). Similar severity rates are also used in the risk assessment final report, e.g., treatment by a physician, hospitalization, and mortality. Both sources use the CDC data on severity.

Based on the avoidance of medical costs, ERS estimated the economic values of prevention of these cases. ERS calculated the range of low estimate of avoidance of all foodborne human salmonellosis-linked diseases and deaths, at $900 million and $3.6 billion respectively (in 1996 dollars). ERS calculated the range of high estimate of the health costs at $4.8 billion and $12.3 billion (in 1996 dollars). The wide variation in this range of estimates is attributed both to the wide range in estimates of the number of cases and the economic methods used for the analysis.

The economic methods are the human capital method and the labor market method. The human capital method yields a lower estimated range of $0.9 to $3.6 billion because the cost of premature death in this analysis varies with age and ranged from $15,000 to $2,037,000 (in 1996 dollars). The labor market approach yields the higher range of $4.8 to $12.3 billion because it values the cost of premature death at $5 million per person (in 1996 dollars) (Jean C. Buzby and Tanya Roberts, ''Guillain-Barré Syndrome Increases Foodborne Disease Costs,'' *Food Review* (September–December 1997): 36–42).

Since the ranges of estimates for salmonellosis-related costs estimated by Buzby and Roberts are based on salmonellosis from all food sources, it is necessary to adjust the estimates downwards to obtain only the cases of salmonellosis related to consumption of SE-contaminated eggs. The medical cost data shown in the first rows of Tables 1 and 2 represent 25 percent of the ERS estimates because FSIS assumes that SE-contaminated eggs are responsible for approximately 25 percent of salmonellosis cases. This assumption is based on the percentage of SE cases reported to the CDC and the fact that eggs are responsible for the vast majority of these cases. As noted above, from 1985 to 1993, consumption of eggs was associated with 83 percent of SE-related outbreaks where a food vehicle was found. Also noted above, a food vehicle is found in only about 25 to 30 percent of cases. Given the level of uncertainty in this data, for estimation purposes, the Agency believes it is appropriate to assume that SE-contaminated eggs are responsible for 25 percent of total salmonellosis cases.

Humphrey and Whitehead (1993) suggest that an egg's contents can become contaminated with SE before the egg is laid. They also note that after an infected egg is laid, SE contamination tends to grow inside the egg (T. Humphrey and A. Whitehead, ''Egg Age and Growth of Salmonella Enteritidis PT4 in Egg Contents,'' *Epidemiological Infection* 111 (1993): 209–219). Humphrey suggested that refrigerating during storage can prevent such growth (T.J. Humphrey, ''Growth of Salmonella in intact shell eggs: Influence of Storage Temperature,'' *Veterinarian Record* (1990): 1236–1292). Other measures for preventing growth include refrigeration during transportation and retail sales, reducing shelf life of eggs at retail, thorough

cooking, pasteurization, and processing shell eggs into frozen, liquid, or dry egg products (FSIS, *Salmonella Risk Assessment,* June 12, 1998; T. Hammack, et al., ''Research Note: Growth of Salmonella Enteritidis in Grade A Eggs During Prolonged Storage,'' *Poultry Science* 334 (1993): 1281–1286).

In order to determine the benefits of refrigerating eggs at 45°F, it is necessary to determine the percentage of reduction in the number of egg-related deaths and illnesses from SE cases referred to above. To determine these benefits, this analysis relied on input from a risk assessment model. In June 1998, FSIS completed a risk assessment concerning shell eggs and egg products in response to an increasing number of human illnesses associated with the consumption of shell eggs. The risk assessment developed a model to assess risk throughout the egg and egg products continuum. The risk assessment model consists of five modules. The first module, the Egg Production Module, estimates the number of eggs produced that are infected (or internally contaminated) with SE. The Shell Egg Module, the Egg Products Module and the Preparation and Consumption Module estimate the increase or decrease in the number of SE organisms in eggs or egg products as they pass through storage, transportation, processing and preparation. The Public Health Module then calculates the incidences of illnesses and four clinical outcomes (recovery without treatment, recovery after treatment, treatment by a physician, hospitalization, and mortality) as well as the cases of reactive arthritis associated with consuming SE positive eggs.

Refrigeration of shell eggs at an ambient air temperature of 45°F or below during storage and transportation will retard growth of SE and hence is likely to reduce the associated illnesses and deaths. The risk assessment model estimates that refrigeration of shell eggs at an ambient temperature of 45°F or below can bring about a mean reduction of 1.54 percent in egg-related human illnesses associated with SE. This estimate has a 90 percent confidence interval, with a lower bound of 0 percent and an upper bound of 7 percent. Therefore, there is a range of possible outcomes. Although a 1.54 percent reduction in illnesses associated with SE is the most likely outcome, the regulation could result in no reduction in illnesses or in a reduction as high as 7 percent. This estimate and its confidence interval are based on a model with the assumption that eggs are maintained at an ambient temperature of 45°F after processing through transportation to retail, or other, end users. This result also assumes complete compliance with the regulation. The effect of the regulation was modeled by adjusting the baseline model (consisting of the Production, Shell Egg Processing/ Transportation, Preparation/ Consumption, and Public Health modules) to reflect the regulation's effect. The model adjusted the following temperature variables in the Shell Egg Processing/Transportation module: Storage temperature after processing at off-line processor, Storage temperature after processing at in-line processor, Temperature during transportation to egg users. In the baseline model, these variables were modeled as extending from a low of 41°F, in the case of the storage temperature after processing at in-line processors, to a high of 90°F. The baseline model assumes that eggs are handled under a variety of different temperatures. In modeling the regulation, these variables' distributions were truncated at 45°F. Therefore, all eggs were exposed to ambient temperatures of 45°F or less after packing in the regulation model. The effect of the regulation was calculated as the difference in simulated total human cases between the baseline model and the regulation model. The percent reduction in human illnesses was then calculated by dividing this difference in human cases by the simulated total human cases from the baseline model. It must be noted that the estimated mean reduction in SE illnesses of 1.54 percent referred to above was estimated in a separate run of the model for this rule performed by FSIS scientists and is not included in the risk assessment final report. As noted above, the risk assessment final report estimates the benefits that would result from maintaining an ambient temperature of 45°F throughout processing and distribution (that is, from pre-packing and through retail) and the benefits of maintaining the internal temperature of eggs at 45°F throughout processing and distribution.

The last rows in Tables 1 and 2 show the reductions in SE cases associated specifically with refrigeration of shell eggs based on the mean value of 1.54 percent reduction in cases referred to above. These are the incremental social benefits of the rule. These estimates range from a low of $3.47 million to $13.86 million in Table 1 to a range of $18.48 million to $47.355 million in Table 2 (in 1996 dollars). Requiring refrigeration of eggs at an ambient air temperature of 45°F does not address all the food safety risks posed by shell eggs. Responses to the ANPR will assist FSIS and FDA in the development of a comprehensive, farm-to-table food safety strategy that will address a variety of food safety measures in addition to ambient air temperature. Actions taken subsequent to the analysis of alternatives identified in the ANPR may provide additional benefits associated with further reductions in foodborne illness associated with the consumption of shell eggs.

As noted above, FSIS and FDA have published an ANPR concerning SE in shell eggs (63 FR 27502; May 19, 1998). The number of cases in Tables 1 and 2 are larger than those reported in the ANPR (63 FR 27504) because the figures in the ANPR are based on outbreaks reported to the CDC, while the data on Tables 1 and 2 take into account the fact that many of the cases are unreported. In addition, the cost of illnesses in Tables 1 and 2 differ from those in the ANPR (63 FR 27504) because the estimates in the ANPR were based on 1991 data. FSIS used 1996 data for the cost and benefit analysis in these regulations.

Incremental Social Costs

The incremental social costs associated with the rule include the first year fixed capital costs and the annual recurring costs of compliance to be incurred by the industry. The first year costs would include the costs of replacing or retrofitting refrigeration units, compressors, and coils. These capital costs are required for storing shell eggs at 45°F or below after washing and packing. The capital costs to the industry would also include the costs of replacing or retrofitting transportation vehicles that have refrigeration units capable of producing air at 45°F or below. The annual recurring costs would encompass the energy costs of maintaining ambient temperatures in storage facilities and transportation vehicles at 45°F or below. These capital and recurring costs would be incurred either by shell egg producers or by their contractors for storage and transportation. When the storage or transportation services are contracted out, however, it is very difficult to separate the costs associated with shell eggs because these contractors store or haul not only shell eggs but also several other products.

An additional element of the social costs would be the *incremental* budgetary costs, if any, to USDA for enforcing this regulation. The Agency has not determined how it will enforce this rule. AMS may check the ambient temperature of shell egg storage

facilities and the labeling of shell egg containers during its surveillance of egg handlers and during grading activities. FSIS compliance officers may check the ambient temperature of shell egg storage facilities and transportation vehicles and the labeling of shell egg containers once the eggs leave the plant. For example, while compliance officers are checking meat and poultry products in commerce outside inspected establishments or at uninspected facilities, if such facilities store shell eggs, compliance officers may also check temperatures at these locations and verify that the labeling of egg containers meets the requirements in this rule.

Whether AMS or FSIS checks the temperature of shell egg storage facilities and transport vehicles and verifies that the labeling of egg containers meets the requirements in this rule, these activities are likely to be in addition to other Agency activities conducted at the same location. Checking temperatures and labeling will increase the time required for AMS or FSIS personnel to conduct their oversight activities. However, FSIS is unable to determine the amount of additional time that will be required. Therefore, the Agency is unable to estimate the additional costs (e.g., personnel costs and costs of equipment such as thermometers) that will be required for monitoring compliance with the requirements in this rule.

The costs of compliance to the industry are not likely to be excessive for three reasons. First, the rule exempts small producers with flocks of 3,000 layers or less. There are approximately 80,000 such small egg producers that would not be required to comply with the refrigeration and labeling provisions of this rule.

Second, of the approximately 700 producers currently registered with USDA as of July 1998, 329 are major producers with flocks of 75,000 or more who produce about 94 percent of U.S. table eggs. Most of these producers are members of United Egg Producers (UEP), an organization that provides a variety of services to member egg producers. The UEP already has a quality assurance program that recommends refrigerating eggs at 45°F or below as quickly as possible after washing and grading and that the same temperature be maintained during transportation. A letter from UEP indicated that many of these producers have already started refrigerating at 45°F or below. Therefore, these producers are unlikely to incur additional costs of compliance. (This aspect is elaborated later in a section on the Regulatory Flexibility Act (RFA).) It is likely that most producers that are not members of UEP or are not major producers have also begun refrigerating shell eggs during storage and transportation because of State requirements (discussed below). With regard to producers that are not members of the UEP or are not major producers, specific information regarding whether they store and transport shell eggs at 45°F is not available. The structure of egg industry is changing toward greater concentration of large producers. For example, the number of producers registered with AMS has declined from about 1,200 in 1992 to approximately 700 in July, 1998. The resulting concentration of larger producers who refrigerate their supplies is likely to have reduced the costs of compliance.

Third, many States have already enacted laws requiring specified ambient air temperatures for shell egg storage and transportation. Approximately one-half of all States require 45°F or less for storage and transportation. Approximately ten of these States have adopted 45°F refrigeration requirements since 1992. Some of these States are large producers. Many States also require that shell eggs be refrigerated at 45°F at retail. Approximately ten States retain the 60°F traditionally required under USDA grading standards. Approximately one dozen States have no refrigeration requirement for shell egg storage and transportation. Costs of compliance for the shell egg producers in the States already requiring refrigeration at 45°F are not likely to increase significantly. Some of the States that require 45°F refrigeration of shell eggs during storage and transportation are among States in which major producers are located, e.g., Ohio, Pennsylvania, and Georgia. However, there are States with major producers and other producers that do not require 45°F refrigeration during storage and transportation of shell eggs. The Agency requests information concerning the costs these regulations may impose on producers who are currently not refrigerating shell eggs at 45°F during storage and transportation. The Agency also requests information concerning the size of these establishments.

The rule proposed on October 27, 1992 for refrigerating shell eggs at 45°F or below estimated the first-year capital investment costs at $40.67 million (57 FR 48571). The annual recurring operating costs were estimated at $10 million. The capital investment costs involved replacing or retrofitting existing refrigeration units with larger compressors or coils. The recurring annual operating costs involved the energy costs of maintaining ambient air temperatures in storage facilities and transport vehicles at 45°F or below. These cost estimates were based on data obtained from a survey of 80 (7 percent) out of the 1200 shell egg processing plants located throughout the country representing about 25 percent of production. 59 plants (75 percent) responded to the survey. The Agency was unable to evaluate the comments regarding the specific large costs of acquiring trucks and equipment because the survey did not contain such detailed data.

The costs to comply with this final rule will be lower than the costs estimated for the proposed rule in 1992 because about ten States (e.g., Arkansas, Florida, Georgia, Louisiana, Ohio, Oregon, Rhode Island, and Texas) have already adopted refrigeration requirements at 45°F or below for storage and transportation since 1992. These States represented 29 percent of shell egg production in 1996. FSIS updated the 1992 estimates to account for inflation and changes in State laws. The Agency requests specific information concerning costs that will be incurred in States that have not enacted refrigeration requirements.

The costs estimated in 1992 were not adjusted upward for any of the comments to the proposed rule because about 10 States have implemented the 45°F refrigeration requirements since 1992. Since about ten out of fifty States representing 29 percent of production have implemented the rule since 1992, this analysis reduced the capital and recurring costs estimated in 1992 by 29 percent. This adjustment reduced the capital and recurring costs to $28.40 million and $7.1 million respectively. Therefore, costs were reduced based on shell egg production data. FSIS reduced costs based on production data because the 1992 costs were estimated and reported on a production basis (see 57 FR 48571–48572). The fact that the number of producers has declined since 1992 may further lower the costs to the industry because a smaller number of larger producers tend to have lower costs due to scale economies.

The updated costs referred to above were adjusted upwards because of inflation over the last six years. To adjust for this increase, FSIS increased the $28.40 million capital costs by 8 percent (based on U.S. Department of Commerce, Bureau of Economic Analysis, price index of transportation and related equipment index, 1992 = 100, 1997 = 108.5). This adjustment increased the capital cost estimate from

$28.40 million to $30.67 million, or $31 million approximately.

The updated recurring costs of compliance, estimated at $7 million per year in 1992, were assumed to comprise mostly energy costs of refrigeration. These estimates were increased for inflation over the last six years to $7.63 or $8 million approximately (based on U.S. Department of Commerce, Bureau of Economic Analysis, Price Index of Electricity and Gas, 1992 = 100, 1997 = 108.98, or by 9 percent). FSIS requests alternate cost estimates and data to support these estimates from commenters who disagree with the Agency's cost estimates.

The estimated costs of compliance and the associated social benefits of this rule are likely to be realized over the next twenty years. Therefore, these costs and benefits were discounted over this time span by using a 7 percent mid-year discount rate recommended by the Office of Management and Budget.

Table 3 reports FSIS estimates of the discounted costs and benefits of the rule under alternative assumptions about cost of salmonella induced foodborne illness. Depending on the assumption used, the estimated net benefits range from −$79.6 million to $401.30 million. Under the assumption that the cost of foodborne illness varies with age, the net benefits from the rule range from −$79.6 million to $34.2 million. Alternatively, if it is assumed that the cost of premature death is $5 million per person, the net benefits from the rule are higher, from $84.9 million to $401.3 million. In light of the uncertainty surrounding the benefit estimates and refinements to costs, FSIS cannot make a definitive statement about the net benefits associated with the rule.

TABLE 3.—DISCOUNTED BENEFIT-COST ESTIMATES OF REFRIGERATING SHELL EGGS

[Fixed Costs=$31 million, Recurring Costs=$8 million]

	Lower bound of low est.	Upper bound of low est.	Lower bound of high est.	Upper bound of high est.
Recurring benefits: ($ million)	3.47	13.86	18.48	47.36
Discounted Benefits*: ($ m.)	38.03	151.88	202.51	518.93
Discounted Costs*: ($ m.)	117.63	117.63	117.63	117.63
Net Discounted Benefits: (Row 2–Row 3) ($ m.)	−79.60	34.17	84.88	401.30
Benefit-Cost Ratio: (Row 2:Row 3)	0.32	1.29	1.72	4.41

*Discount Rate=7%, Time Period=20 years.
Source: Tables 1 and 2.

The preceding costs are likely to be passed on to consumers by the industry because of the elasticity of demand and supply of eggs. The demand for shell eggs is very inelastic, i.e., an increase in the price of shell eggs is not likely to reduce significantly the demand for them. For example, Kuo reports that the price elasticity of demand for shell eggs is only (−0.11), i.e., an increase in price by one percent is associated with only 0.11 percent decrease in quantity of shell eggs demanded (Huang S. Kuo, *A Complete System of U.S. Demand for Food*, USDA/Economic Research Service, Technical Bulletin No.1821, 1993, Appendix B and C).

The inelastic demand is due to the fact that there are no good substitutes for eggs that consumers might use when prices of shell eggs are increased. Also, a typical consumer spends an insignificant proportion of the food budget on shell eggs and consumes a limited number of eggs.

The supply of shell eggs is very elastic because this industry has hundreds of producers who can increase the supply of eggs with little increase in costs. This prevents price increases by any single producer and no producer can increase prices without losing significant market share. Therefore, egg prices have been stable, if not declining, for several years. For example, wholesale egg prices declined from 91.5 cents/dozen in 1996 to 83.8 cents/dozen in 1997. In the first quarter of 1998, this price declined to 82.5 cents/dozen. The average retail price of grade A large eggs was $1.1063/dozen in 1997 (U.S. Department of Labor/Bureau of Labor Statistics). Per capita consumption of eggs increased only slightly, from 237.8 eggs in 1996 to 239.3 eggs in 1997.

Regulatory Flexibility Act (RFA)

The Administrator has determined that this rule will not have a significant economic impact on a substantial number of small entities. As noted above, this rule exempts from compliance small producers with flocks of 3,000 layers or less. Most of the establishments not exempt from this rule are small establishments with employment of 500 or less. Also, the compliance costs are likely to be spread over a large volume of output that will be produced over the life cycles of these capital assets (e.g., refrigeration equipment). For example, according to the National Agricultural Statistics Service, 5.456 billion dozen eggs were produced between January 1, 1997 and December 31, 1997. During that time, the wholesale price for table eggs, estimated by ERS, was 83.8 cents per dozen, and the gross industry receipts were estimated at $3.96 billion. Therefore, the compliance costs would represent less than a penny per dozen eggs or less than one percent of revenues. Since these first year costs include nonrecurring capital costs for storage facilities and refrigerated vehicles, the impact on the industry would be substantially less in subsequent years. For example, the recurring costs in the subsequent years were estimated at $9 million per year. This cost would represent primarily the energy cost of generating refrigeration and the maintenance and replacement costs of storage facilities. The relative impact on small producers would be insignificant also because the current structure of the shell egg industry is more concentrated than in 1992. For example, currently there are only about 700 producers, compared to about 1,200 producers in 1992. The smaller number of producers with increased output is likely to have resulted in a greater concentration of larger firms in this industry. These larger firms are more likely to absorb the compliance costs relative to smaller firms. FSIS notes that increased costs will not be evenly distributed across the industry because some producers are currently storing and transporting shell eggs at 45 °F, while others are most likely storing and transporting shell eggs at higher temperatures.

The shell egg industry would be able to ''pass through'' this cost in the form of higher prices to consumers because, as noted earlier, demand for this product is very inelastic and the supply

of shell eggs is highly elastic. The inelasticity of the demand follows from the fact that household expenditures on eggs are a small share of household budgets and because substitutes for eggs—at least in some applications—are limited. The high elasticity of supply is based on the fact that there are hundreds of shell egg producers in the U.S. with relatively flat marginal cost curves. Thus, producers expand egg production with little increase in average costs.

The rule would not be burdensome to other small entities such as State and local governments because they are not in the business of storage and transportation of shell eggs. However, to the extent State and local governments are consumers of eggs, they will pay a little more for eggs.

Alternatives to the Rule

FSIS considered several alternatives to this rule. FSIS found the alternatives, which are described below, to be inferior to this rule because of their expected benefits and costs, administrative burden, efficiency, and equity.

No Action

This alternative would continue the current practice of no Federal requirement for refrigeration of shell eggs. The public health benefit would be zero because this alternative would not reduce *Salmonella* related illness. FSIS considered and rejected this alternative because, as noted above, the EPIA amendments mandate promulgation of this rule. In addition, as noted earlier, the Appropriations Committee has withheld $5 million of the FSIS appropriated funds for Fiscal Year 1998 until a final rule is promulgated to implement the refrigeration and labeling requirements included in the 1991 EPIA amendments. A loss of $5 million in the Agency's appropriation is likely to impair FSIS's inspection activities, and degrade food safety in general.

Sliding Scale Approach

This alternative does not require maintenance of a specific ambient temperature, such as the 45°F rule does. Under this approach, a specific ''sell-by'' date is mandatory, which would vary depending on the temperatures at which eggs are maintained. To provide an incentive for processors to chill eggs before shipping, yet retain flexibility to accommodate reasonable alternatives to an absolute temperature requirement, a regulation might prescribe a range of ''sell-by'' dates based on the egg temperature achieved by the packer. Such an approach is under consideration by the European Union but is not recommended for the U.S. because of differences in climate, and vast distances in the U.S. relative to within or even between countries in Europe. This alternative would be burdensome to the industry and difficult to implement because it would require detailed recordkeeping by the industry. Some public health benefits would be expected and would depend on the sell-by date/temperature matrix. Industry costs would depend on the matrix and which temperatures producers select. Finally, this alternative would be very difficult to enforce since USDA inspectors would have to keep track of hundreds of shell egg producers and billions of dozens of eggs.

State Rules Instead of Federal Rule

FSIS considered the alternative of actively encouraging State governments to promulgate their own laws instead of a Federal rule but did not adopt it for several reasons. First, as noted earlier, about half of all States currently have laws requiring refrigeration of shell eggs at 45°F. On the other hand, some States do not have any refrigeration requirements for shell eggs. Other States require refrigeration during storage but not during transportation. Some States require refrigeration of shell eggs at temperatures greater than 45°F. In contrast to these inconsistencies and non-uniformities, with the exception of shell eggs packed by egg handlers with 3,000 or fewer hens, this rule requires that all shell eggs packed in containers for the ultimate consumer be refrigerated during storage and transportation at 45°F or below. The public health benefits of this alternative are expected to be zero, since this alternative is essentially the same as no action except that States would be put on notice that they should deal with public health risks from eggs.

In view of the disparities within and across the States, FSIS determined that it would not be appropriate to defer to the States.

Summary and Conclusions

This section analyzed compliance of this rule with Executive Order 12866. It estimated discounted social benefits of the rule and juxtaposed them against discounted capital and operating costs of compliance with the rule. The analysis concluded that potential net social benefits may result from this rule.

This section also analyzed compliance of this rule with the Regulatory Flexibility Act. It is concluded that the costs of compliance are not likely to have a significant economic impact on a substantial number of small entities because the industry's cost of compliance amounts to less than a penny per dozen eggs, demand for eggs is inelastic, and the supply of eggs is highly elastic. In short, the egg producers could easily ''pass through'' the costs of compliance to consumers without losing their market shares. Other small entities such as local and State governments are also not likely to be adversely affected by this rule because they are not in the business of producing, storing, or transporting shell eggs. To the extent that they are large buyers of eggs, they would be adversely impacted by the estimated increase in price of a penny per dozen eggs.

Finally, this section analyzed several alternatives to the rule. These alternatives included: (1) no action, (2) sliding scale approach, and (3) State rules instead of a Federal rule. These alternatives were rejected because of their costs, administrative burden, efficiency, or equity.

Paperwork Requirements

The paperwork and recordkeeping activities associated with this rule are approved under OMB control number 0583–0106.

List of Subjects in 7 CFR Part 59

Eggs and egg products, Exports, Food grades and standards, Food labeling, Imports, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, FSIS is amending 7 CFR Part 59 as follows:

PART 59—INSPECTION OF EGGS AND EGG PRODUCTS (EGG PRODUCTS INSPECTION ACT)

1. The authority citation for part 59 continues to read as follows:

Authority: 21 U.S.C. 1031–1056.

2. Section 59.5 is amended by adding alphabetically the definitions for ''Ambient temperature'' and ''Ultimate consumer'' and revising the definitions for ''Container or Package'' and ''Egg handler'' to read as follows:

§ 59.5 Terms defined.

* * * * *

Ambient temperature means the air temperature maintained in an egg storage facility or transport vehicle.

* * * * *

Container or *Package* includes for egg products, any box, can, tin, plastic, or other receptacle, wrapper, or cover and for shell eggs, any carton, basket, case, cart, pallet, or other receptacle.

(a) *Immediate container* means any package or other container in which egg products or shell eggs are packed for household or other ultimate consumers.

(b) *Shipping container* means any container used in packing an immediate container.

* * * * *

Egg handler means any person, excluding the ultimate consumer, who engages in any business in commerce that involves buying or selling any eggs (as a poultry producer or otherwise), or processing any egg products, or otherwise using any eggs in the preparation of human food.

* * * * *

Ultimate consumer means any household consumer, restaurant, institution, or any other party who has purchased or received shell eggs or egg products for consumption.

* * * * *

3. Section 59.28 is amended by revising the first two sentences in paragraph (a)(1) to read as follows:

§ 59.28 Other inspections.

(a) * * *

(1) Business premises, facilities, inventories, operations, transport vehicles, and records of egg handlers, and the records of all persons engaged in the business of transporting, shipping, or receiving any eggs or egg products. In the case of shell egg packers packing eggs for the ultimate consumer, such inspections shall be made a minimum of once each calendar quarter. * * *

* * * * *

4. A new undesignated centerhead and new § 59.50 are added to read as follows:

Refrigeration of Shell Eggs

§ 59.50 Temperature and labeling requirements.

(a) No shell egg handler shall possess any shell eggs that are packed into containers destined for the ultimate consumer unless they are stored and transported under refrigeration at an ambient temperature of no greater than 45°F (7.2°C).

(b) No shell egg handler shall possess any shell eggs that are packed into containers destined for the ultimate consumer unless they are labeled to indicate that refrigeration is required.

(c) Any producer-packer with an annual egg production from a flock of 3,000 or fewer hens is exempt from the temperature and labeling requirements of this section.

5. § 59.132 is revised to read as follows:

§ 59.132 Access to plants.

Access shall not be refused to any representative of the Secretary to any plant, place of business, or transport vehicle subject to inspection under the provisions of this part upon presentation of proper credentials.

6. § 59.134 is amended by revising the section heading, designating the existing text as paragraph (a), and adding a new paragraph (b) to read as follows:

§ 59.134 Accessibility of product and cooler rooms.

* * * * *

(b) The perimeter of each cooler room used to store shell eggs packed in containers destined for the ultimate consumer shall be made accessible in order for the Secretary's representatives to determine the ambient temperature under which shell eggs are stored.

7. Section 59.410 is amended by revising the section heading, designating the existing text as paragraph (b), and adding a new paragraph (a) to read as follows:

§ 59.410 Shell eggs and egg products required to be labeled.

(a) All shell eggs packed into containers destined for the ultimate consumer shall be labeled to indicate that refrigeration is required, e.g., ''Keep Refrigerated,'' or words of similar meaning.

* * * * *

8. Section 59.690 is amended by revising the first sentence to read as follows:

§ 59.690 Persons required to register.

Shell egg handlers, except for producer-packers with an annual egg production from a flock of 3,000 hens or less, who grade and pack eggs for the ultimate consumer, and hatcheries are required to register with the U.S. Department of Agriculture by furnishing their name, place of business, and such other information as is requested on forms provided by or available from the U.S. Department of Agriculture. * * *

9. Section 59.760 is revised to read as follows:

§ 59.760 Inspection of egg handlers.

Duly authorized representatives of the Secretary shall make such periodic inspections of egg handlers, their transport vehicles, and their records as the Secretary may require to ascertain if any of the provisions of the Act or this part applicable to such egg handlers have been violated. Such representatives shall be afforded access to any place of business, plant, or transport vehicle subject to inspection under the provisions of the Act.

10. Section 59.915 is amended by revising the section heading, by removing the word ''and'' at the end of paragraph (b)(8), by redesignating paragraph (b)(9) as paragraph (b)(10) and by adding a new paragraph (b)(9) to read as follows:

§ 59.915 Foreign inspection certification required.

* * * * *

(b) * * *

(9) A certification that shell eggs which have been packed into containers destined for the ultimate consumer have, at all times after packing, been stored and transported under refrigeration at an ambient temperature of no greater than 45°F (7.2°C); and

* * * * *

11. In § 59.950, paragraphs (a)(4) through (a)(8) are redesignated as paragraphs (a)(5) through (a)(9), respectively, and a new paragraph (a)(4) is added to read as follows:

§ 59.950 Labeling of containers of eggs or egg products for importation.

(a) * * *

(4) For shell eggs, the words, ''Keep Refrigerated,'' or words of similar meaning;

* * * * *

12. Section 59.955 is amended by redesignating paragraphs (b) and (c) as paragraphs (c) and (d), respectively, by redesignating the last sentence of paragraph (a) as new paragraph (b), and by revising paragraph (a) to read as follows:

§ 59.955 Labeling of shipping containers of eggs or egg products for importation.

(a) Shipping containers of foreign product which are shipped to the United States shall bear in a prominent and legible manner:

(1) The common or usual name of the product;

(2) The name of the country of origin;

(3) For egg products, the plant number of the plant in which the egg product was processed and/or packed;

(4) For egg products, the inspection mark of the country of origin;

(5) For shell eggs, the quality or description of the eggs, except as required in § 59.905;

(6) For shell eggs, the words ''Keep refrigerated'' or words of similar meaning.

* * * * *

Done at Washington, DC, on: August 20, 1998.

Thomas J. Billy,

Administrator, Food Safety and Inspection Service.

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