



# United Egg Association

December 21, 2004

Division of Dockets Management  
U.S. Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

**[Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203, and 2000N-0504 and RIN number 0910-AC14]**

Dear Sir or Madam:

These comments are submitted on behalf of the United Egg Association (UEA) Further Processors Division in response to the Food and Drug Administration's (FDA) proposed rule entitled "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production; Proposed Rule." UEA is a national trade association whose members represent over 90 percent of the production of liquid, frozen, and dried egg products in the United States.

Members of UEA have long promoted the safety of egg products consumed in this country. Many of its current members were instrumental in Congress's enactment of the Egg Products Inspection Act in 1970. The organization has sponsored the E3A Standards program for the development of sanitary design standards for equipment used in the egg products industry; many of its members have implemented Hazard Analysis Critical Control Point Programs in the absence of any regulatory mandate for these programs; it prevailed on the U.S. Department of Agriculture to prohibit the use of centrifuge egg breaking procedures in official meat and poultry plants; and UEA and the United Egg Producers (UEP) worked with the American Egg Board to develop the International Egg Pasteurization Manual.

Egg products processors have a long history in promoting safe egg products for U.S. consumers. Prior to enactment of the Egg Products Inspection Act, eggs and egg products were frequently associated with outbreaks of human illness. The industry recognized that some unscrupulous or unsophisticated operators were jeopardizing the well-being of U.S. consumers and sought mandatory Federal inspection of all egg products firms. Since implementation of the Act, the Centers for Disease Control have not reported any outbreaks of *Salmonellosis* in humans that were associated with egg

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products. This record demonstrates the effectiveness of this legislation and food safety practices employed by the egg products industry.

On December 21, the United Egg Producers (UEP) representing about 90 percent of U.S. shell egg production filed extensive comments on the proposed rule. While supporting the egg safety initiative, UEP stated that several modifications would strengthen the rule while not changing its underlying principles – safe food for consumers. In these comments, we will address two areas that are of particular concern to the egg products industry and respond to a question posed by FDA in the rule. One area of concern is specific to on-farm refrigeration requirements, while the second issue addresses a broad concern with how the rule is applied to our industry.

### **On-Farm Egg Refrigeration**

The proposed rule would require refrigeration of all shell eggs held for longer than 36 hours before grading or further processing. It goes on to explain that only the shell egg refrigeration requirement is applicable to shell eggs produced for egg products processing. We agree that refrigeration of foods, including eggs, is an effective food safety measure. However, the rule should be based on sound science and applied to achieve the greatest improvement in food safety in a cost-effective manner.

As noted in the UEP comments, research into the effects of refrigeration on the growth of SE in eggs demonstrates that the natural antimicrobial characteristics of shell eggs will inhibit the growth of SE even when eggs are stored for several days or more at ambient temperatures. Most shell eggs are broken within a few days after production. Indeed the industry is rapidly evolving into the use of in-line shell egg production where eggs move immediately from the production facility into the further processing plant and are processed into pasteurized products. However, in some situations, eggs are still held for several days or longer before processing and we agree that these eggs require refrigeration to assure the highest degree of food safety.

All egg products production in the United States is accomplished under the continuous supervision of USDA inspectors that assure strict time and temperature requirements are followed in every phase of processing. All processors refrigerate egg liquid after breaking, unless the product is immediately pasteurized. Similarly all egg products are refrigerated after pasteurization at temperatures that effectively inhibit bacteria growth. All egg products produced in the United States are pasteurized in accordance with time and temperature combinations that have been proven effective in the destruction of pathogens harmful to humans. These products are tested for Salmonella and other potential microbial contaminants before release into consumption channels.

As part of its egg safety measures, USDA intends to publish performance standards for the processing of egg products. These standards, as discussed in a draft risk assessment published by the Food Safety and Inspection Service in October 2004, will require that

processors demonstrate effective pasteurization of egg products based on a log reduction in the number of bacteria in the raw product.

An argument could be made that the antimicrobial characteristics of eggs, a long history of safe egg products, and the pending egg pasteurization performance standards negate the need for any refrigeration of shell eggs intended for breaking. We would not make that argument; rather, we continue to believe that good food processors are knowledgeable of the raw materials they incorporate into their products. In that regard, egg products processors seek to use the highest quality raw materials that are available at a reasonable cost, even when safety is not in question. We believe this can be accomplished by a reasonable and practical egg refrigeration requirement in the egg safety rule.

Accordingly, UEA supports the parameters proposed by UEP in its comments. That is, the final rule should require refrigeration of shell eggs if they are held longer than 72 hours after production rather than the 36 hours suggested by the proposed rule. The science supports time periods without refrigeration that are much longer than this. However, 72 hours would accommodate shell egg production over weekends and other than daily pickup of eggs from smaller production facilities. At the same time, it would assure that eggs are not accumulated and held over long periods without refrigeration.

In accord with research on SE in shell eggs, we suggest an ambient temperature of 55-65°F for eggs held longer than 72 hours after they are laid. This is again supported by research and eliminates the host of practical and food safety concerns outlined in the UEP comments. When eggs have not been processed within 7 days after lay, the ambient temperature should be reduced to 45°F or below.

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

#### **Application of the Regulation to Egg Products Manufacturers**

Over the last several years, numerous shell egg production facilities in the United States were built to produce eggs only for processing into egg products. As acknowledged in the definition, these companies could own numerous poultry houses. While the

production from all of the houses is intended for egg products processing, when market conditions or seasonal production patterns warrant, some of these eggs may be diverted for table egg use. This is done when demand for egg products is weak and the producer can avoid or minimize potential economic loss by moving temporary surpluses to the table egg market.

The proposed rule would require that producers whose entire production will be processed into egg products in accordance with the Act need comply only with the refrigeration requirements for on-farm storage. However, it requires compliance with all of the egg production requirements of the proposed rule if part of the production is not processed into egg products or does not receive a treatment that achieves at least a 5-log destruction of SE. Many firms that produce shell eggs for use primarily in the manufacture of egg products now have extensive on-farm programs to assure the safety of eggs and egg products. However, some of these producers that may also sell into the table egg market will need to impose additional food safety measures at the production site. Has the agency considered these expenditures in determining total costs of the proposed rule on the egg industry?

#### **5-Log Reduction in Microbial Counts**

On page 56834 of the proposed rule, the agency poses a question in regard to the appropriateness of a 5 log reduction of treated shell eggs and pasteurized egg products. Specifically, the rule says:

“We are soliciting comment on whether a 5-log reduction or an alternative approach to achieve an equivalent level of protection is still appropriate to ensure the safety of shell eggs. We intend to work with USDA to ensure that shell eggs and egg products are given adequate treatments to destroy SE.”

The UEP comments on the proposed rule respond to this question in detail and UEA supports those comments. Both organizations, in conjunction with the American Egg Board, arranged for a survey of egg processors to determine their current pasteurization practices. After looking at the results of this survey, we conclude that from a regulatory standpoint, a 5-log reduction remains the appropriate requirement. Many processors achieve a substantially greater kill than the mandated level.

The current 5-log reduction requirement appears to provide an extra margin of safety, since specified temperatures and holding times do not take into account the additional kill achieved in the product while it is heating up to, and cooling down from, the pasteurization temperature. We do not see a need to change the 5-log standard at this time.

UEA and UEP also worked with the American Egg Board to develop an International Egg Pasteurization Manual, a project carried out by a team of distinguished researchers at three universities, led by Dr. Glenn W. Froning of the University of Nebraska. This

manual reflects a multi-year effort to update pasteurization times and temperatures for a range of products at various pH levels. Given the impressive results documented in the pasteurization manual, we believe the 5-log requirement should be regarded as entirely sufficient at this time. We note that the pasteurization manual won praise from food safety leaders at USDA, including then-Administrator William Hudnall of the Food Safety and Inspection Service, who wrote that "FSIS believes the data from the University of Nebraska study provide a reliable source of information for use in developing models for predicting the lethality of *Salmonella spp.* for pasteurization treatments and thus can be considered in developing guidelines."

UEA and its members appreciate this opportunity to file detailed comments on a regulation that will profoundly affect the shell egg and egg products industries. Our food safety record and actions that we have initiated over many years demonstrate that we are responsible food producers who want to deliver safe foods to our customers. We believe that the suggestions offered here will make the egg safety action plan better.

Thank you for your consideration of our comments.

Sincerely,



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United Egg Association



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