

**Executive Summary**

of the comments filed by

***United Egg Producers***

**and**

***United Egg Association***

**on the**

***"Current Thinking" Papers on the National Standards for Egg Safety***

**FDA Docket No. 00N-0504**

and

**FSIS Docket No. 98-045N4**

UEP and UEA commend FDA for stating intentions of conducting an economic impact analysis to consider the effects of the Egg Safety Action Plan (Plan) on the U.S. egg industry and is a critical step in preparing and designing the Plan.

**ON-FARM STANDARDS**

1. *Producers (other than those who sell all of their eggs directly to consumers (e.g., roadside stand operators)) who provide eggs for the table egg market must comply with all requirements (Strategy I). Farms with less than 3,000 layers are less likely to implement quality assurance programs, including refrigeration. No eggs should be exempt from the on-farm standards.*
2. *Producers whose eggs will be treated to destroy SE must comply only with the refrigeration requirement below (Strategy II). UEP and UEA strongly urge that this strategy be broadened to include additional Prevention and Control Procedures, including vaccination, pasteurization of liquid eggs, irradiation, and other new technologies.*

**SE RISK REDUCTION PLAN**

UEP and UEA commend the agencies for identifying many components that will contribute to the reduction of SE. There are a few concerns. No. 5: Instead of *Salmonella*-negative feed, *Salmonella*-monitored would be more appropriate. No. 6: Eggs taken from a 45 degree F refrigerated cooler and washed in water temperatures of 90 degrees F will develop thermal checks. The benefits of refrigeration on-line must be weighed against the damage that may occur due to thermal checks. One addition to the list of components should be vaccination. Vaccination should not be a mandatory component, but their use can play a critical role in prevention and control.

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Executive Summary

**FDA Docket No. 00N-0504 and FSIS Docket No. 98-045N4**

Page two

## **VERIFICATION OF THE SE RISK REDUCTION PLAN**

### **Environmental Testing:**

*40-45 weeks of age + 25 weeks after end of each molting period (i.e., same time period as initial environmental test)*

UEP and UEA support an environmental test the justification for one producer-paid environmental test to serve as verification of their SE risk reduction program. The additional environmental test after each molting period lacks sound scientific justification.

## **ADMINISTRATION OF THE SE RISK REDUCTION PLAN**

Instead of one individual at each facility, UEP and UEA recommend that one person from each company be trained and designated to administer the SE risk reduction measures.

## **STANDARDS FOR SHELL EGG PACKERS AND EGG PRODUCTS PROCESSING ESTABLISHMENTS**

UEP and UEA are supportive of providing a level playing field through mandatory grading and inspection program with equal enforcement. A quality assurance seal signifying compliance with the SE Risk Reduction components is recommended to provide consumers with confidence that everything practical has been done to safeguard the product. The industry stands ready to assist the agencies in the development of this "Seal of Safety" for egg packaging.

## **PROHIBITION ON REPACKAGING FOR RETAIL SALE**

UEP is supportive that *Shell eggs that have previously been shipped for retail sale will be prohibited from repackaging.*

## **RETAIL ESTABLISHMENTS**

### **Serve At-risk Consumers**

UEP and UEA support the *Substitution of treated eggs or pasteurized egg products for raw eggs.* **The immunocompromised, such as in nursing homes and in hospitals, should be served pasteurized egg products. We are gratified that the FDA is moving forward in this area.**



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## United Egg Producers

August 13, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Dear FDA Dockets Management Branch:

Reference:

### Docket No. 00N-0504

United Egg Producers (UEP) representing 80% of the nation's egg production, and United Egg Association (UEA) representing 95% of all further processed egg products, appreciate this opportunity to comment on the "*Current Thinking*" Papers on the National Standards for Egg Safety (Current Thinking).

### EGG SAFETY ACTION PLAN BACKGROUND

The President's Council on Food Safety has identified egg safety as one component of the nation's food safety program that warrants immediate federal interagency action. The Council developed an Egg Safety Action Plan to address the presence of Salmonella Enteritidis (SE) in shell eggs and egg products using a farm-to-table approach. The Action Plan proposed two SE reduction strategies, to meet the Action Plan's interim goal of a 50% reduction in egg-associated SE illnesses by 2005. Risk reduction in Strategy I is based on measures designed to reduce SE contamination of eggs during production, while risk reduction in Strategy II is based on measures designed to eliminate SE from contaminated eggs at the packer. In addition, the Action Plan proposes retail and education objectives to reduce the risk of SE illnesses. UEP and UEA commend FDA for stating its expectation that the proposed rule will be economically significant. An economic impact analysis will allow FDA to consider the effects of the Plan on the U.S. egg industry and is a critical step in preparing and designing the Plan.

### PUBLIC MEETINGS

On March 30, 2000, and April 6, 2000, FDA and FSIS held public meetings in Columbus, OH, and Sacramento, CA, respectively, to solicit and discuss information related to the implementation of the Egg Safety Action Plan and to gather information for reducing or eliminating the risk of SE in eggs.

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In addition to the two public meetings, FDA and FSIS conducted a third public meeting July 31<sup>st</sup> to present their current thinking on the integral features of the farm-to-table egg safety standards to reduce egg-associated SE illnesses. Draft current thinking documents (on-farm, packer/processor, and retail) were presented at this third public meeting on July 31<sup>st</sup> and the industry is offering comments on these papers.

### **ON-FARM STANDARDS**

Three **categories** for coverage by the standards were presented.

1. *Producers (other than those who sell all of their eggs directly to consumers (e.g., roadside stand operators)) who provide eggs for the table egg market must comply with all requirements (Strategy I).*
2. *Producers whose eggs will be treated to destroy SE must comply only with the refrigeration requirement below (Strategy II).*
3. *All producers who sell eggs must register with FDA.*

Category 1: UEP and UEA cannot support exemptions based on our observations and experience. Smaller farms or hobby farms are less likely to implement quality assurance programs, including refrigeration. Eggs from these operations may provide a more hospitable environment for SE. Producers who sell their eggs directly to the consumer represent a small percentage of the total eggs sold, but do contribute a volume of eggs to the market that could skew the results of the Plan objectives to reduce SE by 50% by 2005. Under the Egg Products Inspection Act, producers with less than 3,000 chickens are exempt. Yet, a flock of chickens numbering 2,999 selling eggs directly to the consumer can produce during peak periods of production more than 2400 eggs every day. That one flock could sell more than three quarters of one million eggs during the course of the year. This exemption is not supported by either the egg industry striving to provide a safer product, nor by consumer organizations.

Category 2: Strategy II involves a "kill-step" such as in-shell pasteurization. In-shell pasteurization holds great promise, but in its commercial infancy. Strategy II should not prejudice other prevention and control technologies. UEP and UEA strongly urge that this strategy be broadened to include additional Prevention and Control Procedures, including vaccination, pasteurization of liquid eggs, irradiation, and other new technologies. Furthermore, FDA should study and review the technological advances in the use of SE vaccines. Vaccines offer great potential for prevention and control of this pathogen and are already in use in the UK and Germany.

UEP and UEA recognize FDA's desire to create incentives for producers to choose Strategy II. We believe that participation in either strategy should provide the producer a legal defense against lawsuits arising from outbreaks or similar events, and that this protection should be incorporated into the regulations if possible, and into statute if necessary. In this regard, FDA could create an additional incentive for participation in Strategy II by stipulating that this strategy would provide partial or complete immunity from investigation in a traceback procedure.

### **SE RISK REDUCTION PLAN**

UEP and UEA commend the agencies for identifying those components that will contribute to the reduction of SE. While supportive of many of these measures, we have concerns about certain items.

**Number 1: Use of chicks and pullets from SE-monitored breeder flocks.** The National Poultry Improvement Plan (NPIP) "U.S. Sanitation Monitored Program" has proven effective in minimizing poultry disease pathogens through a surveillance program, and should provide the means for monitoring breeding flocks for SE. Participation by **all** poultry breeding companies in the NPIP is an excellent first step in starting an egg operation with clean poultry stock. Egg producers should require their chick or pullet supplier to provide NPIP Document Form 9-3 which certifies participation. Currently, not all poultry breeders are participating in NPIP.

**Number 2: Biosecurity.** All egg producers should practice biosecurity measures to prevent the introduction of pathogenic bacteria into the pullet or layer houses. Effective biosecurity measures will cut down the transmission of diseases to other production facilities. Biosecurity also includes sourcing materials brought onto the premises, including feeds and microingredients.

**Number 3: Rodent and Pest Control.** Research has demonstrated that rodents and other pests, including insects, are potential carriers of bacteria. Record-keeping would enhance this component.

**Number 4: Cleaning and disinfection.** Even if facilities test negative for SE, this management practice for controlling bacteria is important. Either wet cleaning or dry cleaning measures are acceptable procedures for implementing this management practice. In either measure all vectors that may contain bacteria are removed from the facility including eggs, feed, rodents and pests, manure and other debris. The application of disinfectants are introduced only after the house and equipment is completely cleaned out. Fumigation is also a management practice soon after the disinfection procedures are completed.

**Number 5: Use of *Salmonella*-negative feed.** UEP and UEA would request that feed be monitored for *Salmonella*. UEP and UEA have grave concerns about the feasibility of mandating *Salmonella*-negative feed if that would require extensive and commercially infeasible testing by feed manufacturers. UEP and UEA strongly recommend that feed ingredients should be monitored for *Salmonella* by the supplier and there are already programs documenting sources and quality control programs, e.g., Good Manufacturing Practices & Animal Protein Products Industry (APPI) *Salmonella* Education/Reduction Program.

**Number 6: Refrigeration.** Eggs must be refrigerated after washing and grading. Cooler room temperatures must be maintained at an average ambient temperature of 45 degrees F. or below. Transportation vehicles must have refrigeration units capable of producing air at 45 degrees F. or below. Temperature recording devices are available to record the desired temperatures. UEP and UEA strongly recommends that *Current Thinking* by the agencies follow the refrigeration requirements under the present law, which begin to apply refrigeration mandates when eggs are packed. Since Congress has legislated a specific temperature and refrigeration regime for eggs, we question whether FDA's authorities under other statutes are sufficient to override this detailed (and subsequent) legal requirement.

FDA needs to consider that its proposed 36-hour Rule could have unintended consequences that would make SE growth more likely, not less. In an in-line operation, eggs washed at 90 degrees F or warmer are subjected to small temperature increases since eggs coming from the laying house are approximately 80 degrees F. But in off-line operations, mandating that eggs be cooled to 45 degrees means there will be a greater temperature difference when washed. Eggs taken from a 45 degree F. refrigerated cooler and washed in water temperatures of 90 degrees F. or warmer will develop more thermal checks, i.e., hairline cracks in the shell. This is the scenario that will occur with off-line egg production under this proposed *Current Thinking*. UEP and UEA recommend that a balance be struck. The benefits of refrigeration in this proposal must be weighed against the damage that may occur due to thermal checks as a result of the thermal differentiation. Refrigerated eggs from off-line, such as nest run eggs on racks from contract farms, will cool to temperatures that when subjected to wash water temperatures will develop thermal checks.

UEP and UEA respectfully requests that an additional component be added. This new component would be the use of approved vaccines. Vaccination should not be a mandatory component. Vaccines can play a critical role in prevention and control procedures. Research is showing that vaccines can play a significant part in our food safety efforts and therefore should be one of the components of the *Current Thinking*. In its consideration of this suggestion, we urge FDA to conduct a review of the literature on vaccination and meet with vaccine manufacturers and producers familiar with the promising results of various vaccine protocols, including experience in Europe.

**VERIFICATION OF THE SE RISK REDUCTION PLAN**

**Environmental Testing:**

*40-45 weeks of age + 25 weeks after end of each molting period (i.e., same time period as initial environmental test)*

*Negative*

*Positive*

*Egg Testing*

*Negative*

*Positive*

*Diversion*

UEP and UEA support an environmental test at 40-45 weeks of age. If the environmental test is positive, then a random sample of 500 eggs would be tested. If the egg test proved positive, then eggs from that particular house would be diverted. The additional environmental test after each molting period lacks sound scientific justification. An analysis of the Pennsylvania Pilot Project data on SE prior to molting and in a post molted situation do not show a difference between the groups. A spike in the graphical results for five weeks following a molt must be tempered by the knowledge that effectively molted chickens do not produce eggs. Those few eggs found during this period may show a disproportionate increase. These "eggs" are often thin-shelled or lack shells entirely with only the shell membranes containing the contents. Eggs that are thin-shelled or lacking shells would not be graded for the consumer market. Eggs produced after that molt do not show increases in the incidence of SE compared to the pre-molt period. Groups opposed to the management practice of molting chickens have cited the federal research by Dr. Peter Holt, USDA/ARS. This researcher has stated in a letter to UEP dated May 28, 1999, that "I do not support the claims that molting contributes to increased human illness because I am not aware of any epidemiological studies done in the field which substantiates such assertions."

**ADMINISTRATION OF THE SE RISK REDUCTION PLAN**

*The Current Thinking specifies one individual at each production facility must successfully complete training on SE risk reduction measures for egg production. That individual is responsible for administering the SE risk reduction plan.*

UEP and UEA recommend that one person from each company, rather than each facility, be trained and designated to administer the SE risk reduction measures to include coordinating the education of company officials in procedures and necessary record-keeping to demonstrate compliance with the Plan. In addition, we recommend that FDA establish procedures to recognize or certify academic and private-sector groups to conduct the training.

**Recordkeeping Requirements**

*Producers will maintain a written SE risk reduction plan and records indicating compliance with all components of the plan. UEP and UEA is supportive of this proposal.*

**STANDARDS FOR SHELL EGG PACKERS AND EGG PRODUCTS PROCESSING ESTABLISHMENTS**

*FSIS has statutory authority over egg packers and egg products plants. The FSIS overall approach to regulating shell egg packers and processed egg product plants is to eliminate, modify, and add requirements to the egg and egg products inspection regulations that will make the regulations consistent with the Agency's regulatory approach to meat and poultry products under 9 CFR Part 416, Sanitation, and Part 417, HACCP. An economic analysis is being developed around the options under consideration with the feasibility study in implementing these requirements.*

**REQUIREMENTS FOR SHELL EGG PACKERS AND EGG PRODUCTS PROCESSORS MAY INCLUDE:**

**I. Coverage**

- A. *All shell egg packers*
- B. *All egg products processors*

UEP and UEA are supportive of providing a level playing field through a mandatory **grading and inspection** program for all packers and egg products processors with equal and uniform enforcement. A quality assurance seal signifying compliance with the SE Risk Reduction components is being recommended in these comments to provide the consumer with confidence that everything practical has been done to safeguard the product. The industry stands ready to assist the agencies in the development of this "Seal of Safety" for egg packaging.

**Sanitation SOPs, Hazard Analysis and HACCP Plan**

UEP and UEA have been supportive of a HACCP-like protocol allowing for monitoring shell egg packers and egg products processors. The verification for enforcement is already in place through USDA/AMS or USDA/APHIS.

This organizational structure for enforcing the HACCP-like protocol for egg safety standards would permit monitoring records kept on egg wash water temperatures as well as pH. Reductions in the incidence of SE have already resulted from HACCP-like quality assurance programs and public health surveillance systems operated on a voluntary basis. Uniformity in enforcement is essential to the effectiveness of this component of the Plan. A mandatory grading and inspection program would level the playing field and provide added levels of consumer confidence in the effectiveness of the verification for enforcement. It is critically important that the relationship between the FSIS and FDA authorities for packing and farm facilities be clarified. The Plan must avoid overlapping jurisdiction, double regulation and duplicative monitoring or inspection, particularly in in-line operations.

### **PROHIBITION ON REPACKAGING FOR RETAIL SALE**

*Shell eggs that have previously been shipped for retail sale will be prohibited from repackaging.* UEP is supportive of this provision in the *Current Thinking* and commends FDA for adding this important public safety measure.

### **GENERAL OPERATING PROCEDURES TO BE WRITTEN AS PERFORMANCE STANDARDS**

*The Current Thinking may include performance standards for shell egg handling, storing, cooling, and performance standards for lethality requirements for processed egg products and pasteurized shell eggs.* Before adopting performance standards for lethality of possible pathogens, UEP and UEA would want to see the specifics being called for so that a scientific evaluation could be conducted.

### **RECORDS AND RELATED REQUIREMENTS**

*The Current Thinking will not be duplicative across regulatory authorities, for example, producer-packers may combine a SE Risk Reduction Plan (FDA) with the HACCP plan (FSIS) This component would include information that accounts for the movement of eggs, including restricted eggs, through the food chain, documents HACCP and SSOP program compliance with performance standards, and documents labeling, product formulation and processing procedures.* Allowing for individual protocols to be accepted by all agencies detailing egg movement along with HACCP-like documentation is supported by UEP and UEA.

## **II. Coverage**

*All shell egg handlers except for producer-packers with an annual egg production from a flock of 3,000 or less who grade and pack eggs for the ultimate consumer, persons who must register with the Food and Drug Administration, and hatcheries.* A flock of chickens numbering 2,999 can produce during peak periods of production more than 2400 eggs daily.

**Docket No. 00N-0504**

Page Eight

That one flock could sell more than three quarters of one million eggs during the course of the year. Any exemption from coverage creates risks for the entire strategy.

**REGISTRATION OF SHELL EGG HANDLERS**

**III. Coverage**

*Any shell egg producer-packer with an annual egg production from a flock of 3,000 or fewer hens who also does not pack eggs for other producers is exempt from the temperature and labeling requirements. UEP and UEA would like to propose that this coverage exemption be stricken from the *Current Thinking*. All producers who produce shell eggs and sell eggs, give, or trade eggs should be required to register as egg handlers.*

**RETAIL ESTABLISHMENTS**

The components of the *Current Thinking* for retail establishments are supported by UEP and UEA.

**Raw eggs:**

- 1. Have been transported at an ambient temperature of 7 ° C (45 ° F) or below; and*
- 2. Are clean and sound; and*
- 3. Do not contain more restricted eggs than allowed in U.S. Consumer Grade B.*

**Egg products:**

*Liquid, frozen, and dried egg products are in pasteurized form.*

**Serve At-risk Consumers**

UEP and UEA support the *Substitution of treated eggs or pasteurized egg products for raw eggs in food items that:*

- 1. Contain raw egg ingredients and are not subsequently thoroughly cooked; or*
- 2. Are prepared by combining and holding eggs prior to service; or*
- 3. Are prepared by holding eggs following cooking prior to service.*

UEP and UEA have been calling on the Government to take appropriate steps of dealing with the immunocompromised such as in nursing homes and in hospitals by substituting with pasteurized egg products. We are gratified that the FDA is moving forward in this area.

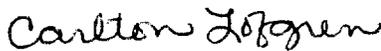
**Serve the General Public**

- 1. Options for serving ready-to-eat foods prepared with raw or undercooked eggs.*
- 2. Times and temperatures for cooling and holding foods containing raw or undercooked eggs that are not thoroughly cooked.*

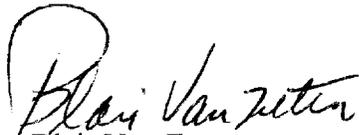
UEP and UEA support the need for greater consumer education in the safe handling and preparation of all perishable foods, including eggs.

UEP and UEA appreciate the opportunity to file these comments.

Yours sincerely,



Carlton Lofgren  
UEP Chairman



Blair Van Zetten  
UEA Chairman

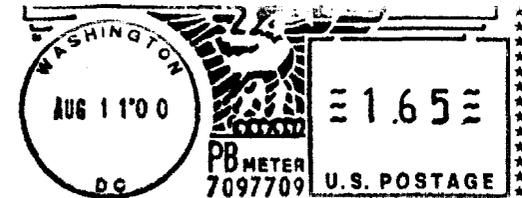


Al Pope  
President

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