

## **Comments on the Proposed FDA Regulations to Prevent SE in Shell Eggs During Production**

These comments are made after review of the Department of Health and Human Services, Food and Drug Administration, 21 CFR parts 16 and 118 document "Prevention of *Salmonella enteritidis* In Shell Eggs During Production."

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### **General**

I testified at the hearing in Southern California. I have been a Cooperative Extension Poultry Specialist in California since 1966 retiring 7/1/04. I was one of the authors of the California Egg Quality Assurance Program (CEQAP) and have chaired the educational committee since the program was initiated. I am continuing to support CEQAP with financial support from CDFR through 7/1/05. My back up and educational program co-chair is Doug Kuney, Statewide Poultry Farm Advisor, UC Riverside Campus [drkuney@ucdavis.edu](mailto:drkuney@ucdavis.edu).

The general background and the assessment of the current situation for SE risk seems generally on track although I might question some statements. I also agree with the conclusion that farm level quality assurance programs have been shown to reduce SE contaminated flocks. The proposed FDA program for control of SE in eggs describes the important components for a good quality assurance program. However, the program lacks the necessary record keeping requirements that would make it possible for inspectors (or even farm managers themselves) to determine if the program was successfully carried out at the farm level.

Environmental testing is far less useful than effective quality assurance in protecting egg safety. Why then is FDA only requiring records on flock environmental testing? Records are a critical part of a quality assurance program and are needed on disease status of chicks, pullet rearing, employee biosecurity training, rodent monitoring and control, human and vehicle traffic control, flock health and cleaning and disinfection procedures. Adequate training for the "person responsible" and for the farm level employees is critical for program success. Any quality assurance approach will not be successful if it is not carefully applied.

I believe that the emphasis of this program should be to assure that all table egg producers participate in a good quality assurance program. As cited in the document only about 50 percent of the eggs are currently produced under a quality assurance program. In California 90 to 95 percent of the eggs are produced under the California Egg Quality Assurance Program. Our quality assurance program advisory committee would certainly like to have 100 percent participation. Among non-participating companies, several have managers who have completed all of the CEQAP training and have good ranch

biosecurity and sanitation. The easiest way to get egg producers into EQAPs would be to work through existing programs that meet the standards of this regulation allowing any changes needed so state programs qualify. Company developed programs can provide an alternative for producers in states without EQAPs.

Vaccination has proven to be very effective in preventing systemic infection of hens and subsequent SE contamination of eggs. It is not discussed in this regulation although it may be the most practical and possibly the only successful intervention strategy for control of SE on a premise that has become SE positive.

### **Training for Quality Assurance Supervisors**

Our original CEQAP training was done with a large meeting format. Students received a CEQAP handbook and a certificate of completion for each session. Tests were given before and after each section. Everyone that participated passed but they were required to present the exit test to receive the certificate (some left early and did not get credit). Subsequent training was done with small meeting groups using video tapes of the original training sessions and more professional video tapes as they became available. The same tests and certificate requirements were used but students were not required to purchase a book. After training of over 200 people a comprehensive exam was developed. Individuals that now want to complete the training can obtain educational materials as needed. If they complete the comprehensive exam with at least a 90 percent score they are certified (many don't pass on the first try!). This exam is administered by University of California Cooperative Extension and we also keep records of those who complete training and provide this to CDFA for use in compliance reviews. The successfully completed tests are kept on file by the Pacific Egg and Poultry Association to resolve any possible dispute about completion. CDFA, Animal Health Branch maintains records of compliance reviews.

The original training sessions were as follows:

- Need for a Program, and Developing QA Plans - 3 hr.
- Egg Processing - 3.5 hr.
- Flock Health Management - 2 hr.
- Cleaning, Disinfection & Biosecurity - 2 hr.
- Vector Control - 3.5 hr.
- Environmental Sampling – 2 hr.

A complete list and set of the videos currently in use can be obtained from the Pacific Egg and Poultry Association <http://www.pacificegg.org/>. Three videos are now available on biosecurity. Two of these videos were made by USDA and one by the US Poultry and Egg Association.

If FDA wants a national requirement for egg quality assurance then I believe that a good educational program should be developed and offered on a national basis. This might logically consist of regional workshops and an individual or small group study alternative. Large producers would probably prefer a training workshop for key

managers. An individual study package could be developed using modern technology with computer or video technology. Some problems will be encountered with limits of available technology and language. These can best be handled by obtaining help from the USDA Cooperative Extension educators in states. If you want a list of potential extension cooperators at state level I would be glad to assist or you can contact Richard Reynnells at USDA <rreynells@reeusda.gov>

### **Environmental Testing**

The environmental testing and egg diversion requirements of the proposed program are totally inadequate to protect consumers from SE contaminated eggs without effective quality assurance. Testing environments when flocks reach 45 weeks of age and again after recycling would be useful to determine the success of quality assurance programs. The proposed testing schedule would provide little consumer protection without concurrent quality assurance. This would be true regardless of the age selected for testing. I find the ages selected some of the least useful for determining management changes needed when an SE positive house is found.

### **Dealing With SE Positive Houses**

The suggested procedures for dealing with positive houses do not consider that regulations regarding the handling of manure may prohibit clean out at certain times of the year. Manure can not be spread on frozen ground and can only be spread during certain times in the crop cycle. Of course the farm could build a storage building for the manure but the proposal does not seem to address any cost of this type. In some locations local regulations prohibit storage of manure on the production site at any time.

In cold climates a complete wet cleaning may not be possible during cold weather. When hens are removed from houses the house temperature will drop rapidly and water would freeze within the house. **It would seem advisable for a regulation to allow a farm to cope with a positive house in the best way possible after consultation with a veterinarian.** Vaccination of the next flock of pullets in combination with rodent control, dry cleaning and/or fumigation may be very successful without manure removal. Manure piles have been shown to turn salmonella negative after a few days. Research at UCD by Hans Riemann has indicated that this may be due to the ammonia levels present.

The severity of the economic penalty associated with detection of a house with a positive environment during the subsequent lay cycle will be a strong stimulus for successful clean up of positive houses.

### **Quality Assurance Plans**

As discussed in this document the NAHMS study has indicated that practices, housing systems and conditions on egg farms throughout the country differ in many respects. As a result of these differences, appropriate requirements for quality assurance differ for each farm. **A procedure is needed for quality assurance plans to be specific to the**

**needs of individual farms. In my opinion this requires individually-developed, written QA plans for each egg production company.** We accomplished this by assisting CEQAP producers with their program draft. With our Squab Quality Assurance Program (75 farms) small group meetings were held for the farmers in which the QA programs were hand written from an outline during the meeting. They were then reviewed, approved and returned to the participants.

Successful oversight for any quality assurance program requires knowledgeable inspectors and appropriate records for review. All of the veterinarians in California that conduct compliance reviews have participated in all of the quality assurance training. If FDA intends to provide some sort of oversight for this proposed program they need to consider that good biosecurity restricts visitors including FDA inspectors. Inspectors can not expect to visit a farm every day. In most cases visits should be limited to two per week. This will add to the cost and complexity of oversight. It might be advisable to have state agencies perform the necessary oversight for this proposed program if an arrangement can be made for this service.

### **Farm Egg Refrigeration**

The details of the regulation about required refrigeration of eggs at the farm before processing specify a temperature of 45°F. That storage temperature would present a problem for safe and sanitary washing of these eggs when they are transported to a shell egg processing plant. USDA, AMS recommends an egg washing temperature of 110°F. Lower temperatures are allowed (as low as 90°F) but the control of bacteria in the wash water and successful egg cleaning are improved with 110°F to 115°F wash water.

Research has shown that thermal checks increase when there is more than a 50°F difference between egg temperature and wash water temperature. If eggs were refrigerated on the farm at 45°F the egg wash water temperature could not exceed 95°F. While this is technically possible, it is clear that any regulations requiring farm refrigeration before processing should be coordinated with egg washing regulations.

### **Environmental Sampling Procedures**

A statement under this section indicates that in the California program swabs are dragged for 30 ft. This is not correct; the program requires swabs to be dragged the entire length of selected manure rows.

Research in California has demonstrated that drag swab samples can be pooled four per bag for culture. This change could reduce costs and laboratory loads associated with the proposed regulation.

You need a program to assure integrity of environmental samples and proper collection procedures. I would suggest that FDA require that a copy of every environmental sample result is mailed to them directly from approved laboratories. This would provide

notification of positive flocks and state partners could be requested to follow up on positive houses to assure that required samples were taken.

In the CEQAP program only people who have completed the training for the sampling component are allowed to collect environmental samples. This is true for farm managers or veterinarians. Veterinarians that have completed the training can train others in conjunction with a house sampling exercise.