

California Egg Quality Assurance Program

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Division of Dockets Management
Food & Drug Administration
5630 Fishers Lane, Room 1061
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COMMENTS

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

Dear Mr. Lou Carson:

As the facilitator for the California Egg Quality Assurance Plan (CEQAP) I am submitting comments on the proposed Food & Drug Administration (FDA) rule on Prevention of *Salmonella* Enteritidis (SE) in Shell Eggs During Production, 21 CFR Parts 16 and 118, published September 22, 2004. The CEQAP program was established in April 1994 in response to an increase in SE foodborne illnesses nationwide and in California. The program became operational in August 1995. Since that time the rate of SE foodborne illnesses has declined in California to levels below the Healthy People 2010 objective as cited by the California Department of Health Services (1996 SE outbreaks 21.84% and 3.4% in 2003). In addition there have been no known egg related SE outbreaks linked to California eggs since 2000. Although there are numerous possible reasons to explain this phenomenon, one could pose that the CEQAP has played an integral role in protecting public health.

While we applaud the FDA for proposing this rule, we believe the agency has not gone far enough to regulate food handlers in an equal manner. Although the FDA does not have regulatory authority in processing plants, it can encourage those agencies that do. In addition, the FDA should require the Model Food Code be implemented on a mandatory nationwide basis. The Risk Assessment report concluded that *Salmonella* Enteritidis (SE) levels could be greatly reduced if multiple interventions were applied. By concentrating on production only, the agency is not following a science based strategy. It is politically more expedient to place an unfunded mandate on a small number of egg producers than it is to follow the agency's own report.

In 1994 California egg producers worked cooperatively with the California Department of Food & Agriculture (CDFA), the US Department of Agriculture (USDA), the California Department of Health Services (CDHS), the California Animal Health and Food Safety Laboratory (CAHFS), the University of California Cooperative Extension, local accredited poultry veterinarians and the FDA to develop the California Egg Quality Assurance Plan (CEQAP). The program is supervised by CDFA and ranches are

inspected by CDFA veterinarians to validate that ranches are following their approved Quality Assurance Plan.

The CEQAP program utilizes a Hazard Analysis Critical Control Points (HACCP) approach to assure that eggs are produced SE free. In addition, all producers, their employees and government representatives are required to successfully pass the instructional educational coursework in: *Preparing a Quality Assurance Plan; Egg Handling; Flock Health Management; Cleaning, Disinfection and Biosecurity; Vector Control and Biosecurity; and Environmental Monitoring and Sampling*. Producers must develop a written HACCP Quality Assurance Plan, which is reviewed by a California Department of Food & Agriculture (CDFA) veterinarian. The producer must also keep a myriad of records related to biosecurity, environmental SE monitoring, production, cleaning and disinfection and vector control. These records are periodically reviewed by a CDFA veterinarian. Producers who fail to meet the minimum standards are provided a deficiency letter and given a 30 day time period to correct the matter. If the matter is not corrected, the producer is declared out of compliance and is removed from the compliance list. They are allowed back in the program once they meet the minimum standards, but they must initiate the approval process from the start. As a matter of record, the plan has removed several producers from the program for cause. CEQAP is a voluntary statewide program but marketplace competitive forces pressure the majority of poultry producers to remain in good standing. Currently the producers enrolled in CEQAP represent approximately 95% of the state's egg production. This rate of enrollment has been steady since its inception.

At the public hearing in Los Angeles the FDA posed four questions regarding the CEQAP program.

Question 1: Diversion capacity, and what actions are taken in response to a positive SE environmental?

The CEQAP has always remained a flexible program that is tailored to the individual farm since not all farms are operated or designed in the same manner. The CEQAP requires that each flock be environmentally sampled at least once per year or at the end of the lay cycle. Private accredited poultry veterinarians take many samples on behalf of their clients. Producers that take samples must first be certified by successfully passing the *Environmental Monitoring and Sampling* coursework offered by the plan. Samples are sent to the state laboratory. If positive samples are recovered the producer consults with a private veterinarian who will usually conduct the following procedure: review all flock and CEQAP monitoring records, review all CEQAP procedures, intensify rodent control, remove birds and properly dispose of feed and manure. The farm will conduct a dry and wet cleaning and disinfection (C&D) program that is appropriate for the facility in question. The building will be resampled. Environmental monitoring will be intensified on the incoming flock depending on post C&D environmental results and farm history. If positive samples are found, egg testing will be conducted. Vaccination and competitive exclusion products will be considered depending on the flock and farm history. California is primarily a shell egg producing state. There are a limited number of breaker plants that are running at full capacity. The CEQAP program is not aware if these plants have a policy of taking known SE positive eggs or what market discounts would be applied to these eggs.

Question 2. Would the CEQAP program share records with the FDA? The CEQAP is a voluntary program and all testing records are maintained by the state lab and CDFA. It is our understanding that the CDFA is willing to allow FDA to review these records.

Question 3. What are the additional costs associated with operating the CEQAP program? We refer this answer to the CDFA comments which address the costs under “Section VI. Funding and Section VIII. Economics.”

Question 4. How is CEQAP different from the proposed FDA rule? Again, we refer the answer to the CDFA comments which explain the difference between process control and test and divert. This is especially important because the FDA rule does not fully address the entire recommendations made in the FSIS SE Risk Assessment by incorporating a farm to table approach. The FDA proposal only addresses production farms, but ignores the transportation, sale and preparation of eggs at the food service level. To adequately achieve the Healthy People 2010 objectives the agency must address the entire continuum of eggs from farm to table as recommended in the risk assessment report. Otherwise FDA is balancing the entire objectives on the backs of egg producers.

In regard to on farm refrigeration we believe that requiring on-farm refrigeration of eggs at 45⁰F if held for greater than 36 hours creates the very real problem of thermal checking. This has the potential of allowing SE or other pathogens the opportunity to penetrate the egg. These eggs are downgraded and can add up to a sizeable economic loss. Increasing the temperature variation between the wash water temperature and egg will only worsen this loss. It also raises the potential for a greater number of undetected thermal checks to enter the marketplace. In addition, added refrigeration equipment may be needed on the farm to meet the new temperature requirement. The refrigeration requirement appears to have too many downside risks and it creates the unintended result of increasing the nation’s flock size to produce more eggs to compensate for the greater number of loss eggs due to thermal checks. Increasing the nation’s flock size will further exasperate producer profits by placing more eggs into commercial channels.

The industry believes that FDA should mandate the model food code rather than let it remain as a voluntary recommendation. This will help assure that eggs are handled appropriately after leaving the farm gate. The FDA should also make the proposed rule effective on all egg producers regardless of size. If not, FDA is admitting that it is willing to accept some risk which is in contradiction to its zero tolerance policy.

We also propose that FDA consider exempting producers from the FDA rule who are enrolled in good standing in the CEQAP program. The program is working well in California. Food illnesses are down substantially since the program was initiated. We encourage FDA to contract with the CDFA as the primary agency in California to enforce the rule. The CDFA has trained veterinarians who are already familiar with our farms and their production/processing facilities.

Thank you for the opportunity to present these comments. Although the proposed SE regulation is worthy, it should be just one piece in a comprehensive plan. Therefore, the rule should be held in abeyance until a more inclusive plan is developed for the entire food continuum. Anything less comprehensive will lead to unequal enforcement.

The FDA could also consider allowing states with a viable quality assurance plan (QAP) to be opted out of the federal requirements and only require producers not participating in those QAP's to be subject to the new FDA rule. In those states where no viable or approved QAP is administered, the FDA regulation would apply to all producers.

On behalf of the California egg producers in the CEQAP, we invite FDA officials to request any documentation that would be helpful in understanding our state quality assurance plan. Please let us know if we may be of further assistance.

Sincerely,

David J. Goldenberg
CEQAP Facilitator