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Division of Dockets Management  
Food & Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

COMMENTS

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

Dear Sir or Madam:

I am submitting comments on the proposed Food & Drug Administration (FDA) rule on Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, 21 CFR Parts 16 and 118, published September 22, 2004. I am an egg producer who will be affected by this rule. My company takes pride in producing a wholesome and safe product and that's why we joined the California Egg Quality Assurance Plan in 1995. We know that everyone in the food business has a stake in assuring a safe food supply.

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, and the FDA to develop the California Egg Quality Assurance Plan (CEQAP). The program is supervised by CDFA and my ranch is inspected by a CDFA veterinarian to validate that we are following our approved Quality Assurance Plan. We have also trained our employees so that they have a proper understanding about the issues of food safety and animal husbandry.

We propose that FDA consider exempting producers who are enrolled in the CEQAP program. The program is working well in California. Food illnesses are down substantially since the program was initiated. In fact there have no known SE outbreaks associated with California eggs in five years. We encourage FDA to contract with the CDFA as the primary agency in California to enforce the rule. The CDFA has trained veterinarians that are already familiar with our farms and their operations.

As a producer I am concerned with the test and divert initiative since it can be economically devastating. Our CEQAP program is geared to accomplish the same goal but allows producers to select the least disruptive time to test. We encourage our producers to test prior to push out so that producers can take corrective action prior to

ODN-0504

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repopulation. We also test right after a molt so that an economic decision can be made on the flock as it begins the lay cycle.

The FDA proposal is silent when it comes to paying for the egg tests. We have consulted with the state lab and although the lab is subsidized by public funds, we are unsure if the lab can continue that practice if the lab becomes overwhelmed. We also feel that the proposal is not specific enough on the testing requirements. We feel the technical issues can be best addressed by our lab officials. Because the FDA is silent on providing testing subsidies, the agency has proposed an unfunded mandate on egg producers. We believe this to be an unfair burden especially in light that the agency has taken no other steps to regulate other sectors of the food chain.

As an egg producer and shell egg packer, I must point out the economic and potential health fallacy the proposal creates in regard to on-farm refrigeration. Requiring on-farm refrigeration of eggs at 45<sup>0</sup>F 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 loss to my business. 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.

Thank you for the opportunity to present these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom M. Silva", written over a horizontal line.

Thomas M. Silva  
Vice President

Go West With Confidence