



Hidden Villa Ranch

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November 22, 2004

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 1997 (call if you are unsure when your company was certified). We know that everyone in the food business has a stake in assuring a safe food supply. Egg producers are only one component in the food continuum. Food illnesses can be caused by a break in any phase from farm to table.

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 all interventions were targeted. By concentrating on production only, the agency is not following a science based strategy. It is politically expedient to place an un-funded mandate on a small number of egg producers than it is to follow the agencies 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, 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.

Eggs, Egg Products, Cheese and Milk

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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 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.

California has a deficit capacity of breaker plants as compared to the Midwest, and not every company has equal access to diverting eggs. We can predict that producers will not only have to absorb a greater discount, but trying to find a breaking plant could become problematic as eggs may have to travel further than the nearest breaking plant as some closer plants may be unwilling to pasteurize the diverted eggs.

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 un-funded 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 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 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. In addition, added refrigeration equipment may be need 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 loss of thermal checks. Increasing the nation's flock size will further erode producer profits by putting more eggs into commercial channels.

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 short of that initiative will be met with unequal enforcement.

Sincerely,

A handwritten signature in black ink, appearing to read "M. I. Sencer", with a long horizontal flourish extending to the right.

Michael I. Sencer
Executive Vice President