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12-08-2004

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

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

Dear Sir or Madam:

I am writing to comment on the Food and Drug Administration's proposed rule on Salmonella Enteritidis in shell eggs. I am a family farm egg producer with operations in Lake Park, Minnesota. As a family farmer, I take very seriously my role in delivering a safe and wholesome product to my customers. FDA should review medical information from Centers for Disease Control, which finds egg quality assurance programs have already made a difference wherever they have been implemented. These programs have been initiated by producers voluntarily with no federal mandate.

I am already regulated by many different federal and state agencies. Although the aim of the regulation may be good the cost of compliance with another layer of regulations can be high especially for a small family farm producer. I respectfully urge the FDA to minimize additional regulations.

I urge FDA to review existing state and private egg quality assurance programs to see if they provide equivalent protection. If so, producers in compliance with those programs should be considered in compliance with FDA's regulations.

FDA should use The Agricultural Marketing Service which already inspects my facility to carry out any inspections for compliance that may result from the proposed regulations.

I would also suggest that FDA needs more information from scientists and veterinarians that are experts in disease eradication and control. Some parts of the proposal appear to conflict with sound science.

The proposed rule does nothing to encourage vaccination that has proven highly effective in controlling SE. I suggest that producers be allowed to vaccinate and then perform an environmental test prior to depopulation. I have been voluntarily vaccinating all my layers for several years as a precaution against SE.

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FDA does not indicate in their analysis whether there is sufficient laboratory testing capacity available for all the proposed testing that could be required.

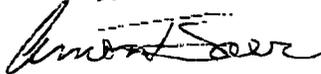
FDA's requirement for wet cleaning would be extremely costly in my part of the country in the winter months. FDA says in the proposed rule that some studies show an increase in SE after wet cleaning and yet the agency is still proposing just that.

FDA's biosecurity requirements should be more flexible. Biosecurity is important, but the extensive steps proposed will be extremely burdensome on smaller farms. It could potentially cause smaller producers to go out of business and lead to further consolidation in our industry.

Has FDA surveyed processors to see whether they are willing to buy eggs from flocks known to be SE positive? If a producer has a positive flock and can not sell the eggs the loss to producers would be much higher than what FDA has estimated. The flock would then have to be depopulated. FDA should address this problem through an indemnity program payable to producers if a flock needs to be destroyed.

In conclusion, as the owner of a family farm that I would like to be able to pass on to my children, the regulations passed by FDA should be reasonable, scientifically based and flexible enough to allow me to continue in operation. Any cost associated with your regulation will be borne directly by my farm. I strongly urge you to consider the changes that producers are asking, so that this regulation can be workable and I will be allowed to continue in business.

Sincerely,



Amon Baer president  
Baer Bros. Inc.