



VANDE BUNTE EGGS

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

[Docket Nos. 1996P-0418, 1997P-0197, 1998P-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 an egg producer with operations in Martin, Michigan. As an egg producer, I take pride in delivering a safe product to my customers. Food safety is in my interest as a farmer and small business operator. FDA should review medical information from the Centers for Disease Control, which finds egg quality assurance programs have already made a difference wherever they have been used. Producers and states have been implementing these plans voluntarily, with no federal mandate.

I am already regulated by many different federal and state agencies. Even when the aim of regulation is good, the burden of complying can be heavy, especially on farms and other small businesses. I respectfully urge FDA to minimize the additional burden:

1. **Recognize and reward what states and the industry are already doing.** FDA should thoroughly review all existing state and private egg quality assurance programs to see if they already provide protection equivalent to what FDA is seeking. If so, then producers who are in compliance with one of these plans should be considered to be in compliance with FDA's regulations.
2. **Carry out inspections and enforcement through federal and state agencies that already regulate our industry.** The Agricultural Marketing Service already inspects egg packing facilities four times a year under the Shell Egg Surveillance Program, often in cooperation with state agencies. AMS and the states are knowledgeable of the egg industry, and using them will avoid diverting FDA employees away from homeland security, import inspections and other work.

I would also suggest that FDA needs more input from scientists who are experts in egg and poultry science. Several parts of the proposal should be changed because they are either impractical, unnecessarily costly or in conflict with sound science.

- **The proposed rule does nothing to encourage vaccination,** even though it is a highly effective means of controlling SE. I suggest that producers have the ability to demonstrate the effectiveness of a vaccination program,

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and if they can do so, then they should be able to follow a protocol of a single environment test shortly before depopulation.

- **FDA does not give any indication whether it has surveyed existing laboratories to find out whether they can handle the increased testing workload** as a result of this proposed rule. Before implementing the rule, FDA should survey public and private laboratories to assess whether lab capacity is adequate, especially in case of an outbreak of avian influenza, exotic Newcastle disease, or another serious animal illness.
- **FDA's requirement for a wet cleaning is unrealistic.** In winter months, it is not practical to do this in large parts of the United States. FDA should not impose a requirement that producers cannot carry out. FDA says in the proposed rule that some studies show an increase in SE after a wet cleaning – and yet the agency is still proposing to require wet cleaning! FDA should make the wet cleaning optional, and require only a dry cleaning after an environmental positive.
- **FDA's requirement that eggs held more than 36 hours be refrigerated at 45 degree F is also unrealistic and unnecessary.** This would mean new refrigeration requirements *every weekend and holiday* for further processors who have production capacity – and yet the eggs will immediately be pasteurized, killing the bacteria! In addition, this requirement could actually be detrimental to food safety for eggs that go into the table market. When the eggs are washed, there will be a higher incidence of checks and cracks if they have previously been refrigerated, simply because of the sudden change in temperature. FDA should lengthen the 36-hour limit to something more realistic, like 72 hours. FDA should then require refrigeration at 55 degree F unless the eggs are held more than a week, and then impose the 45 degree F requirement if necessary.
- **FDA's biosecurity requirements should be more flexible.** Biosecurity is important, but the extensive steps the agency lists will be extremely burdensome on smaller farms, especially off-line contract farms. Along with other costs, these requirements could cause further consolidation in our industry, with smaller operations unable to afford the additional labor and compliance costs. Yet our government always professes to be concerned about increasing concentration in agriculture.
- **Has FDA surveyed processors to see whether they are willing to accept eggs from SE-positive flocks?** In the years since FDA first began working on egg safety, more and more egg processors have arranged for dedicated sources of egg production, on-site or off-site, so their need to buy eggs on the open market is less to begin with. If eggs from SE-positive flocks could not be sold at any price, then the loss to producers would be much more than the FDA has estimated and might require the regulation to be submitted to Congress under the unfunded mandates law. One way for FDA to address this problem would be through an indemnity system, payable if producers have fully complied with the regulatory requirements.

In closing, I repeat that my farm is dedicated to delivering a safe product to our customers. We will always comply with the law and regulations to the best of our ability. But we need regulations that are flexible, reasonably applied, and scientifically based if we are to survive as a business. In agriculture, we usually cannot pass on increased costs to our customers. The producer ends up absorbing the cost of regulations. I strongly urge you to make the changes that producers are asking, so that this regulation can be workable for our industry.

Sincerely,

A handwritten signature in black ink, appearing to read 'P. V. Bunte', written in a cursive style.

Paul Vande Bunte
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