



November 15, 2004

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. My company, Primera Foods, employs 175 employees at its operations in Altura MN, Barron WI, Cameron WI, Perham MN and Stockton IL. We also have a layer farm, Creekwood Farms, with 50 employees in Lake Mills WI. A large percentage of our food ingredient business deals with the processing of shell egg into a liquid or powder food ingredients for consumer food companies. As an egg processor, I ensure a safe product to our customers by emphasizing food safety throughout the company's operations, and by pasteurizing all egg products, as required by law. Primera Foods has a well defined HACCP program to ensure our products are safe and wholesome for the customer before the product leaves our dock.

No traceback has ever identified pasteurized egg products as the source of a Salmonellosis outbreak – evidence that pasteurization is working under our current laws and regulations.

Egg processors have a strong desire to make FDA's proposed rule as workable as possible for producers. Many egg processors now have their own egg production facilities that supply eggs for breaking plants, while egg processors without production must still be concerned about how regulations will affect their suppliers. Producers are 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

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of a vaccination program, and if they can do so, then they should be able to follow a protocol of a single environmental 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 area where most of our eggs are sourced (Wisconsin, Minnesota, Illinois and Iowa). 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! Primera Foods is very opposed to conducting wet wash practices that potentially will increase the risk for Salmonella and other pathogens. 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° 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! Before mandatory inspection of egg products was implemented in 1971, eggs and egg products were frequently associated with Salmonellosis outbreaks. Since this time no traceback has ever identified pasteurized egg products as the source of a Salmonellosis outbreak – evidence that pasteurization is working under our current laws and regulations. We do not understand why the existing statutory requirement for pasteurization is not sufficient for processed egg products. 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° F unless the eggs are held more than a week, and then impose the 45° F requirement if necessary.
- **FDA's biosecurity requirements should be more flexible.** This provision sets the stage as anti-small farm. Many of our egg suppliers are small farm operations who can not afford to implement the requirements proposed. 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 some smaller operations unable to afford the additional labor and compliance costs. This action would accelerate the departure of these farms. Yet our government always professes to be concerned about increasing concentration in agriculture.

Producers will always comply with the law and regulations to the best of our ability. But our industry needs 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. I strongly urge you to make the changes that producers are asking, so that this regulation can be workable for our industry.

Best regards,



Jon Luikart
President & CEO