



December 14, 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 FDA's proposed rule on Salmonella Enteritidis in shell eggs. I am an egg producer in north central Indiana. As a producer I take pride in delivering a safe product to my customers. Egg quality and safety are vital to my future success. I encourage FDA to 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. We have been using UEP's "Five Star Quality Assurance Program", with an enhanced monitoring program, voluntarily for several years without federal mandate. We recognize the need to produce a safe product and have made it a high priority and will continue to do so.

I understand the need for regulations and the protection they may afford, however I respectfully request FDA to minimize the heavy regulatory burden and producer costs and consider the progress we have made without federal mandates thru our voluntary programs and implementation of new and developing "best management practices". I also request that you consider the potential impact of the "one size fits all" requirements that may not be practical for all producers.

The proposed biosecurity requirements need to be more realistic. We are very concerned with the health and disease protection of our birds. However we have by necessity become very labor efficient with individuals doing a multitude of tasks. It is critical that we allow our labor to work. With the "Five Star" standard for biosecurity we feel we have demonstrated protection of birds and eggs with the flexibility of allowing our workers to accomplish their tasks in a timely and efficient manner. The proposed biosecurity requirements would only increase our costs and at best provide minimal security over what we currently are doing.

I would also like to comment on the proposed wet cleaning requirement. We operate in north central Indiana. It gets cold here in the winter, sometimes very cold. Our houses are designed to be ventilated and heated based on bird population. When we have no birds we can not heat or ventilate our layer houses. We do schedule some houses for wet cleaning when they are empty in the summer months but not during the winter. It is not practical for us to attempt such a project, please don't ask us to do something we can not do.

The requirement that eggs held more than 36 hours be refrigerated at 45 degrees is very unrealistic for us and unnecessary. We have production facilities at multiple locations within our county and all eggs are brought to a central processing facility. The proposed rule would force us

to replace all of our present refrigeration units at the farms (dropping from 55 degrees to 45 degrees requires units with different capabilities and capacities). Even if we did comply with that requirement the results would be disastrous when we tried to process our eggs at the required temperatures (wash water) in both our shell egg plant and breaking facility. When we wash the eggs it would result in a higher incidence of checks and cracks if they have been refrigerated to that low of a temperature simply because of the sudden change in temperature. In the breaking facility we would also create more safety issues than we would be preventing. We strongly suggest that FDA lengthen the 36-hour limit to something more realistic and doable. We would also recommend that FDA require refrigeration at 55 degrees prior to processing. I am not aware of any science that would indicate your proposal would be significantly more protective than our suggestion. FDA's proposed refrigeration requirement would generate an unnecessary financial burden while doing little to improve the safety of our product.

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 I have requested so that this regulation can be workable for myself and my industry.

Sincerely



Ron Truex, General Manager
Creighton Brothers