



Creighton
Brothers

"A Family Farm"
Quality Since 1925

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 am spending more and more of my time documenting all of my activities to appease a variety of regulatory agencies, which leaves me less and less time to actually work and be productive. 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".

One such practice is the use of new vaccines which have been shown to be effective in protecting the birds and reducing shed of SE. With the tool of vaccination, a producer such as myself, could protect his birds such that monitoring would not be necessary. A one time validation by an environmental test prior to depopulation would be demonstration that the vaccination program was effective. This approach would allow the producer to spend his money on preventative measures rather than expensive monitoring programs.

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

OCN-0504

C235

not heat or ventilate our layer houses. We will schedule some house 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.

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



Cal Jackson
Creighton Brothers