

December 16, 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, 2000N-0504 and RIN number 0910-AC14]

Dear Sir or Madam:

We are writing to comment on the Food and Drug Administration's proposed rule on *Salmonella* Enteritidis in shell eggs.

Rose Acre Farms, Inc. is an Indiana based egg production company with production facilities in Indiana, Illinois, Iowa, Missouri, and Georgia. We believe that our opinions bring a unique prospective to these proposed rules because of our prior experience with *Salmonella* Enteritidis. The practices we adopted have been successful in preventing any further human illness instances attributed to our company.

This rule would have been a reasonable response to the problem, as it existed in 1992. It actually incorporates many of the suggestions that Rose Acre Farms made in their response for comments in 1992. That was twelve years ago and will probably be fifteen years in the past by the time this proposed rule could be implemented. We believe that the events that have transpired since that time should be considered.

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. Rose Acre Farms, Inc. strongly believes that its SE Control Program is highly effective and our record of the last twelve years proves it.

It is our belief that the breeding line of bird that we were utilizing in 1990 was a major factor in the environmental contamination that was found in our facilities. Dekalb breeders have been involved in the majority of outbreaks. Our breeders came from the Northeast and were sold to us as extra, price-reduced breeders. Rose Acre Farms does not use these lines today; in fact the Dekalb Company is out of business.

We vaccinate all pullets for SE. **We believe that vaccination should be required of all producers and of all birds.** Worldwide, it has been proven to be the most effective and cost efficient form of prevention of SE contamination. Although some parts of the country are more prone to SE contamination, SE is ubiquitous in our environment and vaccination offers the most insurance to cross contamination from natural and man-made sources.

We do not believe wet cleaning should ever be used due to problems inherent in the process. Wet cleaning can wreak havoc on the metal equipment in a building and can substantially reduce the buildings useful life. Rose Acre Farms, Inc has more experience with this issue than any other company in the US and it is not only expensive but is also dangerous to worker safety, and ineffective in accomplishing its goal.

Wet cleaning has been shown in some studies to actually increase SE. It is impossible to clean between nailed together pieces of wood and the moisture that remains especially during winter for an extended length of time provides a bloom that actually makes the situation worse. We do not believe the agency should propose to use a process that could actually increase the prevalence of SE.

The current proposal exempts producers with fewer than 3,000 laying hens. However, again, if food safety is the purpose of the proposal, exempting hens based on the size of the operation defeats its purpose. The program as it is being proposed would be expensive for all flock sizes but **a program that required vaccination of all flocks regardless of size would certainly be cost effective.** It would also provide the most effective and cost efficient barrier to transovarium contamination for a population of birds that traditionally are housed in facilities that allow access to the out of doors.

From a competitive prospective, **we don't believe that anyone could have written a better rule to eliminate competition in our industry.** The administration costs are prohibitive to a large producer and will be overwhelming to even a producer with one million birds. This is a government program with government record requirements; not an industry based program.

When, and NOT if, due to the regulation, a producer must face for any reason the requirement to divert eggs for breaking and pasteurization, (even because of lab error) they will find that no viable options exist in today's world. The breaking industry has changed dramatically in the last five years and no market exists for these eggs that will return even the cost of production. The destroying of the flock will be the only alternative in most cases. This will be a financial catastrophe to any company. The only viable solution to this exposure of our producers would be an indemnification program. We understand the limitations of FDA to such a program but we would also remind FDA that providing a reasonable cost food product is in the best interest of everyone. Putting people out of business should not be a reasonably expected result of a government program.

If the FDA contention were that the desired public health outcome could only be achieved through a mandatory Federal Program, than we would also contend that the next step should **be to require that the Model Food Code be mandatory law at the food preparation and serving environment. At establishments that serve high percentages of highly susceptible populations, ONLY pasteurized shell eggs or pasteurized egg products should be served.** These products are readily available today

and the minimum additional cost for these products afford the best possible insurance from exposure for these populations.

We do not agree that the cost to benefit analysis is a reflection of either the true costs or the true possible benefits. Generally, we believe that the most effective and efficient steps that could be taken are the **national requirement of vaccination for SE of all domesticated egg producing birds and the adoption of a mandatory National Food Code with the required use of pasteurized shell and egg products for susceptible populations.**

Sincerely,

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