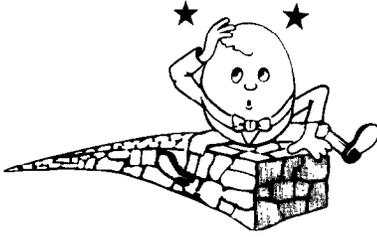


HUMPTY DUMPTY EGGS, INC.



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December 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 and
RIN number 0910-AC14)**

Dear Sir or Madam:

I am writing to comment on the FDA's proposed rule on *Salmonella* Enteritidis in shell eggs.

We are an egg producer in Reedsville, Wisconsin and have been in business since 1956. We produce, process and direct market our eggs to restaurants, hotels, bakeries, grocery stores, etc. We have 71,000 laying hens derived from four different sized flocks: 21,000; 21,000; 16,000 and 13,000. All of these flocks are housed in separate buildings, as we are an off-line producer. Each of these flocks is kept for exactly one year. We do not molt or force molt any of our birds. After one year the flock is shipped and the building is wet sprayed and thoroughly cleaned before restocking with new birds a week later. Since we are a small, family-owned business most of this labor is done by our family.

In the 48 year history of our business we have been involved in two SE tracebacks, one in 1989 and one in 1997. As a requirement of the FDA, samples were taken by state and federal agency personnel and sent away. In both instances all tests came back negative – thus proving the proactive approach we take toward preventing SE does work. Our company prides itself on cleanliness and works hard on a daily basis to keep it that way. Daily cleaning, regular maintenance, rodent control, wet spraying between flocks, etc. are the norm on our farm.

Enclosed are highlights from the USDA National Animal Health Monitoring System survey results from February 1999 which show that wet spraying is clearly essential in SE prevention. In this survey, no houses that were wet sprayed tested positive for SE. Since the onset of this company we have wet sprayed between every flock, without fail. We understand the costs associated with this are extensive, yet we choose to do all this in our ongoing fight against preventing SE. I believe that on a per bird basis, this company spends as much or more on SE prevention than anyone. If we are required to allot money

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for this type of proposed testing it is certainly going to force us to cut back in the area of prevention. This proposal defeats everything we work so hard to accomplish. Testing is reactive. We choose to be proactive. Isn't money better spent on proactive prevention? We believe it is. Putting a small producer like us on this type of testing program may actually increase the chance for SE rather than prevent it, simply because we will be forced to spend money on testing rather than on the real issue which is keeping a clean facility. We have always prided ourselves on the amount of time, effort and money we invest in running a clean operation. This proposal puts that in jeopardy.

Certainly SE testing is not done without a huge cost. In the 1997 case we spent over \$750.00 for testing alone. This did not include the materials or our labor necessary to perform the tests. These costs will assuredly be considerably higher today. While we understand the need for tracebacks and the costs that are associated with it, to impose testing on a regular basis is simply not feasible. For example, the economic output of a 13,000 bird flock doesn't begin to justify the cost of even the first round of testing. In the event of a positive first round test the proposal requires egg testing or diversion. Given the size of the flock, this means certain depopulation simply because the number of eggs required for testing and the costs associated with it are too great. Producers do not produce shell eggs only to divert them to the breaker. This, as well, would not be cost effective. Being that all of our flocks are smaller in size it certainly puts this producer at a huge disadvantage – to the point of being career ending. This is not a “one size fits all” proposal.

Statistics clearly show that the number of SE outbreaks linked to eggs has gone down in recent years and continues to decline. Producer awareness has certainly increased in an industry-wide attempt to curtail outbreaks. Not only are producers aware but have also implemented safety measures which are reflected here. This shows that egg producers do in fact care about consumer welfare. While needing to run a profitable company, priority #1 remains producing a safe product. That's why we believe investing the time, effort and money in keeping a clean facility far outweighs testing “after the fact”.

In closing, we urge you to reconsider this proposal. Our livelihood depends on it.

Sincerely,

HUMPTY DUMPTY EGGS, INC.



Paul R. Brandt
President

PRB:ejb

Enclosure



United Voices



United Egg Producers
Gene Gregory - Editor

November 6, 2000

NAHMS SURVEY RESULTS

The USDA National Animal Health Monitoring System (NAHMS) has published the results of their egg industry survey to determine the prevalence of Salmonella enteritidis in the environment. In February, 1999 statistical data was collected from 526 farm sites within a 15-state target population accounting for approximately 75% of the table egg layers in the U.S. During the period of May through October 1999, environmental samples were collected from 200 layer houses. Rodents were collected in 129 houses.

A total of 17 environmental samples were taken from the manure, egg belts, elevators and walkways of each of the 200 layer houses. A layer house was considered to be SE positive even if only one (1) sample was positive. Highlights of the survey include the following:

- 58% of farm sites routinely tested for SE in 1999. The percentage of farm sites with a SE testing program ranged from 25.6% of farm sites in the Central region to 83.8% of farm sites in the Southeast region.
- A total of 14.6% of layers (on 5.4% of farm sites) had been vaccinated as pullets against SE.
- 56.1% of farm sites participated in a SE quality assurance food safety program.
- At least one (1) environmental sample was found to be SE positive in 7.1% of the layer houses. Regional prevalence estimates ranged from 0% in the Southeast to 17.2% in the Great Lakes region.
- None of the houses tested positive for SE on farms where the feeders were cleaned and disinfected between each flock. No houses tested positive where cages, walls, and ceilings were washed between each flock, whether or not they were fumigated.
- Overall, 3.7% of house mice cultured were positive for SE.
- Flocks less than 60 weeks of age were 4.7 times more likely to test positive than older, unmolted flocks. Flocks that were 0-16 weeks post-molt were 9.3 times more likely to test positive compared to flocks that were 60 or more weeks of age and unmolted, but flocks more than 16 weeks post-molt had very little increased risk.

Anyone interested in a full report of the NAHMS survey may find it posted on the web site at www.aphis.usda.gov/vs/ceah/cahm (see Poultry).

