



December 19, 2004

Food and Drug Administration
FDA Docket Clerk
Docket nos 1996P-0418, 1197P-0197, 1998P-0203 and 2000N-0504
5630 Fishers Lane Room 1061
Rockville, MD 20852

On behalf of the State of Minnesota, Department of Agriculture, I am submitting comments on the proposed rule *Prevention of Salmonella Enteritidis in Shell Eggs During Production*, as promulgated by the Food and Drug Administration and published in the September 22, 2004 (Volume 69, Number 183) *Federal Register*.

We support many of the proposed rules in relationship to strengthen safety and the egg supply by limiting the exposure of pathogenic organisms such as *Salmonella enteritidis* (SE) to humans. Our comments are in support of sections that we agree need to be codified in the Code of Federal Regulations (CFR) and to those sections of the proposed rule which, in our judgment, need to be revised.

Current Federal Egg Safety Measures for Shell Egg Production and Retail

The FDA asserts that some "activities" have taken place to reduce the risk of exposure to SE, such as the labeling of shell eggs with a "Safe handling instructions" statement. Yet, in reality, the effect of a safe handling statement is negated when there is no requirement that it be listed on the principal display panel. In fact, presently FDA allows for the safe handling statement to be printed on the back cover of the carton. If the FDA believes that a safe handling statement is an effective means of educating the consumer to properly handle eggs that statement must be required to be in plain view of the consumer. Nevertheless, a 1995 study by CDC, FDA and other State collaborators showed that less than half (45.4%) reported seeing a safe handling statement on packages of raw meat and poultry. As a result, we believe that safe handling statements contribute little or nothing to safe food handling practices.

Since a majority of the documented cases of foodborne illness outbreaks are from a pooled egg source, food service operations should be required to use either pasteurized eggs in the shell or liquid eggs and the FDA Food Code should be modified to include this requirement. A change in the FDA food code will have a significant effect at the state level, since according to the Association of Food and Drug Officials (AFDO) 48 of 56 States and territories (86%) have adopted codes patterned after the 1993, '95, '97, '99, or 2001 versions of the Food Code. Those 48 states and territories represent 79.0% of the US population

Section E. The SE Preventive Measures

1. Chicks and Pullets

We agree that all pullets and chicks should be procured from a hatchery or breeding flock that participates in the National Poultry Improvement Plan (NPIP). The NPIP participants have developed effective strategies that have reduced the prevalence of many poultry diseases including SE.

2. Biosecurity

A required biosecurity program for SE appears impractical. Most egg layer operations already have a biosecurity plan in place to prevent the spread of poultry disease such as Avian Influenza and exotic Newcastle

3. Rodents, Flies and Other Pest Control

Rodent control is undisputedly the primary SE prevention measure for layer facilities. However, the benefit of fly control is much less clear as the role of flies in the spread of SE is uncertain. Insect control is important, but not to the extent of conducting indexing of flies. Consequently, we agree that a rodent control program must be implemented as suggested under § 118.4 (c)(1), but recommend elimination of the insect indexing control plan under §118.4(c)(2).

4. Cleaning and Disinfection

Cleaning and disinfecting of an environment positive barn is imperative before a new laying flock is placed into the barn. However, more complete studies must be conducted before the FDA should prescribe a particular method of cleaning such as wet cleaning vs. dry cleaning. Therefore, §118.4(d) should not include the methods used, rather the cleaning and disinfecting procedures must be sufficient to eliminate SE. Furthermore, SE environmental samples must be obtained after sanitization and before placing the new flock.

5. Refrigeration of Shell Eggs Stored More Than 36 Hours

Although research has shown that the refrigeration of shell eggs controls the growth of SE, requiring refrigeration of shell eggs to 45°F if kept on the farm greater than 36 hours may create a greater hazard with subsequent handling. Cooling an egg to 45°F causes significant sweating when the eggs are removed from the cooler. Since the eggs on the farm have not been washed or sanitized, this sweating provides conditions whereby microorganisms on the outside of the shell can migrate through the egg shell pores. Keeping egg shell surfaces dry is very important to prevent excessive microbial contamination and shell penetration. In addition, eggs must be washed at the processing plant in water that is a minimum of 90°F. Most processing plants wash eggs at 110°F as this temperature is most effective at removing soil and fecal material from the shell. Washing eggs at 45°F at 90°F or at 110°F causes thermal checks (cracks in the shell) leading to excess loss of eggs.

F. Indication of the Effectiveness of the SE Prevention Measures: Testing

1. Environmental Testing for SE

A wide range of egg laying facilities exist in the United States, from free-range to confinement operations using either cages or nesting boxes. Because of this variety, one single sampling plan cannot be used effectively in all types of operations. Therefore, we recommend grouping of operation types and associated sampling plans. For example, we recommend that in §118.5 all confinement barns where the layers are confined to cages be sampled similarly. A minimum of one manure drag sample must be obtained from each bank of cages. For other types of egg laying facilities, the sampling plan determination is much more difficult. More research needs to be conducted to determine the most appropriate sample sites for operations that are cage free or using more traditional methods of pasture raised or free-range.

Regarding the timing of environmental sampling, the selection of 40 to 45 weeks is arbitrary and should not be so prescriptive. Rather, samples should be obtained within the time period of active production. Since data shows that layers are most likely to be shedding prior to the 60th week of production, we suggest that the time span be from between the 40th and the 60th week of production. In addition, if the environmental samples taken at this time are negative there is no need to conduct additional samples for those birds which have undergone an induced molt.

Further, when a facility is found positive for SE, it is not practical to begin egg sampling within 24 hours after receiving the positive result as proposed in §118.5(a)(2). Laboratories must be prepared to accept multiple samples of eggs and the sampling procedure should be witnessed by a regulatory agency such as a State Department of Agriculture

2. Egg Testing for SE

We agree with the sampling protocol established in §118.6(c) with the aforementioned exception that 24 hours is not a practical timeline to begin egg testing after a positive environment is found. We suggest that §118.6(c) require egg producers to immediately notify the appropriate state agency of the positive environmental findings and that egg sampling commence within two weeks after the test results are received. In addition, the sampling of eggs must be conducted under the supervision of the State regulatory agency.

G. Sampling and Testing Methodology for SE

1. Sampling of the Poultry House Environment

We agree on the methods for conducting sampling of the environment with the exception that FDA must conduct more research on the appropriate means of sampling certain environments. The procedure for sampling manure pits in a high rise facility with caged layers is fairly straight forward. However, those non-confinement operations do not have a clear direction on what is the most appropriate sampling site. It would be unreasonable to expect an operation with 10,000 layers to develop a scientifically valid sampling program when FDA cannot define what is scientifically valid.

2. Egg Sampling

Except for the egg sampling suggestion covered previously in F.1 Environmental Testing for SE, we agree with the procedures outlined in § 118.5(a)(2)(B) and (b)(2)(B). Additionally, due to potential breakage, a sample size of 1,050 eggs eliminates the problem of having to use cracked or broken eggs (i.e. The laboratory can select 1,000 eggs from this 1,050 egg pool).

J. Recordkeeping Requirements for the SE Prevention Measures

7. Comment Solicitation on Recordkeeping Measures

Other than the proposed records requirements in numbers 1 through 6, we do not see the need to require further documents related to a written SE prevention plan. The final rules will mandate what type of a program the industry will follow and we see the requirement of additional plans or records as a means for regulatory agencies to issue violation notices while conducting audits of the firms. Requiring such records would only add additional costs for producers.

K. Enforcement of On-Farm SE Prevention Measures for Shell Eggs

Before these rules are enforced, the FDA should strongly consider delegating layer operation inspections to appropriate State agencies that already have inspection authority in many areas of these egg laying operations. For example, a number of the egg layer facilities contain grading stations which are subject to the Shell Egg Surveillance (SES) portion of the United States Department of Agriculture (USDA) Egg Products Inspection Act (EPIA). The duties of enforcing the EPIA have been contracted out to State agencies. Audits of egg laying facilities could be conducted at the same time as the SES inspections. Further, State agencies have close working relationships with Universities many of which have poultry science or animal science departments that can assist in the development of educational programs for the industry. Likewise FDA should make funding available to State agencies and Universities to develop those programs.

We hope the above comments will receive proper consideration in order to prevent potential human exposure to *Salmonella enteritidis*.

On behalf of the State of Minnesota,

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