

December 21, 2004

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
fdadockets@oc.fda.gov

Re: Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203, and 2000N-0504 and RIN number 0910-AC14

To Whom It May Concern:

To follow are my personal comments on the FDA Proposed rule on control of *Salmonella enteritidis* (SE) in layer flocks:

1) **Diversion of flocks that test SE egg positive to pasteurization** – Although this is a very good means of taking eggs from high risk flocks off the shell egg market, not all producing areas in the US have pasteurization plants available for diversion. Also, breaker plants are not usually looking for additional product as they have contracts to supply their needs. The difference in price between the shell egg market and breaker market is great at times, especially for eggs from a high-risk flock. In order to not unfairly burden an egg producer with sending eggs to pasteurization, either not require it or pay for the difference in income lost by diverting.

If diversion is not possible, what is the alternative? Depopulation? This is an economically devastating step to control a food borne disease that totally preventable by proper cooking. USDA indemnifies producers for depopulation of flocks for disease control purposes. Again, avoid this economic issue by either not requiring diversion or paying indemnity that includes full profits that the flock would have given the producer.

Pushing the manure test back to 12 to 15 weeks prior to end-of-lay, not requiring egg testing or diversion for positive flocks, and allowing the producer time to plan for control of SE in the next flock (increased rodent control efforts, vaccination, cleaning and disinfection (C&D), etc.) would serve a similar purpose of SE reduction and alleviate the many problems associated with diversion and egg testing.

2) **Laboratory capabilities and costs**– Very few laboratories in the US currently are testing either manure drag swab samples or egg pools for SE. Significant increases in expenditure for lab personnel and equipment will be required for the required testing as set forth in the proposal.

A great deal of the costs are associated with egg testing. Manure testing alone can be used to determine high risk flocks thus dropping the costly egg testing requirement. These high risk flocks can then be allowed to lay out and the producer concentrate efforts at reducing SE in the next flock (C&D, vaccination, rodent control).

Requiring the egg producer to bear the costs of manure and egg testing for the benefit of public health implies that these costs should be subsidized or paid for entirely by public funds. For example, the costs for testing manure and eggs is paid completely by the state of PA for PEQAP.

3) Requiring wet washing during C&D between flocks after finding a manure positive flock- The Pennsylvania Egg Quality Assurance Program (PEQAP) has allowed C&D without wet washing between flocks after the previous flock was found to be manure positive since early 2003. A producer is not eligible to use the Dry Clean Program unless a) the PEQAP coordinator approves it, b) the number of manure samples positive for SE does not exceed 25%, c) a rodent index of 2 or less has been achieved for the last 3 months, and d) the next flock will be vaccinated against SE. The PEQAP SE Dry Clean Program consists of a) complete and thorough dry cleaning of house with removal of all manure, dust, and organic material, b) fumigation with formalin, c) down time of at least 10 days between flocks, d) a concerted effort to rodent-proof house between flocks, and e) SE vaccination of incoming pullets.

A research project performed by the University of Pennsylvania studying 7 houses that had two consecutive flocks that were positive for SE by manure testing with a wet wash C&D in between. These 7 houses were completely dry cleaned and fumigated, rodent-proofing was accomplished, and incoming pullets were SE vaccinated. Only 2 of 7 houses tested manure positive at either 30 or 45 weeks of age, much better than prior results. Results after approval of this procedure has lead to equal to or better results compared to wet washing. This program allows the producer to reduce the costs associated with wet washing, not have to deal with waste water disposal, and improve the longevity of equipment. The program allows an EQAP to require SE vaccination in exchange for eliminating the wet washing step.

4) Training – Basic training of on-farm personnel in the basics of SE prevention programs (biosecurity, rodent control, C&D, vaccination, etc.) should be required. More extensive training is needed for flock supervisors, EQAP technicians, and flock owners to include more extensive training in HACCP techniques.

5) Biosecurity – Only basic premises of biosecurity should be given in any EQAP leaving the details to the flock owners. Efforts should concentrate on eliminating transmission of disease between farms and not between houses on farms. Maintaining complete isolation of houses on multi-age layer complexes is not practical and maybe impossible. The following should be stressed in reducing the risk of SE transmission between farms: a) decontamination of vehicles and people used to move pullets between the growing house and layer house, b) decontamination of vehicles and people used to move out spent fowl, c) people entering the farm, d) equipment entering the farm, e) rodent control, and f) traffic control on-farm between egg rooms and chicken houses.

6) Pest control – There is no doubt that rodent control is an integral part of any SE control program. The requirement for a formal detection and action program for fly control is questionable. There has been no evidence to indicate that the lack of fly control has lead to problems with SE infection of layers.

7) On-farm 45°F egg refrigeration – SE multiplication in contaminated eggs does not take place for several days at room temperature and even less at the normal 55°F routinely used refrigeration temperature for on-farm egg storage. In addition, eggs held at less than 55°F will suffer from an increase in thermal checks during egg washing hence decrease the egg's resistance to contamination by Salmonellae.

Respectfully submitted,

Eric Gingerich, DVM, dipl. ACPV
Staff Veterinarian
University of Pennsylvania School of Veterinary Medicine
New Bolton Center Poultry Lab
382 West Street Rd.
Kennett Square PA 19348
Phone: (610) 444-4282
Fax: (610) 925-8106
Email: ericging@vet.upenn.edu