



Minnesota

Board of Animal Health safeguarding Animal Health
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December 20, 2004

Division of Dockets Management (HFA305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: FDA Docket Numbers 1996P-0418, 1997P-1097, 1998P-0203 and 2000N-0504 Prevention of Salmonella Enteritidis in Shell Eggs During Production

I have worked for Minnesota Board of Animal Health for almost 20 years as the director of a poultry field laboratory and have cooperated with the egg-layer industry on several occasions in their efforts to deal with Salmonella Enteritidis (SE). The comments and observations are my own and are not meant to express the position of the Minnesota Board of Animal Health.

The Minnesota Board of Animal Health is an independent state agency whose mission as the official animal disease control and eradication agency of the State of Minnesota, is to protect the health of the state's domestic animals. In carrying out our mission, the Board is part of a network of state agencies protecting public health and providing an abundant, wholesome food supply to Minnesota consumers. My experience with the egg layer industry in Minnesota is that they are extremely interested in the proposed egg regulations relating to prevention of Salmonella Enteritidis. They support improving food safety but have concerns with the strategy that FDA is proposing.

I realize that others have submitted comments that offer far greater detail on proposed components of the regulations. Specifically, I support the comments offered by the Salmonella Committee of the United States Animal Health Association (USAHA), a committee of which I am a member. I would like to comment on some specific areas:

1. There is a need to create a structure for industry and government to work cooperatively to develop an SE prevention program. The egg laying breeding companies have successfully eliminated SE through USDA's National Poultry Improvement Plan (NPIP). I have seen first hand how NPIP can be a model of how industry, state and federal government agencies can work together to solve a problem. The egg laying industry is committed to improving food safety for consumers. NPIP offers the structure to develop such a program. It appears that FDA did not discuss proposed regulations with any of the recognized avian health experts with experience in eradicating SE from breeder operations. Members of the USAHA Salmonella Enteritidis subcommittee would certainly be the place to start. NPIP, or a related framework, insures the inclusion of industry experts in the process of establishing programs that accomplish the identified goal.

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2. Vaccination should be included in the proposed regulation. The evidence for the efficacy of Salmonella vaccines although not perfect is very good under the most challenging of research and field circumstances. When either live or killed vaccines are used with appropriate programming, and associated with bio-security measures, testing, and rodent control the result will be a reduction of SE. An SE program is always a work in progress and not a course to elimination.
3. The FDA proposal does not specify which laboratories will be able to conduct the testing nor if there are any requirements that must be met in order to conduct such testing. I would recommend that FDA adopt the methodology used by the NPIP for isolating *Salmonella* from poultry environmental samples. I propose that laboratories must agree to follow the proposed minimal standard guidelines for isolating SE or use other procedures that have been shown to be as effective. Such laboratories would include laboratories that are authorized by the NPIP or those that submit to the NVSL check test.
4. Egg laying operations below 3,000 layers need to be included in an SE prevention program. If we are committed to preventing SE, it is imperative that the whole industry be included in the program. Again, the cost of FDA's proposed program needs to be restructured because as currently proposed; farmers with less than 3,000 layers will be forced out of business.
5. Remove the inclusion of a "pest" control program from the regulation. I know and research has shown that rodents have an epidemiological link to SE, but there is no research to indicate that flies play a role in infecting layers.
6. Remove wet cleaning from the proposed regulation.

Minnesota's egg industry is firmly committed to reducing SE in eggs; however I do not support the methods that FDA is currently proposing. I suggest that more research be conducted and that industry experts be included in further FDA discussion regarding the proposed SE regulation.

Please contact me with any questions at 320-231-5170 or dale.lauer@bah.state.mn.us

Sincerely,



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