



UNITED STATES ANIMAL HEALTH ASSOCIATION

8100 THREE CHOPT ROAD, SUITE 203 • P.O. BOX K227

RICHMOND, VIRGINIA 23288

(804) 285-3210 FAX (804) 285-3367

E-Mail: usaha@usaha.org Web Site: www.usaha.org

1561 5 JUN 10 P2:36

June 6, 2005

RICHARD D. WILLER
PRESIDENT
ARIZONA DEPARTMENT OF
AGRICULTURE

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

BRET D. MARSH
PRESIDENT-ELECT
INDIANA STATE BOARD OF
ANIMAL HEALTH

Re: Docket No. 2000N-0504

To Whom It May Concern:

LEE M. MYERS
FIRST VICE-PRESIDENT
GEORGIA DEPARTMENT OF
AGRICULTURE

These comments are submitted on behalf of the United States Animal Health Association (USAHA) in reference to Docket No. 2000N-0504, Egg Safety; Proposed Rule for Prevention of *Salmonella enteritidis* in Shell Eggs During Production: Reopening of Comment Period.

JAMES W. LEAFSTEDT
SECOND VICE-PRESIDENT
NATIONAL PORK BOARD

USAHA is a 109 year-old science based, dues supported, voluntary national organization of state and federal animal health agencies and other governmental departments, animal agriculture industries, university animal scientists, and veterinary laboratory diagnosticians that addresses issues of food safety, animal health and disease control, homeland security, animal welfare and public health. USAHA serves as a clearinghouse for new information and methods that may be incorporated into laws, regulations, policy and programs. It acts to develop solutions to animal health and food safety issues based on science, new information and methods, public policy, risk/benefit analysis and the ability to develop consensus for changing law, regulations, policies and programs.

DONALD E. HOENIG
THIRD VICE-PRESIDENT
MAINE DEPARTMENT OF
AGRICULTURE

This letter is intended to address a request for comments published in the Federal Register / Vol. 70, No. 89 / Tuesday May 10, 2005, by the United States Food and Drug Administration. The comment period was extended in order to collect further information regarding pullet testing for *Salmonella enteritidis* (SE) in the U.S. Responses to questions posed in the Federal Register notice follow below:

J. LEE ALLEY
SECRETARY

- 1) How many pullet-growing facilities are there in the US?

It is estimated that there is 1 pullet house for approximately every 3 layer houses. United Egg Producers (UEP) may be conducting a survey to better answer this question. Also, the equipment manufacture companies may have supportive information.

J. W. BRYAN
TREASURER
CLEMSON UNIVERSITY

- 2) What is the range in the number of houses on those facilities?

The range is from 1 to up to 21 houses per facility. Approximately 60% of pullet grow units are single house farms with the rest (40%) multi-house farms. An estimate of the number of how many pullet complexes are single-age vs. multi-age that 90% of pullet units are single age units with the other 10% being multi-aged.

00N-0504

C381

- 3) What percentage of pullet growers are under programs or have practices aimed at preventing chicks from NPIP SE clean breeders from becoming infected by SE during the period of pullet rearing until placement into layer houses?

Inherently due to basic disease control measures directed mostly at Marek's Disease control, 100% of pullet producers use some degree of practices aimed at keeping pullets free from SE. Most if not all use some form of cleaning and disinfection procedure of pullet houses between flocks for Marek's control. Most all practice some biosecurity to preclude SE introduction. As far as the percent of pullet flocks grown under an official program (state or industry (Wal-Mart, UEP, etc.) an estimate is 50% nationally. A much higher percentage (80 to 90%) of growing pullets are on programs in some states. There are also a percentage of flocks (approximately 20%) on company directed programs, with veterinary input, that have practices for controlling and monitoring SE.

- 4) Do State or Regional Egg Quality Assurance Programs include provisions to prevent chicks from NPIP SE Clean breeders from becoming infected by SE during the period of pullet rearing until placement into layer houses?

Yes. Most include the same practices as in layer units – biosecurity, rodent control, C&D of houses, etc.

- 5) How effective have the pullet programs been in reducing the prevalence of SE in layer flocks?

Pullet programs have been very effective. It is a rare event to find pullets as the source of SE in a layer flock. In the PEQAP program, 1 or 2 flocks a year (usually on the same complex) are found positive by manure testing at 10 to 12 weeks of age. For the years 1999, 2000, and 2001 the percent SE positive manure swabs taken at 10 to 12 weeks of age was 0.2%, 0.1%, and 0.5%. All were the same premise each year. Many states report no positive pullet flocks for several years.

A veterinarian working with a large Midwestern producer stated that 2 pullet flocks in the last 10 years have been positive for SE due to rodent control problems in high-rise pullet houses.

Prior to 1995 in a Northeastern program, 1.5 % of pullet flocks (20 of 1372) tested positive. The source of the infection were as follows: A single SE positive parent flock (12), other SE positive parent flocks (3), positive rodent exposure (2), proximity to SE positive layer houses (2), and undetermined (1).

- 6) How is effectiveness measured?

In PEQAP and other programs, the effectiveness is measured by manure or manure belt swabbing at 10 to 12 weeks of age, 2 swabs per row of cages. In some States such as California, a risk based sampling strategy is used based on prior history and current risk.

- 7) During pullet rearing, what programs or industry practices are currently taken to prevent chicks from NPIP SE Clean breeders from becoming infected by SE during the period of pullet rearing until placement into layer houses?

a) Cage rearing (less fecal to oral contamination, b) C&D between flock, c) biosecurity (traffic control, fly control, rodent control, cleaned and disinfected trucks for moving pullets out to the layer house, crews (vaccination, beak trimming, moving) supplied with clean clothing, footwear, and headgear) and d) monitoring of manure or pullet samples prior to movement.

- 8) Are pullets, or their environments, tested for SE between the time they are procured as chicks and the time they enter layer houses?

Some state and industry programs require this. Many programs are considering dropping the chick box paper test and rely on the NPIP SE Clean Program in parent flocks as the very, very low percent positives found is not worth the expense. Some programs use a risk-based approach and do not use the 10 to 12 week manure testing requirement as fewer and fewer positives have been found over the past 10 to 15 year period.

- 9) If so, when?

Five to 10% of chick box papers and manure at 10 to 12 weeks of age to allow time for action before moving to the lay unit for diversion to a different lay facility, vaccination, or destruction, should the flock test positive.

- 10) When tested, approximately how often do pullets or pullet environments test positive?

See number five above.

11) What happens after a positive test?

If positives are found, a decision must be made by the owner to 1) destroy the flock, 2) vaccinate the flock, 3) treat with antibiotics/probiotics and retest, 4) vaccinate and medicate, 5) use the flock for pasteurized egg production, or 6) do nothing. Cleaning and disinfection between flocks is required in programs requiring pullet testing. Some programs require a negative environment test prior to placement of chicks following a positive flock.

12) Is vaccination used as a preventative measure?

Vaccination use is based on the risk of SE infection at the destination of the pullet, the layer unit. If the layer unit has a high risk of detecting SE, inactivated vaccine (with or without 2 priming live *Salmonella typhimurium* (ST) vaccines) is normally applied at 12 to 14 weeks of age. In lesser risk situations, live ST vaccine may be used applied 3 times during growing. The exposure to SE is a problem in layer houses, not in pullet houses. The use of mass applied live ST vaccines is becoming much more common as insurance against SE infection.

13) If so, when and how?

In low risk situations, live ST vaccine is commonly given, 3 doses given at 2, 4 to 6, and 14 weeks. In high risk situations, inactivated vaccine, one application at 12 to 15 weeks of age is given. A combination of live ST and killed vaccine, 2 doses of live ST vaccine are given at 2 and 4 to 6 weeks followed by the killed vaccine at 12 to 15 weeks is used by some producers.

14) What cleaning and disinfection practices are common?

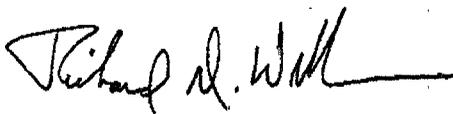
Since Marek's Disease is still a threat, it is estimated that 60 % of houses are wet washed followed by an application of disinfectant. The other 40% are dry cleaned and either fogged with disinfectant or disinfectant is applied by spray. This can vary regionally.

15) Are measures taken to reduce the prevalence of rodents and pests in the pullet rearing houses?

A major effort is not made for rodents due to the comparatively more frequent complete cleanout between flocks in most houses. Rodent problems are not much of an issue in manure belt pullet houses, which make up approximately 30 to 40% of pullet housing.

Thank you for the opportunity to provide these comments.

Sincerely,



Richard Willer, President
United States Animal Health Association
8100 Three Chopt Road, Suite 203
P. O. Box K227
Richmond, Virginia 23288
804- 285-3210 FAX 804-285-3367
E-Mail: usaha@usaha.org
Web Site: www.usaha.org