

DEPARTMENT OF FOOD AND AGRICULTURE

A.G. KAWAMURA, Secretary

Executive Office
1220 N Street, Room A-400
Sacramento, CA 95814
Phone: (916) 651-6870
Fax: (916) 651-0713



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June 6, 2005

United States Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To Whom It May Concern:

Re: **DOCKET No. 2000N-0504**

The following letter is intended to address a request for comments 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 United States (US). Following are the responses to questions posed in the Federal Register notice:

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

A national association such as the United Egg Producers (UEP) can provide national estimates. California, which has 7 percent of egg layers in the US, has approximately 34 pullet growing facilities that range in size from 1 to 21 houses per facility. Some facilities combine pullets during brood (approximately 0 to 8 weeks) and grow (approximately 8 to 16 weeks) periods while others keep pullets in separate brood and grow facilities. Some pullet facilities may also be co-located with egg layer facilities.

What percentage of pullet growers are under programs or have practices aimed at preventing SE-monitored chicks from becoming infected during the period of pullet rearing until placement into layer hen houses?

Approximately 90 percent of pullet-raising facilities in California are owned and operated by companies that are presently members of the California Egg Quality Assurance Program (CEQAP). Core components of the CEQAP include the life cycle of layer hens from hatchery through pullet to adult stages.

Do State or regional Egg Quality Assurance Programs include provisions to prevent SE-monitored chicks from becoming infected by SE during the period of pullet rearing until placement into layer hen houses?

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The CEQAP core components include a comprehensive approach from hatch to the end of lay using the following measures (see Appendix 1):

1. Purchase chicks and pullets from hatcheries participating in the National Poultry Improvement Plan (NPIP) "U.S. *Salmonella enteritidis* Monitored Program" or equivalent state plan. Chicks should be delivered with a certifying letter. Started pullets must be obtained from sources with an acceptable salmonella prevention and control program.
2. Chicks and pullets should always be transported in coops and trucks that are cleaned and disinfected between flocks.
3. Obtain feed from mills that follow accepted feed industry "Good Manufacturing Practices" and the "Recommended Salmonella Control for Processors of Livestock and Poultry Feeds, 1988", published by the American Feed Industry Association (AFIA), 1501 Wilson Boulevard, Suite 1100, Arlington, VA 22209 or an equivalent.
4. Use only animal protein ingredients originating from rendering plants participating in the Animal Protein Producers Industry (APPI) Salmonella Reduction Education Program or equivalent.
5. If used, medications, feed additives and pesticides must be administered adhering to approved label directions.
6. Maintain a flock health program to include vaccinations, monitoring and periodic necropsy of mortality or cull birds.
7. Maintain a farm rodent monitoring and reduction program.
8. Pullet and layer buildings will be cleaned and disinfected before restocking. Third-party visual inspection of cleaning and disinfection is required. This must be done by a certified quality control employee designated by the owner, or by a certified independent professional.
9. The farm will maintain an appropriate biosecurity plan to maintain flock health and will train employees on proper procedures to execute the program. Document employee training and comprehension annually. At a minimum this plan will address:
 - a) Training of employees including documentation
 - b) Premises security
 - c) People movement including visitors
 - d) Disposal of manure, mortality, trash and spent fowl.
 - e) Vehicle, equipment and supply movement and sanitation (Cleaning & Disinfecting) in the secure poultry area.

10. Implement a *Salmonella enteritidis* environmental monitoring program at least once during the life of each lay flock while on the lay farm.

Accredited veterinarians, in conjunction with owners, regularly assess and manage current SE risks for layers of all age. Assessment begins with testing 10 percent of chick papers from each load of pullets delivered to a pullet facility. Risk based testing of the pullet environment is based on past history in addition to the mandatory test of layer hens prior to the end of lay. California poultry veterinarians estimate that 20 percent of pullet flocks are vaccinated with live and/or killed SE vaccines. Most significantly, pullet flocks that may have been at greater risk were vaccinated and have remained negative for the remainder of their productive life cycle. It is important to note that it is economically sound policy for producers to detect SE as soon as possible in order to avoid carrying over risk and future costs from high risk pullets into the lay period.

How effective have the pullet programs (whatever the programs entail – cleaning, testing, etc.) been in reducing the prevalence of SE in layer flocks? How is effectiveness measured?

Existing risk-based pullet programs under CEQAP have been extremely effective in controlling and reducing the level of SE on pullet facilities. Historically, the level of positive pullet environments in California has been low and in the mid-1990's, was estimated to be approximately 2% (at the time that CEQAP was first developed). The incidence of SE positive pullets and pullet environments has declined steadily since that time. No positive pullet facilities have been detected during the past three years in California.

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

The CEQAP is founded on voluntary principles of education, application of Good Agricultural Practices (GAP) record keeping, monitoring and auditing test results and program records. Specific details of the CEQAP and vaccination have been presented previously. The application of CEQAP core components at each pullet facility must be accomplished in such a way as to be individually relevant and effective. It is also important to note that producers have voted to augment biosecurity requirements as a result of the Exotic Newcastle Disease outbreak.

Are pullets, or their environment, tested for SE between the time they are procured as chicks and the time they enter the layer houses? If so, when? When tested approximately how often do pullets or pullet environments test positive? What happens after a positive test?

Ten percent of chick papers from each load of delivered pullets are tested for SE. Risk-based sampling is specifically designed for each facility to address historical or current factors indicating a significant risk. This reason for risk-based sampling rather than uniform sampling at one time during the pullet rearing period is due to the extremely low and at present, negative incidence of SE on layer pullet facilities in California. In the past, pullets may have been tested at brood and/or grow periods depending on the level of risk presented, as assessed by a qualified accredited poultry veterinarian who is familiar with the total poultry health program at a given facility. A positive test results in assessing all components of the CEQAP core components for that facility, corrective action is taken which may also include vaccination and probiotics. Environmental and/or pullet sampling is then undertaken in order to validate whether corrective actions were effective. SE has been successfully eliminated prior to lay using this method. In order to validate that an incoming layer flock is indeed negative, eggs were tested as per FDA protocol (four times over an eight week period) with no positive eggs reported thus far.

The epidemiology of SE in California varies considerably from that in other regions and explains how SE can be successfully dealt with using the methods described above. Specifically, the prevalence of SE in positive environmental drag swab samples from California is below 25 percent of 16 swabs per house and only 1.1 percent of all rows sampled in a California statewide prevalence survey were found to be positive for SE (1). These statistics indicate a lower level of SE prevalence than found in the Pennsylvania SE Pilot Project where positive eggs were associated with over 50 percent of 16 swabs being positive for SE (2, 3). These statistics illustrate the need for regionally appropriate risk based strategies for SE in pullets and layers.

Altering the risk-based strategy used in California will undermine the integrity of a leading risk reduction program for SE in the U.S.

Is vaccination used as a preventive measure, if so when and how?

Approximately 20 percent of California pullet flocks are vaccinated with either live and/or killed vaccines targeted at eliminating or reducing SE from internal organs, intestinal and cecal contents of pullets and layers. Live vaccines are commonly given between 1-3 days of age, at 8 weeks and killed vaccines are given at 16 weeks before pullets are placed into layer houses. Some companies in the U.S successfully also use live vaccines during the molt period.

What cleaning and disinfecting practices are common?

CEQAP employee training emphasizes basic principles of cleaning and disinfection. Both dry and wet cleaning practices are used at California pullet raising facilities depending on the type of management system used. Water lines are treated with citric acid or acetic acid to remove scale in pipes, and chlorine is added to disinfect the water lines. Water lines are flushed prior to arrival of incoming pullets and application of vaccines. Dry cleaning includes blow-down, burning feathers from cages, clean out with or without the application of a disinfectant.

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Wet cleaning includes clean-out, use of high pressure water application (preferably hot), application of hypochlorite and/or phenol disinfectant at effective concentrations. Down time of at least 10-14 days is critical to ensure thorough cleaning and pathogen reduction between pullet flocks.

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

Producers invest a significant amount of money to rear healthy pullets in order to recapture their investment as egg layers. Rodents are important vectors of *Salmonella sp.* and *Pasturella multocida* (Fowl Cholera) as well as other important poultry pathogens. Rodent control is continually promoted and has been acknowledged as an important source of SE for pullets and layers (4). Rodent monitoring, trapping and disposal are part of the CEQAP core components for all facilities and as part of a comprehensive flock health plan.

CDFA encourages FDA to incorporate a flexible approach to SE reduction that preserves the integrity of successful regional Egg Quality Assurance programs such as CEQAP, which has contributed to the improvement of egg quality and safety in California over the past decade.

Thank you for the opportunity to provide comments regarding this important issue and feel free to contact me for any additional information.

Sincerely,



Dr. Richard Breitmeyer
State Veterinarian

Attachments

References

1. Castellan DM, Kinde H, Kass PH, Cutler G, Breitmeyer RE, Bell DD, Ernst RA, Kerr DC, Little HE, Willoughby D, Riemann, HP, Ardans A, Snowdon JA, Kuney DR. Descriptive study of California egg layer premises and analysis of risk factors for *Salmonella enterica* serotype *enteritidis* as Characterized by Manure Drag Swabs. *Avian Diseases* 48: 550-561. 2004.
2. Schlosser, W.D., Henzler, D.J., J. Mason, et al. The *Salmonella enterica* Serovar Enteritidis pilot project. In: *Salmonella enterica* Serovar Enteritidis in humans and animals: Epidemiology, Pathogenesis, and Control, A.M. Saeed, R.M. Gast, M.R. Potter, et al. eds. Iowa State University Press, Ames. pp. 353-365.1999.
3. Henzler, D.J., Kradel, D.C., W.M. Sisco. Management and environmental risk factors for *Salmonella enteritidis* contamination of eggs. *Am. J. Vet. Res.* 59:824-829. 1998.
4. Henzler, D.J., H.M.Opitz. The role of mice in the epizootiology of *Salmonella enteritidis* infection on chicken layer farms. *Avian Dis.* 36:625-631. 1992

9. The farm will maintain an appropriate biosecurity plan to maintain flock health and will train employees on proper procedures to execute the program. Document employee training and comprehension annually. At a minimum this plan will address:

- a) Training of employees including documentation
- b) Premises security
- c) People movement including visitors
- d) Disposal of manure, mortality, trash and spent fowl.
- e) Vehicle, equipment and supply movement and sanitation (Cleaning & Disinfecting) in the secure poultry area.

10. Implement a *Salmonella enteritidis* environmental monitoring program at least once during the life of each lay flock while on the lay farm.

C. Processing

1. Follow plant operating guidelines:

- a) Facilities and equipment must be kept clean and in good repair and shall be completely washed at the end of each day's operation.
- b) Lighting and equipment should be adequate to properly identify egg defects in the candling booth and the processing area.
- c) Potable water with less than 2 ppm of iron shall be used for egg washing.
- d) Wash water shall be maintained at 90 degrees Fahrenheit or higher and at least 20 degrees Fahrenheit higher than the temperature of the eggs to be washed.
- e) A USDA approved cleaning compound shall be used in the wash water.
- f) Wash water shall be added continuously and replaced every four hours.
- g) Washed eggs shall be spray rinsed with warm water and a USDA approved sanitizer.
- h) If eggs are to be oiled, follow USDA guidelines.

2. Refrigerate eggs according to applicable federal, state or local laws.

3. Label egg cartons and cases with a "Keep Refrigerated" or similar descriptor to educate consumers about storing of the product.

4. Label egg cartons and loose pack eggs with a Julian pack date to assist with product rotation. An optional "sell by" date may be used at the discretion of the packer as long as it does not exceed 30 days from date of pack.

5. Label cartons and cases with plant of origin number, and if possible, with a flock identification number.

6. The plant will maintain an appropriate biosecurity plan to limit cross contamination by egg flats, pallets, racks or other materials that are returned to ranches. Plastic egg flats must be washed and sanitized after each use and must be returned to the originating farm. Fiber egg flats cannot be sanitized and thus must be destroyed after first use.

7. The plant will maintain an appropriate biosecurity plan to limit cross contamination of unprocessed and processed eggs. New egg cartons and fiber flats should be used for all consumer packages.

At a minimum the plan must address:

a) Training of employees including documentation

b) Premises security.

c) People movement including visitors.

d) Vehicle, equipment and supply movement and sanitation (Cleaning & Disinfecting) related to the egg processing plant.

8. No returned product shall be reprocessed for retail shell egg sales.