



Public Meeting:
FDA's Final Rule for Prevention
of SE in Shell Eggs During
Production, Transportation,
and Storage



Final Rule

One step in a broader farm-to-table egg safety effort that includes our requirements for safe handling statements on egg cartons, refrigerated storage of eggs at retail, and egg safety education for consumers and retail establishments

What Does the Regulation
Say?

Who Is Covered?

- All requirements for a farm if:
 - 3,000 or more layers
 - Do not sell all eggs directly to consumers
 - Any of your eggs are not treated*
- Only refrigeration requirements for a farm if:
 - 3,000 or more layers
 - Do not sell all eggs directly to consumers
 - All of your eggs are treated*
- Refrigeration requirements for transporters and storage facilities:
 - If transport/hold eggs for shell egg processing or egg products facilities
 - Applies only to eggs from farms with 3,000 or more layers



*Definition of Treated

To *treat* shell eggs means to use a technology or process that achieves at least a 5-log destruction of SE for shell eggs, or the processing of egg products in accordance with the Egg Products Inspection Act (same as proposed)

SE Prevention Measures

- SE-monitored Pullets
- Biosecurity
- Rodent/Pest control
- Poultry House Cleaning and Disinfection
- Refrigeration



Pullets

Must be SE-monitored or
raised under SE-monitored conditions

SE-monitored Pullets

- Chicks are procured from SE-monitored breeder flocks that meet the National Poultry Improvement Plan's standards for “U.S. S. Enteritidis Clean” status or equivalent.
- Pullet environment is tested for SE when pullets are 14 to 16 weeks of age
 - If negative, no additional testing until environmental test at 40 to 45 weeks of age.
 - If positive:
 - Begin egg testing within 2 weeks of start of egg laying.
 - Clean and disinfect pullet environment
 - Removing all visible manure
 - Dry clean
 - Finally, disinfect using appropriate disinfectants.

Biosecurity Program

Measures to prevent introduction or transfer of SE into or among poultry houses

Minimum requirements:

- Limit visitors on farm and in houses
- Protect against cross contamination when equipment is moved among houses
- Protect against cross contamination when persons move between houses
- Prevent stray animals from entering houses
- Prevent employees from keeping birds at home

Rodent and Pest Control

- Monitor for rodents by visual inspection and mechanical traps or glueboards or another appropriate monitoring method.
 - When monitoring indicates unacceptable rodent activity within a house, use appropriate methods to achieve satisfactory rodent control.
- Monitor for flies by spot cards, Scudder grills, sticky traps or another appropriate monitoring method.
 - When monitoring indicates unacceptable fly activity within a house, use appropriate methods to achieve satisfactory fly control.
- Remove debris within houses and vegetation and debris outside houses that may provide harborage for pests.

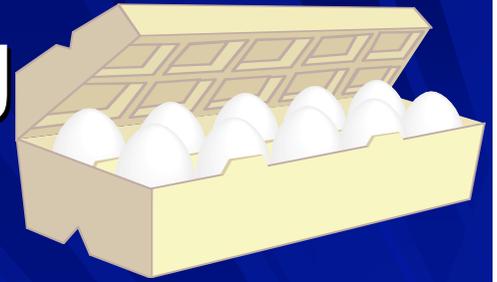
Cleaning and Disinfection of Houses

- Required at depopulation when either the house or eggs from that house have tested positive for SE (but recommended in general)
- Remove all visible manure, dry clean, and then disinfect using appropriate disinfectants

Refrigeration on Farm

- Must refrigerate eggs at an ambient temperature of 45 °F or less if they are held at the farm more than 36 hours after laying
- Refrigeration has been shown to minimize the growth of any SE that might be present in the eggs.
- Applies to all eggs regardless of whether or not they will receive a treatment.

Refrigeration During Transport/Storage



- Eggs must be held and transported at or below 45 °F ambient temperature beginning 36 hours after time of lay.
- If the eggs are to be processed as table eggs and are not processed for the ultimate consumer within 36 hours from the time of lay and, therefore, are held and transported as required at or below 45 °F ambient temperature, then they may be equilibrated at room temperature for up to 36 hours just prior to processing.

Testing for SE



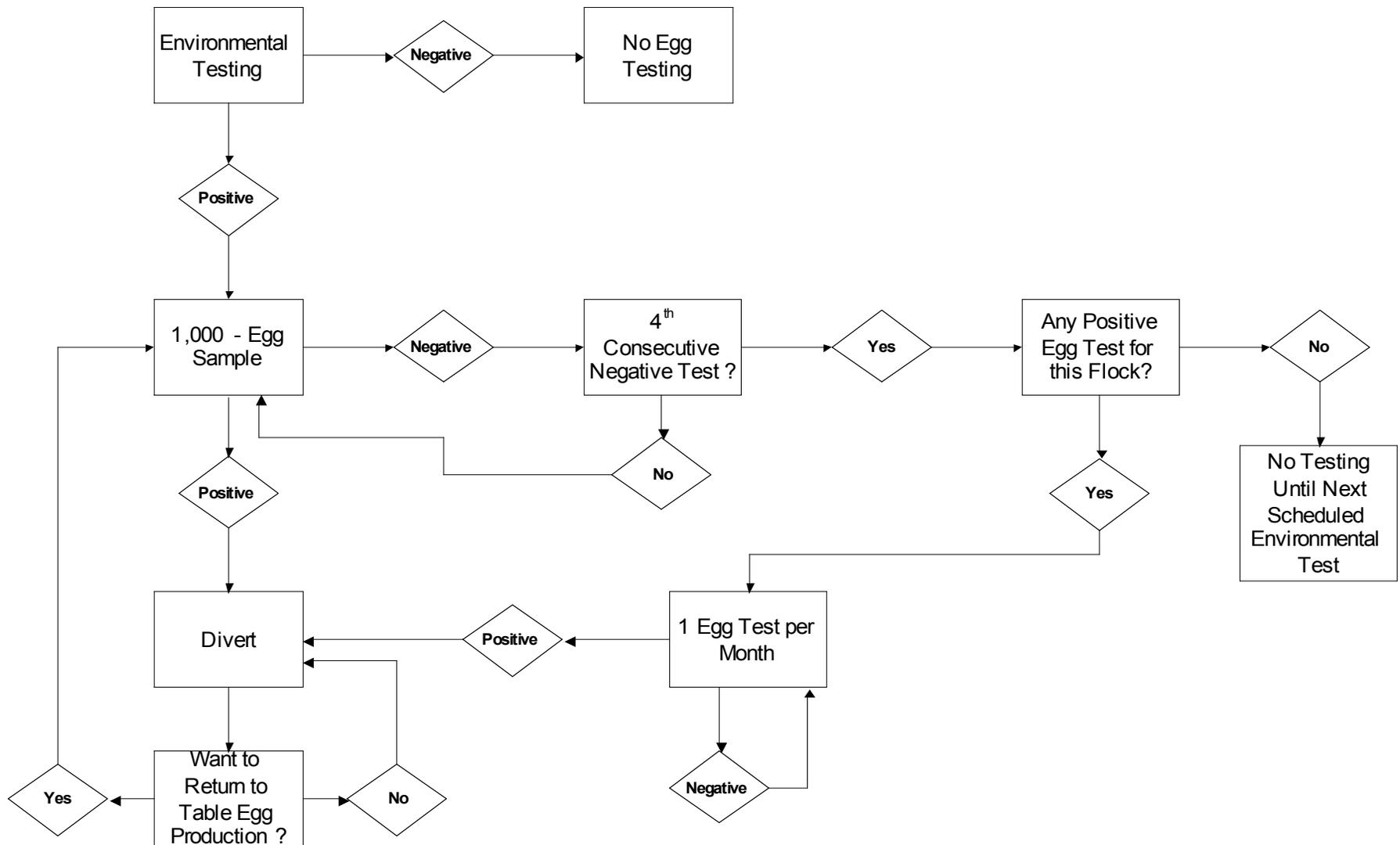
Environmental Testing for SE

- One test when any group of hens in house are 40-45 weeks of age
- One test 4-6 weeks after each molt
- If positive:
 - Review and make adjustments to SE prevention plan
 - Begin egg testing OR divert all eggs from positive house to treatment for life of flock in house
 - If testing eggs, results must be obtained within 10 calendar days.

Egg Testing for SE

- Each test is 1,000 intact eggs representative of a day's production
- 4 tests at 2-week intervals
- If all are negative, no further testing
- If any are positive:
 - Must divert all eggs until 4 tests at 2-week intervals are negative
 - Once 4 tests at 2-week intervals are negative, must still conduct 1 test per month for life of flock
 - If any of the monthly tests are positive, must divert all eggs until 4 tests at 2-week intervals are negative.

Egg Testing



Environmental Sampling Methodology

- Must use a sampling plan appropriate to the poultry house layout
- Official environmental method incorporated by reference in the final rule is a drag-swab sampling method
- Other sampling methods will be provided in guidance

Testing Methodology

- Environmental samples: “Environmental Sampling and Detection of *Salmonella* in Poultry Houses ” (October 2008) or equivalent method
- Egg samples: Chapter 5 of FDA’s Bacteriological Analytical Manual, December 2007 edition, or equivalent method

Administration on Farm

- One or more individuals responsible for administration of the SE prevention plan
- Must have completed training or have job experience equivalent to training
- Responsibilities:
 - Develop and implement SE prevention plan
 - Reassess and modify plan as necessary
 - Review records

Recordkeeping

- A written SE prevention plan
- Documentation that pullets were SE-monitored or raised under SE-monitored conditions, including environmental testing records for pullets
- Records of review and of modifications of the SE prevention plan and corrective actions taken

Recordkeeping

- Records documenting compliance with the following:
 - Biosecurity measures (examples: log-in sheets, inspection reports of boot-dipping stations, and cleaning and disinfection logs for equipment shared among houses)
 - Rodent and other pest control measures (examples: records showing dates of inspection, inspection findings, and steps taken to eliminate problems)
 - Cleaning and disinfection procedures performed at depopulation (examples: records showing names and concentrations of cleaning and sanitizing agents used)
 - Refrigeration requirements (examples: temperature logs or temperature recorder charts)
 - Environmental and egg sampling procedures, when applicable (examples: records showing dates and sampling procedures used)
 - Results of SE testing
 - Diversion of eggs, when applicable (example: records of where eggs were sent and dates sent)
 - Eggs at a particular farm being treated, when applicable (example: records of where eggs were sent and dates sent)

Recordkeeping

- All records must include the following information:
 - Name of producer and location of farm
 - Date and time of activity
 - Signature or initials of the person creating the record

Recordkeeping

- General recordkeeping requirements:
 - Data and information must be entered on records at the time the activity is performed or observed.
 - Records must contain the actual values observed.
 - Records must be retained for at least 1 year after the flock to which they pertain has been taken permanently out of production.
 - Records, except for written SE prevention plan, may be stored offsite, provided they can be retrieved and provided at producer's place of business within 24 hours of request for official review.
 - Electronic records are considered to be onsite if they are accessible from an onsite location.

Registration

- Producers covered by the rule must register their farms with FDA within 30 days of becoming an egg producer.
- Current producers must register by applicable compliance date.
- Registration methods:
 - Electronically: portal will be open May 10, 2010
 - Mail
 - Fax
 - CD-ROM for multiple submissions

Compliance Dates

- July 9, 2010, for producers with more than 50,000 layers
- July 9, 2012, for producers with 3,000 – 49,999 layers
- July 9, 2010, for persons who store and/or transport eggs (refrigeration)

Guidance/Training

■ Guidance

- Draft guidance will be published this year
- Per GGP's, guidance will be published as a draft for comment prior to implementation
- Will cover biosecurity, pest control, cleaning and disinfection, environmental and egg sampling, and recordkeeping

■ Training to Implement

- Industry and Government

Conclusion

FDA expects that this final rule will significantly decrease the number of SE-contaminated eggs produced, and ultimately, decrease the number of SE-associated illnesses and deaths caused by consumption of shell eggs.