Industry Perspective of the FDA Rule for Salmonella enteritidis (SE) Monitoring

Eric Gingerich, DVM
Diamond V
March 28, 2012 – NIAA Annual Conference, Denver CO
Industry Perspective of FDA Egg Safety Rule

- Egg Safety Rule
- Response of industry
- FDA implementation of rule
FDA Egg Safety Rule Components

- Written SE plan
- Designated person responsible for plan
- Plan contents:
  - Negative pullet procurement
  - Rodent monitoring and plan for control
  - Fly monitoring and plan for control
  - Testing plan – pullets, layers (40-45 weeks and post molt)
  - Refrigeration of eggs at 45F within 1 ½ days
  - Biosecurity plan
  - Plan for C&D of positive houses
  - Plan for holding eggs if manure positive until egg tests done
  - Plan for diversion of eggs if egg positive
  - Records for all above
FDA Egg Safety Rule of 2009

- Federal Register Final Rule (July 9, 2009, 74 FR 33030): Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation

- Implementation began July 9, 2010 for all farms over 50,000 layers

- Implementation begins July 9, 2012 for farms of 3000 to 49,999 layers
Egg Recall of 2010

- Number reported
- 5-year baseline mean

Illnesses that began during this time may not yet be reported.
SE Human Prevalence – US

Dr. Jean Guard, USDA-ARS: US – Foodnet data; EU – EFSA data
SE Human Prevalence – US vs. EU

Dr. Jean Guard, USDA-ARS: US – Foodnet data; EU – EFSA data
Response of Industry

- Increased efforts to reduce chance of positive results
  - Vaccination
  - Pest control
  - Intestinal health improvement
  - Feed related contamination
  - Refrigeration
Cost of a Positive Manure Test

- **Cost of testing**
  - Total of 4000 eggs in 20-egg pools divided in 4 submissions every 2 weeks
  - 200 pools x $10 to $50 per pool = $2000 to $10,000

- **Withholding eggs**
  - To avoid recall, eggs are packed in cases and held until egg test results are received
  - Depending on test used, 27 hours to 10 days
Cost of an Egg Positive

- An egg positive requires a clean set of 4000 eggs over an 8 week period to return to shell egg market

- Difference between shell market and breaking market (07 Feb 2011)
  - Shell = $1.17 – 0.40 = $0.77
  - Breaker = $0.48 – 0.05 discount = $0.43
  - $0.77 – 0.43 = $0.34

- 8 weeks production about 3.9 dozen

- 3.9 dozen x $0.34 = $1.33 per hen
Vaccination During Grow

- **SE bacterin**
  - Usually 1x at 13 to 15 weeks

- **Live ST vaccines**
  - 3 applications – 2, 6, and 12 weeks

- **Bacterin + live vaccine**
  - Live vaccine - 2 and 6 weeks
  - Bacterin – 13 to 15 weeks

- **Vaccine Costs**
  - 0.5 cents for live
  - 8.0 cents to add bacterin (5 for handling, 2.5 for vaccine)
Live ST Vaccination During Lay

- Could be used to boost immunity during production
- Shown effective prior to molt
- Live vaccines not human pathogens
- Mass applied, no handling required
Vaccine Efficacy

% SE Manure Positive Flocks

PEQAP Data 2006-2008
Vaccine Efficacy

% SE Egg Positive Flocks

PEQAP Data 2006-2008
Rodent Control

- Rodent control found to be highly correlated to SE infection in layers
- Rodent index formulated in PA
- Twelve live traps (Tin-Cats) placed in layer house
- Mice counted after 7 days
# Rodent Control

## Rodent Index

<table>
<thead>
<tr>
<th>No. of mice caught</th>
<th>Rodent Index</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 10</td>
<td>1</td>
<td>Low</td>
</tr>
<tr>
<td>11-25</td>
<td>2</td>
<td>Moderate</td>
</tr>
<tr>
<td>26+</td>
<td>3</td>
<td>High</td>
</tr>
</tbody>
</table>

An index of 1 or less is acceptable.
Rodent Control

- Integrated approach required
  - Seclusion of rodents from house
    - Plugging all entry holes
  - Reduction of harborage areas
    - No trash or tall grass outside
    - No manure buildup on cross beams
    - Reduced manure levels in high rise houses
- Baiting
  - Rotation programs using effective baiting techniques
Fly Control

- Flies can carry SE from manure to hens
- Requires integrated approach
  - Reduce breeding area and proper conditions
    - Dry manure
    - Reduced amount of manure
  - Predator insects
  - Fungus treatment
  - Insecticides
Intestinal Health Improvement

- Water sanitation
  - Reduces inflammation in intestine

- Feed additives
  - Have an effect on microflora and immune cells in the tract
  - Probiotics
  - Prebiotics
  - Fermentation products
  - Used continuously or during periods of stress
Feed Contamination

- Concern after findings at Wright County
- Most testing ingredients prior to receipt in feed mill to avoid recalls of product
- Meat and bone meal from plants complying to the APPI Salmonella Education Reduction Program
- Anti-Salmonella treatments being used for some high risk ingredients
  - Formaldehyde
  - Organic acids
- Feed mills being certified by AFIA program – Safe Feed/Safe Food
Refrigeration Issues

- Storage of eggs at 45F by 36 hours after laying is required
- Operations that farm pack must upgrade refrigeration or not store eggs over 1 ½ days
- Need good records of temperatures
FDA Inspections

- High risk farms inspected first
- Second tier underway at present
- To begin inspections on farms with 3000 to 50,000 layers 3rd or 4th quarter of 2012
FDA Inspections

- Written SE prevention plan
  - Documentation that pullets were raised under “SE-monitored” conditions
  - Records documenting compliance with the SE prevention measures
    - Biosecurity measures.
    - Rodent and other pest control measures.
    - Cleaning and disinfection procedures performed at depopulation.
    - Refrigeration requirements.
  - Environmental and egg sampling procedures
  - Results of SE testing
  - Diversion of eggs
  - Eggs at a particular farm being given a treatment
  - Records of review and of modifications of the SE prevention plan and corrective actions taken.
FDA Inspections

- Keys to passing inspections – “Say What You Do and Do What You Say”
  - Have valid programs covering the key components of the FDA Egg Safety Plan
    - Pullets are negative
    - Biosecurity
    - Pest control
    - Cleaning and disinfection
    - Refrigeration
    - Testing of manure or eggs
  - Have records to show that you are doing what is in your plan
FDA Inspections – Reasons for Failure

- Records
  - No record that chicks are from NPIP sources
  - No record of times when activities were performed
  - No rodent control records
  - No record of compliance of biosecurity plan
  - No site specific SE plan
FDA Inspections – Reasons for Failure

- **Pest Control**
  - Failure to control rodents
  - Failure to follow the frequency of monitoring stated in the company plan
  - Failure to prevent stray animals entering houses
  - Failure to remove debris and vegetation around houses
  - Failure to provide fly monitoring records with name and location of fly tapes or cards
FDA Inspections – Reasons for Failure

- Egg Storage
  - Failure to maintain eggs at 45F or below

- Testing
  - Failure to test pullets at 14 to 16 weeks of age
  - Failure to test eggs after a manure positive test
  - Shipping eggs from egg positive flock

- Biosecurity
  - Failure to maintain practices to prevent cross-contamination when workers move between houses
**Salmonella heidelberg** (SH)

- *Salmonella heidelberg* found in pullet samples at Wright County traceback investigation
- FDA does not have a program to address SH
- FDA will act as if SE is found if finding SH in records of testing by a producer
  - Do not report SH on lab tests
- FDA is not actively looking for SH during inspections if samples are taken
Summary

- The battle to control SE is going to continue
- SE positivity is expensive
- Implementation of the plan by smaller producers will be a challenge
- The FDA Egg Safety Plan is resulting in increased actions against SE in all states as intended
Questions??