



CFSAN Egg Safety Activities and Updated Biosecurity Measures

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Egg Safety Activities Overview

- Resumption of egg inspections
- Importation of eggs
- Foreign egg inspections
- Guidance (access to areas outside the poultry house)

Egg Safety Activities Overview

- Inspectional update (FY16)
- Upcoming inspections (FY17)
- HPAI

Resumption of Egg Inspections

- Nationwide suspension of egg inspections on May 5, 2015
 - Due to HPAI
 - Abundance of caution
- Resumption of egg inspections on June 1, 2016
 - After careful consideration
 - Consulted with USDA/APHIS

Resumption of Egg Inspections

- Courtesy calls with multiple stakeholders
 - National Egg Regulatory Officials (NERO)
 - National Assembly of State Animal Health Officials (NASAHO)
 - National Association of State Departments of Agriculture (NASDA)
 - USDA/APHIS
 - United Egg Producers (UEP)

Resumption of Egg Inspections

- Courtesy calls with multiple stakeholders
 - Organic Trade Association (OTA)
 - Egg Farmers of America
 - Organic Egg Farmers of America
 - 50 state call
- Updated biosecurity procedures
 - Different arena pre- vs post-HPAI outbreak

Importation of Eggs

- All eggs imported were for breaking none were for the table egg market
- Reduction in availability of eggs for egg products processing due to HPAI
- Eggs imported from a number of different countries
 - Marked decrease in imported eggs compared to previous year
- Worked in conjunction with USDA/AMS
 - Paperwork verification
 - Temperature checks

Foreign Egg Inspections

- Influx of imported eggs from various countries due to HPAI in US
- Four egg firms inspected in Spain
- General findings
 - Belted-houses
 - Differences in pest control practices
 - Different testing schedules
 - Vaccination requirements

Foreign Egg Inspections

- Inspections included review of records and walk-through of houses
 - No samples collected
 - All eggs imported destined for egg products processing
- One 483 issued
 - Failure to refrigerate within 36 hrs. of lay
 - Recordkeeping violation

Guidance

- “Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation (Layers with Access to Areas Outside the Poultry House)”
 - Nearing completion
- When complete it will be the 4th guidance published related to the Egg Rule

FY16 Inspectional Update

- Later start than normal due to suspension of inspections
 - Inspections started around mid June
- 252 total inspections conducted
 - FDA: 203
 - States: 49

FY16 Inspectional Update

- Inspections breakdown
 - 147 targeted (100 FDA and 47 states)
 - 50 comprehensive (all FDA)
 - Remainder were “for cause” inspections
- Types of firms inspected
 - Targeted were a mix of large and small producers
 - Comprehensive were all small producers
- Number of 483’s issued: 71
 - 63 by FDA and 8 by states

FY16 Inspectional Update

- FDA Inspections
 - No Action Indicated (NAI): 140 (69%)
 - Voluntary Action Indicated (VAI): 54 (27%)
 - Official Action Indicated (OAI): 9 (4%)
- State Inspections
 - No Action Indicated (NAI): 41 (84%)
 - Voluntary Action Indicated (VAI): 0 (0%)
 - Official Action Indicated (OAI): 8 (16%)

FY16 Inspectional Update

Most Common Deviations

1. No SE plan or inadequate SE plan (21 CFR 118.4))
2. Failure to prevent stray poultry, wild birds, cats and other animals from entering the poultry house (21 CFR 118.4(b)(4))
3. Failure to monitor for rodents by appropriate monitoring method and/or achieve satisfactory rodent control when monitoring indicates unacceptable rodent activity (21 CFR 118.4(c)(1))

FY16 Inspectional Update

Most Common Deviations

4. Failure to maintain appropriate records documenting biosecurity procedure (21 CFR 118.10(a)(3)(i))
5. Failure to include the name and location of farm on records (21 CFR 118.10(b)(1))
6. Failure to refrigerate eggs at or below 45° F beginning 36 hrs. after time of lay (21 CFR 118.4(e))

FY16 Inspectional Update

Most Common Deviations

7. Failure to conduct environmental testing at 40-45 wks. of age (21 CFR 118.5(a))
8. Failure to include the date and time of activity on records (21 CFR 118.10(b)2))
9. Failure to include signature or initials on records (21 CFR 118.10(b)(3))
10. Failure to limit visitors on the farm (21 CFR 118.4(b)(1))

Current Inventory

- Total registered firms (worldwide): 3,011
- Total US firms registered: 2,774
- Total foreign firms registered: 237
- Total large ($\geq 50,000$ layers per farm): 845
 - US only (does not include foreign firms)
- Total small (3,000-49,999 layers per farm): 1,929
 - US only (does not include foreign firms)

FY17 Planned Inspections

- Inspections expected to begin around March 2017
- Total Inspections
 - 370 targeted
 - 130 comprehensive
- Large Producers ($\geq 50,000$)
 - 136 targeted
 - 41 comprehensive
- Small Producers (3,000-49,999)
 - 234 targeted
 - 89 comprehensive

HPAI

- FDA maintains awareness of HPAI
 - H5N2 finding in a wild Mallard duck in Montana
 - HPAI finding in a commercial broiler breeder operation in TN
- Lessons learned
 - Communication with other agencies

Updated Biosecurity Measures For Egg Inspections

Current Biosecurity Practices

- As trained in FDA107 Egg Safety Inspections Course
 - Should be followed at all times
- Measures
 - Check for quarantines
 - Follow farm's biosecurity practices
 - Do not enter houses with known diseases issues
 - Cannot be a bird owner
 - 72 hr. wait between individual farm visits
 - Wash vehicle before/after inspections

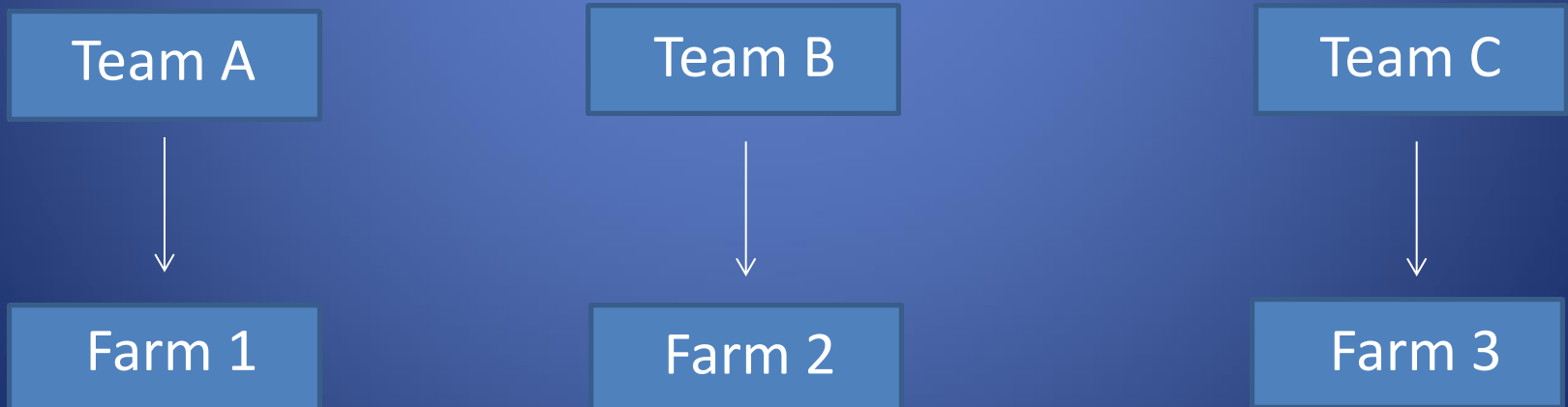
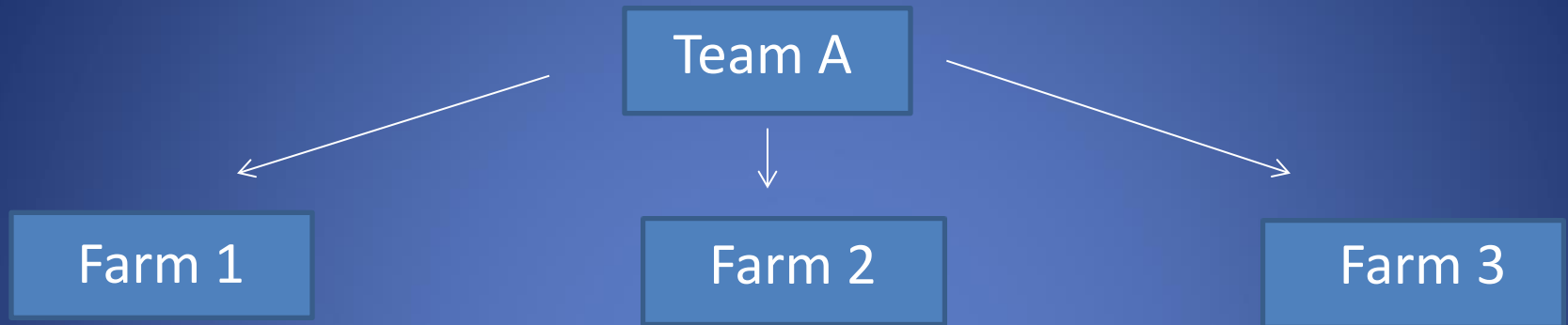
Current Biosecurity Practices (cont'd)

- Measures
 - Wear PPE (disposable body covering, boot covers, hair bonnets, sterile gloves, respirators, eye protection, and hearing protection)
 - No transfer of items between houses without disinfection
 - Disposable cameras (or cameras in plastic bags)
 - Double bag garbage (one bag left at vehicle)
 - No jewelry

Modifications to Current Practices

- Absolute requirement to contact state veterinarian and check for quarantines (ask specifically about HPAI)
 - No inspections without state clearance
 - If delay longer than 2 wks. is expected organize meeting between state veterinarian, District, ORA-OFFO, CFSAN-OC and CFSAN-OFS
- When possible use multiple inspection teams
 - Such as to increase the length of time between farm visits for any specific team

Multiple Team Approach

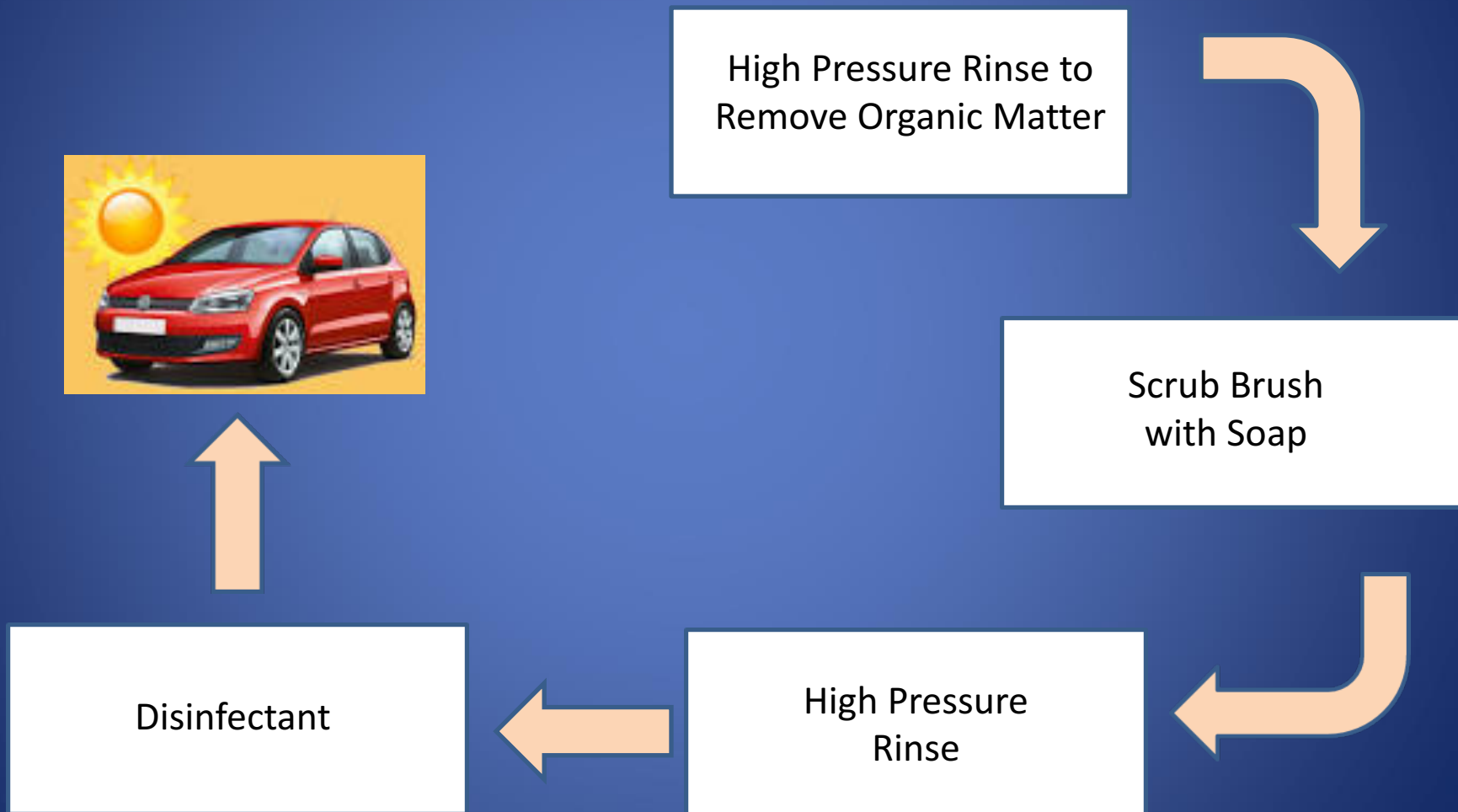


Modifications to Current Practices

- Categorize farms
 - Conduct inspections at farms with outdoor access last
 - Increase wait time between farms to 1 wk. when inspecting farms with outdoor access
- Change disinfectants
 - 70% ethanol has limited effectiveness in the presence of organic matter

Vehicle Wash

- Before AND after EVERY inspection



Modification to Current Practices

- Minimum wait time is 72 hrs; however, abide with the wait time established by the farm if longer
 - If established wait time is longer than 2 wks. organize a meeting between District, ORA-OFFO, CFSAN-OC and CFSAN-OFS
 - Preventive measure to minimize producers trying to avoid or delay inspections
- Stay away from bird feeders/baths for a minimum of 1 wk. prior to an inspection

Additional Biosecurity Measures

- A minimum of 1 wk. prior to ANY egg inspection
 - Stay away from friends/family members who own birds
 - Do not go to fairs and/or bird exhibits
 - Do not visit live bird markets or gatherings where birds may be present
 - Stay away from flea markets, trade shows, swap meets where birds may be shown
 - Refrain from visiting zoos, theme or amusement parks where birds maybe be present

Additional Biosecurity Measures

- Do not go to known bird nesting/breeding grounds, natural refuges, or bird sanctuaries
- Do not attend birthday parties or events where petting zoos with birds are involved
- Stay away from ducks, geese, pigeons, etc. and municipal parks or places where people congregate to feed them
- Do not visit ocean side towns or come in contact with shorebirds (e.g. seagulls)
- Do not go to feed stores or other places where baby chicks, turkey poults, ducklings, etc. may be sold

Additional Biosecurity Measures

- No hunting or handling of wild fowl, if family member hunts stay away from them for a minimum of 1 wk. prior to inspection
- Do not meet with known bird owners as part of work or your social circle
- If possible wear clothes that have not been to another farm
 - When possible launder all clothes in hot cycle
- Park outside of the farm or as far as possible
- Clean eyeglasses with disinfectant wipes

Summary

- Return to normalcy with resumption of egg inspections
- Guidance for producers that provide outdoor access is close to publication
- Upcoming inspections
 - Increase in comparison to previous year
- Maintaining a vigilant eye on HPAI
 - Learned many lessons
 - Established contacts for present and future