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# “Food Safety Assessments: Triggers and Survival”

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March 2020

# FSIS Response to *Salmonella* Performance Standard Failures

For poultry - Federal Register notice (81 FR 7285) indicates that when an establishment does not meet a performance standard, FSIS will schedule a PHRE.

- During the PHRE, an EIAO will assess the establishment's Hazard Analysis and Critical Control Points (HACCP) system, focusing on the establishment's corrective actions and HACCP plan reassessment (if applicable).
- Based on the PHRE, FSIS will determine whether to schedule a FSA.

# FSIS Response to *Salmonella* Performance Standard Failures

## Poultry

- More specifically, FSIS states they will schedule a PHRE in poultry establishments that have....
  - produced products with repetitive *Salmonella* or serotypes of public health concern or repetitive antibiotic resistant *Salmonella*; and for establishments with *Salmonella* whole- genome sequencing patterns matching those found in recent outbreaks or epidemiologically linked to illnesses.
  - FSIS does the PHRE because “it can reasonably be inferred that establishments in these categories have not adequately addressed *Salmonella* in their hazard analysis”



# PHRE...

- Is step one in the FSA process
- May or may not have an FSA afterwards
- PHRE is not shared with the plant
- PHRE is conducted outside of the plant environment using existing data about the plant
- PHRE is the “tool” to determine whether or not conduct the FSA



# Prioritized List for PHREs

- PHR noncompliance history
- Salmonella Cat 3
- Salmonella serotypes of public health concern
- Repeat Salmonella PFGE
- RRVL
- CCMS
- New establishment
- **Instructed by Agency**
- Est. with post-lethality exposed (and no positives)

- **Human Illness linked to product**
- IIT to be conducted
- **Class I/II recall**
- Positive STEC
- Positive Lm or *Salmonella* in RTE
- Sole supplier to positive STEC in ground
- Est. with more than one STEC positive in 120 days

# PHRE Summary

- A decision making tool to determine whether to conduct a FSA.
- **A Paperwork Review -**
  - The EIAO will review the establishment's historical data (previous FSA, FSIS test results, enforcement data, compliance history, consumer complaints, PHIS profile information, weekly meeting notes, MOIs, and recall information) and correlate with the inspection program personnel assigned to the establishment.
- FSAs are scheduled based on the outcome of the PHRE

# PHRE Outcomes

The EIAO will recommend to the District Manager:

- Conduct a targeted FSA;
- Take an enforcement action; or
- Take no action.



United States  
Department of  
Agriculture

Food Safety and  
Inspection Service

Office of Field  
Operations

Building District Office  
4020 10th Parkway  
Raleigh, NC 27609

(EMAIL) : OIE@FSIS

January 24, 2011

Mr. Francis Avey, President/CEO  
Alden Farms, LLC, 131-104441  
14 Silver Springs Lane  
Mooresville, NC 28138

**NOTICE OF RECOMMENDATION OF SUPERVISORY ACTION: ABEY40408**

The Mr. Avey:

On January 16, 2010, your establishment received official notification from the Food Safety and Inspection Service (FSIS) of the recommendation of suspension of the assignment of legal title personnel for slaughter operations at Alden Farms, LLC, the ABEY40408. The details of this recommendation are provided at your establishment via email to you, accompanied by FSIS that your establishment failed to slaughter and handle animals humanely.

On January 14, 2011, you provided FSIS with proposed responses to the suspension action. Your responses outlined various corrective and preventive measures to bring your establishment into compliance with the minimum handling of livestock requirements and to achieve compliance with the Federal Meat Inspection Act (FMIA) (91 Stat. 1002 (b)), the Humane Methods of Slaughter Act (HMSA) (7 USC 1901 (a)), and regulations (9 CFR, parts 16.100(a) and 16.100(b)).

This is a recommendation of suspension filed to determine if you have the required or necessary (9 CFR 200.1) when your establishment was issued a notice of suspension for the suspension of legal title handling of livestock. On December 17, 2010, and 10, 2010, you provided FSIS with proposed corrective and preventive measures to the professional title. Based on your written submission, you were notified that the suspension of legal title personnel of your plant would be held in abeyance effective January 20, 2011, based on the observation cited by inspection personnel on January 20, 2011 and based on letter of recommendation of suspension on January 24, 2011. It was recommended that the plant return to normal operations and personnel were made you aware of the details.

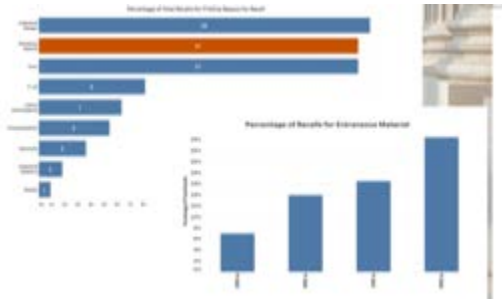
Based on your corrected information on January 24, 2011, you may inform via email that the suspension of suspension of the assignment of legal title personnel for slaughter operations of your plant will be held in abeyance effective January 14, 2011, pursuant to 9 CFR part 16.100.

The suspension will remain in abeyance pending notification by FSIS that your proposed corrective and preventive measures have been effectively implemented. Plans personnel should monitor operations to prevent recurrence of future violations and changes from occurring in the future. You

# PHRE for Failed *Salmonella* Performance Standards that Leads to an FSA

- The EIAO will be focusing on:
  - the establishment's corrective actions and HACCP plan reassessment (if applicable), and the effectiveness of the establishment's system for controlling *Salmonella* in raw poultry products
- You may not have an FSA if...
  - If the EIAO learns from the in-plant inspection personnel that “adequate” corrective actions have been taken
  - If the EIAO learns that the plant has data demonstrating they have re-gained process control

# So I am having an FSA – how do I survive?



[Company logo (if available)] [Company name]

## MASTER SANITATION SCHEDULE

All equipment that does not have to be cleaned daily [Specify, etc: after each use] must be included on the schedule to ensure that it is cleaned when needed or required.

M = monthly; Q = quarterly; S = semi-annually; Y = yearly Year: \_\_\_\_\_

Instructions: Initial and date the columns when the cleaning is completed.

Area	Freq	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
<b>Area 1</b>													
Walls	Y												
ceilings	Y												
Floors	Y												
Drains	M												
Equipment	Q												
Shelves	Q												
<b>Equipment 1</b>													
Equipment 2													
<b>Area 2</b>													
Walls	Y												
ceilings	Y												
Floors	Y												
Drains	M												
Shelves	Q												
<b>Area 3</b>													
<b>Area 4</b>													

## Daily Production Record: HACCP Monitoring

NO DAILY PRODUCTION RECORD PRODUCTION PLAN FOR THE										2010 Good Manufacturing Practices		Average Operating Unit Output		Date published: 2010			
ITEM NO.	Check one:	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
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NC School HACCP 2010-11



Date prepared (date the policy was introduced/revised) Authorized by (manager responsible) Page 4 of 4

# Preparing for an FSA

FSIS will provide:

- 1-2 weeks prior notice before the FSA (unless “for cause”)

**Do not wait until you are notified of a scheduled FSA to prepare.**

- Too late to revise food safety system.



# Preparing for an FSA

## New Tools

- General Tool (All FSAs)
  - Meat Tool,
  - Poultry Tool,
  - Ready-to-Eat (RTE),
  - Not Ready-to-Eat (NRTE) Tool, and
  - Thermal Processing Tool
- These tools are available for you to use at any time.
  - Recommend having a team use the General and all applicable tools at a regular frequency to continuously review the programs and facility.
  - Are you confident in program design? Are you consistently implementing?
    - ALWAYS make continuous improvements! PREVENT problems.
  - Do you review the operation for changes during reassessment?
    - If not, there is likely to be surprises during the FSA.
  - **If the FSA is for Category 3 Salmonella – be prepared to support the decisions in your hazard analysis!**

# Preparing for an FSA

- The FSA will review the hazard analysis.

- *Salmonella does not have to be a hazard likely to occur in your operations, **but** you need to be prepared to support all of your decisions....*



# Hazard Analysis

- If the establishment considered *Salmonella* reasonably likely to occur (RLTO) and addressed *Salmonella* in its HACCP plan, it must take corrective actions as required in 9 CFR 417.3(a)
- If the establishment considered *Salmonella* not reasonably likely to occur (NRLTO), it must take corrective actions and reassess its HACCP plan for that product to determine whether the HACCP plan needs to be modified to address the hazard as required in 9 CFR 417.3 (b).
  - To maintain an adequate HACCP system, the establishment may need to address *Salmonella* in the HACCP plan...

# Relative to Salmonella Control

- The EIAO will review:
  - programs or procedures that are specific to *Salmonella* control (including, but not limited to, procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination, the HACCP plan, Sanitation Standard Operating Procedures and/or other prerequisite programs)
  - Micro sampling data
  - Sanitary dressing data
  - Regulatory waiver data
  - status of the establishment's actions to identify the cause of the failed performance standard, corrective actions, and reassessment of the HACCP plan (if applicable)

# Relative to Salmonella Control

- Establishments typically incorporate multiple interventions or preventative measures to control *Salmonella* in raw poultry.
- Therefore, the establishment may not be able to identify a single intervention or preventive measure as responsible for not meeting a performance standard.
  - “Rather, the establishment’s HACCP system, which incorporates all interventions and preventive measures, may not be effective to meet the performance standard.”
- During the FSA, the EIAO is to review documents supporting *Salmonella* control in raw poultry products throughout the process

# Relative to Salmonella Control

- If the establishment receives and further processes raw poultry (carcasses, parts, or comminuted product) the EIAO will look to see whether the plant understands the controls used by its suppliers to reduce *Salmonella* levels in raw poultry.
  - Does the plant receive letters of guarantee that suppliers meet purchase specifications or certificates of analysis, or do they verify the effectiveness of any supplier controls through audits or by sampling raw poultry at the receiving step?

# Relative to Salmonella Control

- If the establishment routinely measures *Salmonella* levels when receiving live birds or raw poultry products, does it understand whether the combined effects of the interventions documented in its HACCP system are sufficient to reduce *Salmonella* to a level that will consistently meet FSIS's performance standard?
- *If the establishment does not routinely measure Salmonella levels when receiving live birds or raw poultry products, does it provide a rationale to justify that the system will be capable of meeting FSIS's performance standards for Salmonella moving forward without this data?*

# Relative to Salmonella Control

- FSIS will assess the establishment's response when its microbial sampling program results are consistent with FSIS's *Salmonella* results during the same time period to determine:
  - Why the establishment did not implement corrective actions in response to its own microbial sampling program results that indicated poor process control; or
  - If the establishment did take corrective actions in response to its own microbial sampling program results, why the actions taken were unable to prevent the establishment from failing the performance standard.

# Relative to Salmonella Control

- FSIS recognizes that developing or adjusting the plant's microbial sampling program may be the only change initially offered by the establishment following reassessment due to a failed *Salmonella* performance standard
  - the establishment must first be able to identify the problem through sampling and testing before it can determine where additional changes are needed

# Relative to Salmonella Control

- The EIAO is to determine if there are trends in noncompliance, failure to implement corrective actions, or other inspection findings which may be evidence of poor process control.
  - visible fecal contamination and septicemic/ toxemic carcasses

# Relative to Salmonella Control

If based on the reassessment the establishment feels *Salmonella* is still NRLTO the EIAO is to:

- Verify that the establishment's reassessment documents include a rationale for continuing to consider *Salmonella* as NRLTO, and that the rationale is supportable;
- **Assess microbial sampling results from FSIS and the establishment before and after implementing corrective actions;**
- Understand the impact of any changes to the establishment's HACCP system on the rate of *Salmonella* positive samples, or a suitable microbial indicator or a surrogate organism;
- **Verify that the establishment has determined the cause for exceeding a *Salmonella* performance standard, and has fully implemented corrective actions;**

# Relative to Salmonella Control

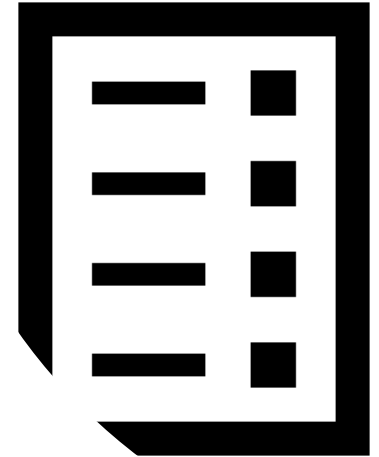
If based on the reassessment the establishment feels *Salmonella* is still NRLTO the EIAO is to:

- Verify that the establishment uses microbial sampling results from FSIS and the establishment's programs (including, but not limited to, FSIS's follow-up sampling set) to demonstrate it is better able to control *Salmonella*; and
- Verify that the establishment has considered its history of meeting FSIS's *Salmonella* performance.

# Relative to Salmonella Control

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- The District is instructed NOT to issue an NOIE or Suspension based solely on the category of the performance standards.
- The District is informed that the basis for an NOIE or suspension would be an inadequate HACCP plan or insanitary conditions.
- Most EIAO will focus on the corrective actions implemented by the plant.
  - Often the FSA is well after the failure. The EIAO is primarily interested in the corrective actions and data moving forward.



# FSA Results

- No further action;
- **Issuance of NRs by the in-plant inspection personnel;**
- Recommendation of a Notice of Intended Enforcement Action (NOIE); or
- Recommendation of Notice of Suspension (NOS).

# Triggers for and Surviving an FSA

## In conclusion –

- *Salmonella* Category 3 is a reason to do a PHRE
- FSIS looking in more detail at specific areas while doing the FSA
  - If you failed the *Salmonella* performance standards, FSIS will want to understand your corrective actions and response.
- YOU should be prepared by knowing the regulations, ensuring your programs are up to date, implementing your programs – and having the documentation to show that you did so!

# Questions

