



# **Within Establishment Public Health Risk-Based Inspection for Processing and Slaughter**

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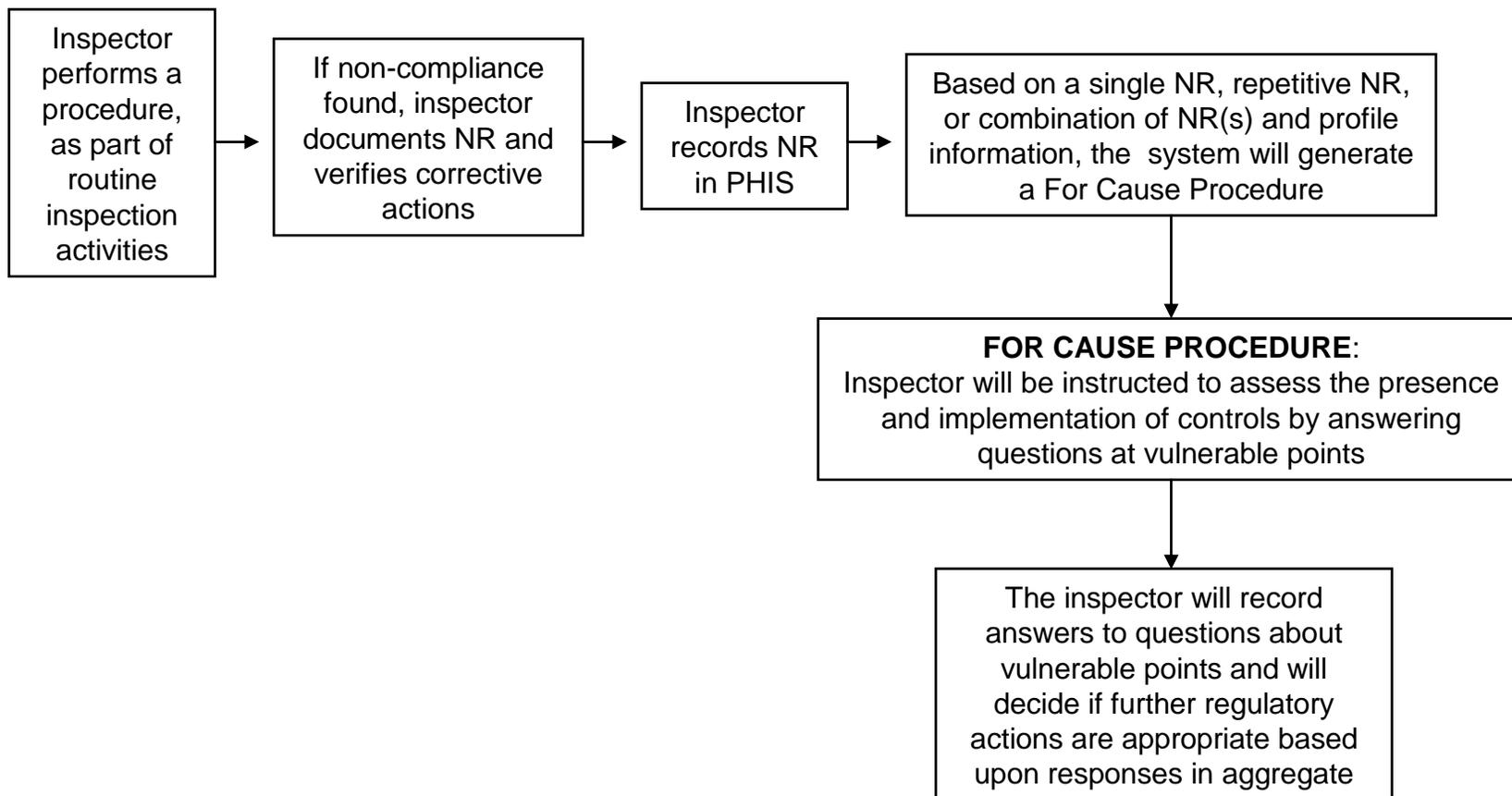
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# System Overview

- Focus inspection activities on vulnerable points
  - **Vulnerable point** - where the greatest microbial contamination or growth occurs if process control is not maintained
- Inspectors carry out existing inspection procedures (e.g., HACCP, SSOPS) and when prompted answer questions regarding vulnerable points
  - Prompts, vulnerable points, and questions specific to each of the 9 HACCP product categories
- Observations at vulnerable points, in aggregate, may lead to an additional NR or may provide support for an enforcement action.
- Compliance guidelines and training will be developed

# Within Establishment Inspection



## Directed Procedure:

Directed procedures are performed in Focused (LOI 2) and In-Depth (LOI 3) Inspection establishments

# System Development

- System is based upon the scientific literature and Agency experiences with HACCP and contamination events
- Literature review was used to identify vulnerable points
- FSIS experts determined inspection prompts and vulnerable point questions

# System Benefits

- Focuses on the identification of vulnerabilities within the overall food safety system
- Helps inspectors verify execution of decisions made in the hazard analysis including responding to plant data and pre-requisite programs
- Bolsters ability to link and respond to NRs and verify corrective actions are fully carried out
- Inspection results monitored automatically and alerts for anomalies built into Public Health Inspection System



**Prompt Example**  
**Fully Cooked, Not Shelf-Stable**  
**Product**



# Prompt Description and Threshold

***Prompt Description:*** Product temperature not controlled by CCP throughout process

***Threshold:*** Two or more observations - noncompliance 03G01



# Vulnerable Points

## Fully Cooked, Not Shelf-Stable

- 1. Receiving and Storage**
- 2. Processing** (e.g. mixing, rework, formulating, grinding, breading, battering, tempering, molding, solution injection, smoking, cooking, cooling)
- 3. Storage and Shipping**



## Receiving and Storage Questions

- a) Does establishment have measures to ensure materials received are wholesome and safe? Are control measures being implemented?**
- b) Does plant have controls on the incoming amount of microbes on product, or adjust their processes according to incoming load? Are controls being implemented?**
- c) Does the establishment have appropriate controls for returned product? Are controls being implemented?**
- d) Does the establishment monitor product temperatures during storage?**



# Processing Questions

- a) If not a CCP, does plant achieve sufficient lethality?
- b) Is rework and carry-over addressed in the hazard analysis?
- c) Does the plant have controls in place to ensure cross contamination including different species does not occur? Are controls being implemented?
- d) Does the establishment have proper procedures to follow-up positive *Listeria (Lm)* results on food contact surfaces or environmental samples? Is plant carrying out follow up procedures?
- e) Are establishments under Alternative II or III that are using sanitation programs adequately implementing the program and controls (not SSOP; spelled out in 430)?
- f) Has establishment undergone recent construction and if so has it increased *Lm* monitoring? Do records show increase in *Lm* in environment?



# Storage and Receiving Questions

- a) Does the establishment have verifiable temperature controls in the storage?
  
- b) Does the establishment monitor conditions in storage areas that would cause adulteration of product (over spray, dripping water, etc.)?



# Potential Regulatory Outcomes

- **301.2 Adulteration/ Misbranding (Meat)**
- **381.1 Adulteration/ Misbranding (Poultry)**
- **416.1 Failure to maintain sanitary practices**
- **416.4(d) Sanitation**
- **416.13 – Implementation**
- **416.13(c) SSOP for operational sanitation**
- **416.14 Maintenance, Monitoring**
- **417.2(a)(2) Intended Use or Consumer**
- **417.5(a)(1) Hazard Analysis decisions not supported**
- **417.3(b) Unforeseen Hazard**
- **430.4(b) Control of Lm in post-lethality exposed RTE product**
- **424.22(a)(b) or (c) Restrictions of products that require labeling**



*Case Study:*  
**Topps Meat Company, LLC**  
(Multistate Outbreak of *E. coli* O157:H7)

# Case Study: Problems

1. Lack of understanding of hazards associated with *E. coli* O157:H7 and appropriate controls
2. Lack of ability to identify problems at establishment level
3. Lack of support for, and sound decisions associated with, the hazard analysis
  - “Hazard Not Reasonably Likely to Occur” determination was not supported in hazard analysis
  - Lack of sufficient process controls in place and verification of appropriate implementation
  - Failure of Purchase Specification Program when receiving imported product
  - Failure of intervention from slaughter supplying establishment which was not detected
  - Failure to properly identify intended use of product



# Case Study: Solutions

1. Improved inspector understanding of *E. coli* O157:H7 hazard and controls
  - System more closely links activities to regulatory foundation and citations to increase understanding
  - System fosters inspector thinking in terms of overall food safety system to provide a broader understanding of *E. coli* hazard
2. Automated monitoring of inspection result and built-in alerts of anomalies, including a lack of inspection activity
  - Also, enhanced data collection and assessment to allow more timely reaction to emerging trends
  - Changes in an establishment's HACCP plan will be identified by inspectors and will automatically send an alert
3. Focuses on the identification of vulnerabilities within the overall food safety system
  - Focused activities include CPs (not just CCPs) that should be addressed in prerequisite programs and SSOPs in support of the hazard analysis
  - Focused verification questions address the presence and appropriate implementation of process controls
  - Receiving has been identified as a potential vulnerable point; focused verification questions at that point include the use of purchase specifications
  - Focused verification questions include some related to whether the product was properly marked for intended use
  - Profile will include the establishment's HACCP system; that will allow review to ensure that food safety hazards are identified and controlled