2:30PM – 3:45PM

MEAGHAN MEYER – AL STCYR – DAN COLLINS

WINNING THE CHALLENGES & MEASURING RESULTS

PEST INVASION
INTEGRATED PEST MANAGEMENT
FOOD SAFETY SEMINAR

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Pest Control – Thinking Beyond the Audit

June 27, 2019

Who "Owns" Pest Control?

"1. You failed to take effective measures to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests, as required by 21 CFR 110.35(c). Specifically,

a. On February 7, 2018, a live rodent was observed running across the east end of the production area, into the laundry room and into a hole in the wall at the northeast corner of the room.

b. On February 9, 2018, a live rodent was observed running up a water pipe on the east wall of the production area, adjacent to the three-compartment sink and hand wash sink. The rodent was then observed running down the pipe, over to a hose on the north wall of the production area, then into the laundry room and into a hole in the wall on the northeast corner of the room. Cleaned and sanitized baking sheets were stacked and drying by the three-compartment sink and by the metal table on the north wall adjacent to the hose used by the rodent.

c. On February 7, 2018, rodent excreta pellets were observed throughout your facility.

i. At least ten apparent rodent excreta pellets were observed behind the oven on the north wall of the production area.

ii. Eleven apparent rodent excreta pellets were observed throughout the laundry room, where clean wash rags and aprons are stored.

iii. Thirty-seven apparent rodent excreta pellets were observed on and among unused equipment stored at the west end of the production room. Additionally, apparent rodent excreta pellets too numerous to count were observed on a table top in the same area. The unused equipment can be a harborage for pests.

The FDA sample INV 1037889, collected during the inspection, was analyzed by FDA's Pacific Northwest Laboratory. The analysis of this sample confirmed the presence of rat excreta pellets. The visual observations and the analytical results for this sample confirm the presence of rodent activity within your facility.

We reviewed your response and find it partially adequate. Your response states that you have patched the holes in the ceiling, cleaned the rodent excreta pellets and sanitized surfaces, covered the trench area, and asked the pest company to provide extra protection to the entire building, which included placing additional traps in areas showing evidence of rodents. However, your response did not provide any documentation of these corrections or details on how your firm intends on preventing this violation from recurring. It is unclear from your response how you will ensure the corrections you completed are adequate to correct the pest activity, such as increased pest control monitoring."

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https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/starlight-desserts-inc-548336-03212018

Management Through Prevention

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- ining a Program using a Risk Based Approach
- vention
- ection and Control
- munication
- lation
- ordkeeping
- iting

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Risk Based and Science Driven

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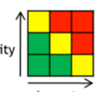
- rstanding Target Pests
  - oducts being manufactured
  - w materials being stored
  - ographical and historical pest pressures
- g Thresholds
  - ures consistency in when to react and how to react
- oring and Identification
  - t Sighting Logs
  - ernal inspections
  - O Service Reports



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Prevention

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- Exclusion
  - Keep pests outside
    - Building design and maintenance
    - Personnel practices – keep doors closed
    - Minimize foliage
- Sanitation
  - Remove food and water sources that attract and allow pests to grow
- Stored product pest
  - Stock rotation
  - Supply chain control
  - Removal of spillage and debris from storage locations

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ction and Control

- qualified licensed and insured pest rofessional to routinely inspect and te issues
- cialization in commercial food nufacturing accounts is critical
- on of low doses of targeted US EPA l pesticides
- baiting techniques
- nspection of the full facility
- vn days
- ening equipment and panels and other d to reach places
- orting of activity and areas of concern h recommendations of resolutions propriate)

Escalation

- should have a routine cadence with the person(s) onsible for the pest management program at the
- acility manager responsible for the program d routinely communicate results of inspections to management team members
- provement to programs will not happen in isolation
- ions are routinely not being addressed, ating to the next level of management is opriate

Recordkeeping

- Starts with having a clear contract between the PCO and their client
  - Includes expectations for current or anticipated service requirements
- Pest Sighting Log
- Pest Activity Records
- Treatment Records
- Trend Reports (quarterly trending at a minimum)
- Facility map with all equipment listed, including temporary devices
- Copies of licenses and certifications (including annual GMP training)

Communication

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- and facilities need to foster strong ionships with open communication
- the end of each PCO service a deep dive of the visit dings should be completed with the facility program wner(s)
- facility is accountable internally communicating ctive actions that need to be completed
- ally a program review should be completed een the PCO and the facility to determine uous improvement opportunities

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Auditing

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- The facility is responsible for ensuring that recordkeeping by the PCO is complete and accurate
- All 3rd party audit results should be reported to the PCO for continuous improvement
- Routine feedback from internal assessments should be shared between the facility and the PCO

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So who does "own" pest control?

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- FSMA clearly states that the food manufacturer is ultimately responsible for an effective pest management program
- It is legal obligation of the facilities management to ensure the program effectively prevents food adulteration.
- Ultimately it is a collaborative relationship between PCO and the facility that ensures product protection.
- Internal resources must be well versed in the pest control program and understand basic entomology

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Questions?

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WINNING THE CHALLENGES: A PMP'S PERSPECTIVE

DAN COLLINS

WE KILL IT

SO YOU DON'T HAVE TO THINK ABOUT IT.

RISK ASSESSMENT

- A systematic process of evaluating the potential risks that may be involved in a projected activity or undertaking.

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“INITIAL RISK ASSESSMENT”

- Prerequisite on-site survey – **MUST**!
- Provides a “quantitative” analysis of structure
- Demonstrates company’s ability to identify pest issues, conduct risk assessments and implement effective CAPA’s.
- Allows pest management company to design program based on “risk”.
- Establishes roles and responsibilities of both parties.

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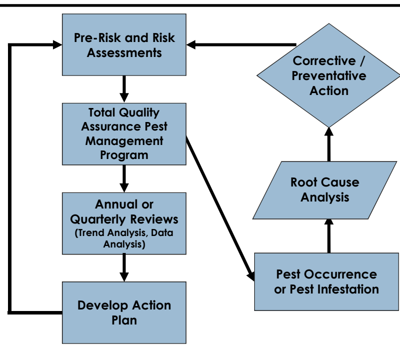
RISK BASED PEST MANAGEMENT SOLUTIONS



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PEST MANAGEMENT SOLUTIONS SINCE 1904

THE ULTIMATE GOAL

Protect the Food Product Integrity

WE KILL IT

SO YOU DON'T HAVE TO THINK ABOUT IT.

Winning the Challenges an Auditors perspective

Al St.Cyr - ASC Consulting

Successful Pest Management

- The auditor's role in the pest management evaluation is to assess the results of the program development and implementation against specific criteria.
- The plant must have knowledge and understanding of the audit criteria

Key Elements of a Successful Pest Management

- Clear and concise contracts for the services to be provided
- A detailed Scope of Service that outlines precisely how the work will be conducted to comply with Federal, State and local regulations.
- Established method and expectations for communication and sharing of information between the contractor and the plant.

Communication concerning the IPM program

- A well executed initial assessment of the entire facility and detailed documentation of the results.
- The current IPM program needs to reflect the issues noted on the assessment report.

Communication

- All reports should provide actionable information.
  - Using simple check off sheets that only provide a "Yes/No" answers do not have much value.
  - Every action taken during a service visit needs to be justified in the documentation of the service provided to the plant.
    - Why were pesticides applied
    - Why were traps replaced
    - Why were the numbers in pheromone traps increasing or other trending of devices.
  - The information needs to be used to develop a corrective action plan for all issues noted and kept open until completed.

Communication

- Every deviation or change from the established program must have supporting documentation justifying the change and approval from the facility.
- A communication section should be added to binders (if used) to have this information readily available to an auditor.
- **Remain calm and be patient.**