

New York State Rapid Response Team On the Job Experience to Full Preventive Controls Investigation

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Introduction

On 4/9/19, New York State Food Inspectors went with a FDA Investigator to Establishment A to conduct a limited scope Preventive Controls (PC) inspection for On the Job Experience (OJE) for the NYS Food Inspectors. Upon arrival, the NYS Food Inspectors and FDA Investigator saw the establishment had egregious conditions and would need a full PC inspection.

Establishment A manufactures donuts and pastries, including cream, icing, pudding, preserves, and jelly filled varieties, for bulk wholesale distribution to sub-distributors, food service establishments, and retail food stores.



Picture 1: Processing area at Establishment A

Investigation

The PC Inspection began on 4/9/19. Some of the critical deficiencies observed by the Inspectors/Investigators were:

- Six 50 pound packs of flour stored in the baked goods manufacturing area were found to be rodent defiled with mouse droppings and gnaw marks. 300 pounds of product were destroyed under signed waiver during the inspection.
- Over 200 finished product cardboard boxes labeled "RETURN EMPTY BOX," which were observed being reused to pack exposed, ready-to-eat finished product for distribution during inspection, were stored around the walls throughout the establishment, and were found to have extensive rodent activity/damage inside boxes, including: 11 live baby mice living in two boxes, 10-15 rodent nests, gnaw marks, chew holes, chewed food scraps, paper liners, and cardboard pieces; 50-100 mouse droppings, and urine stains inside boxes. Boxes also observed to have extensive amount of dried, encrusted food residues, grease stains, and loose materials across interior food contact surfaces. All boxes were removed from service and moved to the loading area, away from production and food storage areas, during the inspection.

- Two adult and eleven baby mice are present in the finished product storage area, where exposed, ready-to-eat baked goods are stored in open cardboard boxes on shelves throughout the area.
- Over 200 intermingled fresh and old appearing mouse droppings are present throughout the establishment, in areas where exposed, ready-to-eat foods are processed, conveyed, and stored, and also in areas where exposed dough is mixed and prepared.
- 50-100 live cockroaches are present throughout the establishment in areas where exposed, ready-to-eat foods are processed, conveyed, and stored, and also in areas where exposed dough is mixed and prepared.



Picture 2: Floor of food processing area in Establishment A



Picture 3: Baby mice in finished product storage area.

During the PC Inspection, evidence for pest activity was collected for filth analysis. Filth evidence found were apparent rodent excreta pellets (both dull and fresh) and nesting material. Eight filth samples (sweepings, pellets and rodent gnawing samples) were collected on 4/9/19. These samples were analyzed on 4/19/19.



Picture 4: More baby mice in storage area



Picture 5: Storage area in Establishment A



Picture 6: Boxes used for storage of ready-to-eat products in storage area of Establishment A.

Conclusion

- Establishment A obviously did not have a passing inspection on 4/9/19 and 4/10/19. On 4/12/19, a Temporary Restraining Order (TRO) was issued against this establishment by New York State Department of Agriculture & Markets.
- Results for the filth samples were positive and the report was issued on 4/19/19. FDA issued FDA Form 483 on 4/25/19 which included corrective actions taken and planned by the establishment.
- A FDA warning letter was issued to Establishment A on 9/6/19. Some of the issues addressed in warning letter.
 - Establishment was not taking effective measures to exclude pests from the processing areas and were not protecting against contamination of food on the premises by pests
 - The food safety plan did not include how the establishment uses preventive controls to prevent food-allergen cross contact.
 - The establishment did not have appropriate quality control operations to ensure that food is suitable for human consumption and food packaging materials are safe and suitable.
 - Establishment did not conduct all food manufacturing, packing, and holding under such condition and controls necessary to minimize the potential for growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.
- One of the first cases where state evidence was used for a PC warning letter. Excellent example of leveraging state and federal authorities to protect public health