

TO: Department of Health and Human Services  
Food and Drug Administration  
One Montvale Avenue  
Stoneham, MA 02180

FROM: Whole Foods Market North Atlantic Kitchen  
9 Commercial St.  
Everett, MA 02149

DATE: 03/17/16

RE: Inspection  
MA-0311  
FEI #: 3001451521

Dear Sir/Madam,

Whole Foods Market North Atlantic Kitchens (WFM NAK) thanks the FDA Department of Health and Human Services investigators for their thoughtful observations during the inspection from 02/10/2016 – 02/16/2016 – 02/18/16. Whole Foods Market takes these observations seriously and our senior leadership is committed to take all the necessary measures to correct all deficiencies. We appreciate the opportunity to respond to the following observations. Please accept this letter as our response.

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#### **OBSERVATION 1**

**Failure to manufacture, package and store foods under conditions and controls necessary to minimize the potential growth of microorganisms and contamination.**

**Specifically, on 02/10/16, 02/16/16 and 02/18/16 the following conditions and practices were observed in the Assembly Room (K4), K8/K9 Room, Veg Prep Room, Pre-Pack Room and Buk Room:**

**A: On 02/10/16, you were mixing RTE pesto pasta directly under an area in the Assembly Room (K4) where condensate from ceiling joints was dripping on the surface below.**

**B: On 02/16/16, you were holding an uncovered rack of RTE mushroom quesadilla in the same area of the Assembly Room (K4) where condensate from ceiling joints was dripping on the surface below.**

**C: On 02/10/16, you were transporting uncovered RTE vegetables through a doorway above which significant condensate had formed and was dripping. The doorway led to the Prepared Veg Cooler from the Veg Prep Cooler.**

**D: On 02/10/16, you were cutting chives and beets on a work surface directly under leaking condensate drainage pipe in the Veg Prep Room.**

**E: On 02/16/16, you were holding uncovered RTE egg salad in a large white barrel that were placed in an area below the condenser that dripped approximately once per second from the condenser fan bolts in the K8/K9 Room.**

**F: On 02/16/16, you were transporting uncovered RTE couscous through an area in K8/K9 where condensate was dripping from an area around the fan bolt at approximately once per second.**

**CORRECTIVE ACTIONS for OBSERVATIONS A through F:**

- Compromised rubber washers were replaced on condensation pans below fan units to ensure a tight seal.
- Specialized ceiling squeegees were purchased and implemented to more effectively capture and remove condensation.

- Leadership will assure compliance with the current Good Manufacturing Practices (cGMP's) during all hours of operations by monitoring condensation.
- Employees were trained to cover and remove product from the area (03/08/16).
- Employees were trained to wipe off condensation (03/08/16).
- On 03/08/16, employees were retrained to cover the product with a bag as soon as they are finished with the recipe to protect food during transport (See attachment).

**G: On 02/10/16, 02/16/16, 02/18/16, you were holding RTE vegetables, utensils such as cutting boards, mandolins, stainless colanders and yellow plastic totes in close proximity to hand washing station in Veg Prep Room. The hand washing station does not have splash guards and is foot operated releasing water from the faucets with significant pressure causing water to splash outside the sink while washing soiled hands. Water was splashing onto covered and uncovered vegetables as well as utensils and food containers.**

**CORRECTIVE ACTION:**

- Splashguards have been ordered for the hand wash stations and are to be implemented by 03/28/16.

**H: On 02/16/16, you measured the strength of the Peracetic Acid from the faucet in the Veg Prep Room with an (b) (4) (b) (4) Peracetic Acid that indicated its strength over 160ppm (maximum level test on the strip). This concentration exceeds the maximum level recommended by (b) (4) product information sheet and the maximum level allowed under 21 CFR Part 173.315 (a)(5) for use of peracetic acid for surface treatment and soaking and rinsing of vegetables.**

**CORRECTIVE ACTION:**

- Water may have entered the chemical drum diluting the strength of the chemical. Rubber stopper gasket has been installed to ensure drum cannot be compromised.
- The PAA (b) (4) was inspected and adjusted to ensure proper dispensing of solution.
- To get a more accurate concentration than by using the test strip. On 02/16/16, QA employees were trained to do PAA Titrations, which will be performed (b) (4) Validation period. One validation is proved successful, plant will move to (b) (4) titration testing. (see attached training).
- The firm is no longer using (b) (4) as an antimicrobial treatment of the vegetables; it has been replaced for (b) (4)

**I: On 02/16/16, your employee was performing multiple tasks in the Pre-Pack Room such as filling and weighing RTE Egg Salad onto retail packs, directly touching product and cleaning work surfaces without hand washing or changing gloves in between tasks.**

**CORRECTIVE ACTION:**

- Throughout the packaging procedures, any debris that may fall on the work surface will be cleaned with a paper towel that is available on the work table.
- Employee trainings are scheduled (b) (4) for all employees. On 03/08/16, employees were retrained on the process of proper handwashing and glove use. A PowerPoint presentation (see attached) was used to train employees (See attachment).

**J: On 02/16/16, your employee performing multiple tasks in the Bulk-Pack Room when packing RTE quinoa cakes and assembling bulk cartons without hand washing or changing gloves in between tasks.**

**CORRECTIVE ACTION:**

- Our policy is that food handling employees do not touch RTE foods and cardboard cartons simultaneously.
- On 03/08/16, employees were retrained on the process of proper handwashing and glove use. A PowerPoint presentation (see attached) was used to train employees. This training is scheduled (b) (4) for all employees. (See attachment)

**K: On 02/16/16, your employee in the Pre-Pack Room was spraying (b) quaternary ammonium based sanitizer to clean the work surface while another employee in close proximity was packing RTE Mesclun Salad. This resulted in sanitizer being sprayed onto an open colander of salad Leafy Greens.**

**CORRECTIVE ACTION:**

- During sanitizing procedures, products will be covered and good separation practices will be implemented to prevent contamination.
- On 03/08/16, employees were trained on the process of proper cleaning and sanitizing procedures. A PowerPoint presentation (see attached) was used to train employees. (See attachment)

**L: On 02/16/16, your employee's unprotected upper sleeves were frequently touching RTE leafy salad greens as they were assembling leafy salad greens into retail packs in the Pre-Pack Room.**

**CORRECTIVE ACTION:**

- As of 02/19/16, employees began using (b) (4) gowns to cover unprotected sleeves to prevent cross-contamination.

**OBSERVATION 2**

**Failure to maintain equipment in an acceptable condition, through appropriate cleaning and sanitizing.**

**Specifically, the presence of non-pathogenic bacteria *Listeria Welshimeri* was found on the environmental swab collected from the internal (rotating drum portion of the (b) (4) machine)(vegetable chopping) located in the Veg prep Room on 02/10/16 at 12:07pm. The presence of non-pathogenic bacteria *Listeria Welshimeri* is indicative of failure to maintain food contact surfaces of equipment in an acceptable condition through appropriate cleaning and sanitizing. See observation # 4-A, 4-B for cleaning and sanitizing of equipment.**

**CORRECTIVE ACTION:**

- Cleaning procedures have been updated to full disassemble vegetable cutting (b) (4) machine (b) (4) (please see updated SSOP).
- Please see attached document (b) corrective action procedures.

**OBSERVATION 3**

**Failure to sanitize and thoroughly dry, prior to use, food-contact surfaces which have been wet cleaned.**

**Specifically,**

**A: On 02/16/16, you had filled the dip tank for soaking sheet pans (used for raw meats and RTE in process and finished products) with a sanitizing agent (b) quaternary ammonium based sanitizer). You measured the sanitizer strength using a color based (b) (4) Test strip which indicated the sanitizer strength of 100ppm. This strength is not adequate for sanitizing food-contact surfaces as per the recommended limit identifies as 200-400ppm by the manufacturer**

**B: On 02/16/16, you measured the sanitizer strength on the spray nozzle located in the dish washing room that is used for filling dip tank and for sanitizing larger portable equipment and parts such as rotating blades of (b) (4) machine and Ribbon Blender Parts. The color based (b) (4) Test strip indicated sanitizer strength of 100ppm. This strength is not adequate for sanitizing food contact surfaces as per recommended limit identifies as 200-400ppm by the manufacturer.**

**CORRECTIVE ACTION:**

- On 03/10/16, the procedure has been updated and Sanitation employees were trained to measure the sanitizer strength of the spray nozzle and dip tank every time the tank is refreshed with sanitizer solution.
- Sanitation employees have been trained that the sanitizing solution should have strength of 200-400ppm and to record the strength in the Sanitizer Check Log (Dip Tank).
- Sanitation employees have been trained that the sanitizing solution should have strength of 200-400ppm and to record the strength in the Sanitizer Check Log (b) (4) (See attachments)

**C: On 02/16/16, you did not clean and sanitize the semi-permanent divider curtain in the K8/K9 Room after using high pressure spray hose to clean and sanitize the ribbon blender and the walls and floors surrounding the ribbon blender.**

**CORRECTIVE ACTION:**

- (b) (4) monitoring will take place throughout the day and deficiencies will be addressed.
- Full deep cleaning of all divider curtains takes (b) (4)
- On 03/10/16, Sanitation employees were re-trained to clean and sanitize the semi-permanent dividers, walls and floors after performing cleaning procedures on the ribbon blender in K8/K9. (See attachment)

**D: On 02/10/16, you were storing utensils and equipment parts inside containers and on rolling carts that had pooling water.**

**CORRECTIVE ACTION:**

- On 03/10/16, Sanitation employees were re-trained to invert utensils to drain standing water and promote air drying. (See attached)

#### **OBSERVATION 4**

**Proper precautions to protect food and food-contact surfaces from contamination with chemicals, filth and extraneous material cannot be taken because of deficiencies in plant design.**

**Specifically, on 02/10, 02/11, 02/16 and 02/18/16 the following conditions were observed:**

**A: You are using portable divider curtains and semi-permanent divider curtains to segregate areas between dishwashing room entrance and exit doors and the Assembly Room (K4) to keep soiled dishes separate from the RTE products assembled in the Assembly Room (K4). However, soiled equipment from various preparation processes including holding of raw chicken and turkey were touching both sides of the portable divider curtains. See observation # 4-C for cleaning and sanitation of these divider curtains.**

**CORRECTIVE ACTION:**

- Portable divider curtains were identified for each area (K4 & K8/9) and labeled one side of the divider "Clean" and the other side "Dirty"
- On 03/08/16, employees were trained not to leave soiled equipment at the "clean" side of the portable dividers (See attachment)

**B: You are using portable and semi-permanent divider curtains to segregate an area in the K8/K9 room when clean-in-place equipment such as ribbon blenders are cleaned and sanitized adjacent to an area where and when RTE foods are prepared. On 02/10/16 and 02/16/16, your use of high pressure hoses to clean ribbon blenders and the curtains were causing water and aerosolized spray from the cleaning activity to go beyond the portable divider curtains and semi-permanent divider curtains into areas where RTE food such as couscous and salad dressing were being prepared. Therefore, these portable and semi-permanent divider curtains do not provide adequate protection of RTE food when high pressure hoses are used to clean and sanitize clean-in-place equipment and the portable and semi-permanent divider curtains. Furthermore, these portable divider curtains do not have a designated clean and unclean side or a designated area of use. See Observation # 4-C for cleaning and sanitation of these divider curtains.**

**CORRECTIVE ACTION:**

- The high pressure hose in K8/K9 will be replaced by a low-pressure hose to prevent water and aerosolized spray from going beyond the portable divider curtains and semi-permanent divider curtains into RTE areas.
- Portable divider curtains were identified for each area (K4 & K8/9) and labeled one side of the divider "Clean" and the other side "Dirty"

**C: On 02/10/16 and 02/16/16, soiled / unclean equipment had accumulated beyond the entrance of the dish washing room. Soiled / unclean equipment, utensils and food containers were being held beyond the portable divider curtains separating the dish washing room and the Assembly Area (K4)/ this resulted in soiled / unclean equipment to be held for indefinite period of time in close proximity to RTE preparation activities such as making of enchiladas, mixing of pesto pasta and quesadillas. The existing entry and exit doors of the dishwashing room that opens into the busy Assembly Room (K4), where RTE products are prepared and the limited capacity of the dish washing room may contribute to this condition.**

**CORRECTIVE ACTION:**

- Leadership will assure compliance with the current Good Manufacturing Practices (cGMP's) during all hours of operations by monitoring the flow of soiled / uncleaned equipment to prevent accumulation beyond the entrance of the dish washing room.
- This process will be followed until the renovation of the dish room takes place. Dishroom will be expanded to accommodate overflow of soiled equipment that is in que to be washed and sanitized. Renovation plans were provided, discussed, and reviewed during exit meeting. Projected completion date July 1<sup>st</sup>, 2016.

**OBSERVATION 5**

**Hand-washing facilities lack running water of a suitable temperature.**

**Specifically, on 02/16/16 the handwashing station located at the entrance of the K8/K9 room did not have warm/hot water. Your employees returning from break and other non-food related tasks continued to use this tagged "out of service, no hot water, 02/16/16" handwashing sink before returning to preparing and handling RTE products.**

**CORRECTIVE ACTION:**

- QA personal monitor handsinks are monitored (b) (4) to ensure water is operating properly.
- On 03/08/16, employees were trained not to use handwashing sinks tagged for not having hot water. (See attachment)

**OBSERVATION 6**

**Failure to properly identify toxic sanitizing agents in a manner that protects against contamination of food.**

**Specifically, on 02/16/16 an unmarked drum of chemical that was connected to the vegetable preparation sink was observed in the Veg prep Room. It was verbally identified as paracetic acid to be used to soak vegetables.**

**CORRECTIVE ACTION:**

- Label on drum deteriorated off over time.
- On 02/17/16, the unlabeled drum of (b) (4) was removed from the Veg Prep room and was replaced by a new labeled drum of (b) (4)
- QA employees will check for chemicals to be properly identified. (See attachment)

Sincerely,

  
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Brian M. Corbley, Facility Team Leader  
Whole Foods Market North Atlantic Kitchens