



December 1, 2014

Remediation of *Listeria* Contamination in a Wheeling, Illinois Food Processing Facility

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Summary:

In July, 2014 a project was initiated to address a problem involving a microbiological pathogen in a food processing facility located in Wheeling, IL, which had been closed due to *Listeria* contamination. In May and June, 2014, the company operating in the facility was implicated in two product recalls due to contamination with *Listeria monocytogenes*. Operations in the Wheeling, IL facility were halted in June, 2014.

A plan was developed in cooperation with the U.S. Food and Drug Administration to identify the source of contamination and eliminate the pathogen from food processing and packaging equipment located in the plant as well as the plant environment. The plan included the application of gas phase ozone (RGF Environmental, Riviera Beach, FL) in all non-processing/packaging areas of the plant and cleaning and disinfecting the processing and packaging areas of the plant and all equipment with an EPA registered disinfectant and food contact surface sanitizer, PURE® Hard Surface (Pure Bioscience, Inc., San Diego, CA). PURE Hard Surface was also used to disinfect the office and administrative areas.

Extensive microbiological testing for *Listeria* was conducted prior to initiation of the reconditioning plan in order to identify potential sources of contamination. Prior to the initiation of the reconditioning plan and microbiological testing, the plant and equipment had been cleaned and sanitized using pre-existing protocols and chemicals. Two pieces of processing equipment and a drain were found to be positive for *Listeria*.

After completion of the cleaning and sanitizing, microbiological sampling was conducted on every piece of processing and packaging equipment and in all areas of the plant. All post-treatment samples tested negative for *Listeria*.

The results of the microbiological tests, prior to and after reconditioning, were provided to the U.S. Food and Drug Administration (FDA) for review. The owners of the Wheeling facility were notified by the FDA that both the equipment and the plant may again be safely utilized for the production of food based on the successful reconditioning of the plant and eradication of *Listeria*.

Introduction:

The Wheeling facility was leased and operated by a specialty food manufacturer, co-packer and private label resource company that produced organic, all-natural, and gourmet foods. The company developed and manufactured salsas, sauces, pesto, hummus, salads, dips, prepared deli salads, and many other gourmet foods. As of June, 2014, the manufacturer was one of the largest producers of hummus and salsa in the United States. The company also had its own line of fresh salsas, hummus and other fresh food products that it produced and sold under its own label.

In May, 2014, the company was faced with the first of two catastrophic food pathogen related events resulting in voluntary product recalls. On May 19, 2014, the company announced that it was voluntarily recalling 14,860 pounds of hummus and dip products due to concerns about possible contamination with *Listeria monocytogenes*. The potential for contamination was found during a routine test of a private label hummus dip by the Texas Department of Health. Although no illnesses were reported, the company's brand was damaged by the *Listeria* recall.

On June 8, 2014, the company initiated a second voluntary recall of 304 containers (approximately 114 pounds) of a private label egg white salad. The Company had instituted a "test and hold" procedure as a temporary corrective action in response to the first recall announced on May 19, 2014. Although the 304 units of product were conspicuously identified as "test and hold", an employee erroneously shipped the product to a customer on June 4, 2014, resulting in the need to initiate a voluntary recall of the product in question. The product was tested and the results indicated a presumptive positive for *Listeria monocytogenes*.

Subsequent to the two voluntary recalls, the company received notice from its largest customer that that they would immediately cease the procurement of food products manufactured by the company, resulting in great economic loss to the company. On July 11, 2014, the company terminated its lease for the Wheeling facility and surrendered the property back to the owner. The Company also simultaneously laid off all of the remaining staff at the Wheeling Facility.

Listeria monocytogenes

Listeria monocytogenes is a bacterial pathogen present in food processing settings and agricultural settings. *L. monocytogenes* is able to survive in the processing environment for long periods of time in areas such as drains, floors, machinery and even on foods. *L. monocytogenes* can cause serious and sometimes fatal infections in young children, elderly and those with weakened immunity. It can also cause miscarriages and stillbirths among pregnant women.

Antimicrobial Treatments Used

Ozone (RGF Environmental, Riviera Beach, FL):

Ozone is an unstable gas with a characteristic odor. Ozone is produced on site from oxygen by either ultraviolet irradiation of air or by passing a high-voltage discharge through air. It is an effective oxidizing agent that decomposes to molecular oxygen at ambient temperature. Ozone can be applied in gaseous phase or as an aqueous solution to decontaminate food-contact surfaces, sanitize equipment, reprocess wastewater, and decrease pesticide levels on fresh produce.

PURE Hard Surface (PURE Bioscience, Inc., San Diego, CA)

PURE's non-toxic, environmentally responsible cleaning products, based on the company's proprietary Silver Dihydrogen Citrate (SDC) technology, provide professional strength cleaning and disinfecting for food processing facilities, commercial kitchens, restaurants, hospitals, public facilities, manufacturing plants, schools and institutional facilities.

PURE Hard Surface is an EPA registered ready-to-use disinfectant and food contact surface sanitizer that rapidly eliminates bacteria, viruses and fungi from surfaces without having to be rinsed off after treatment. PURE Hi-Foam and Multi-Purpose Cleaner is a non-flammable, high foaming, odorless cleaning solution that contains no EDTA, phosphates, ammonia, bleach, VOCs or NPEs, and is a perfect complement to PURE Hard Surface disinfectant and sanitizer.

PURE's SDC-based products can be used on surfaces in food preparation and processing areas where meats, poultry, seafood and produce can harbor and transmit harmful bacteria. SDC rapidly eliminates microbes without any of the safety issues presented by commercial cleaners and disinfectants such as bleach, ammonia and alcohol based sanitizers. Extensive field trials have demonstrated how the introduction of SDC-based products into existing cleaning protocols can significantly mitigate the threat of contamination and improve overall food safety.

Decontamination Plan

In July, 2014 a joint visit was scheduled involving the Chicago Office of the U. S. Food and Drug Administration, the owners of the Wheeling facility, their attorney and Dr. James Marsden – a food safety expert at Kansas State University. After an evaluation of the facility, a plan to remediate *Listeria monocytogenes* from processing and packaging equipment and from the plant environment was submitted to the owners of the facility and to the U.S. Food and Drug Administration. The plan was

designed to systematically address all potential vectors of *Listeria* contamination. It consisted of the following actions:

Phase 1 – Microbiological Mapping

A comprehensive microbiological mapping study was conducted in an attempt to identify the source of *Listeria* contamination and perform a root cause analysis. The study was designed to locate *Listeria* harborage points in the plant environment. Positive *Listeria* samples were serotyped to determine if there were PFGE matches to previous isolates identified in the plant environment. Results of the mapping study and any *Listeria* isolates were provided to FDA.

Environmental samples were taken using EZ Reach Sponge Samplers with Cellulose Sponge in 24 oz. sterile bag containing 10 ml Buffered Peptone Water (World Bioproducts, Mundelein, IL).

Various sampling sites were chosen, and the premoistened EZ Reach Sponge sampler was used to swab a 100 cm² area, using a sterile template as a guide, swabbing the area vertically, horizontally, and diagonally. The sponge was returned to the bag, the handle snapped off and the bag was sealed. Each sample bag was numbered and the sampling sites were recorded as samples were taken. All sample bags were placed in a cooler with ice packs and sent to an independent third party lab for analysis.

Phase 2 – Removal of Remaining Materials from the Plant

All remaining materials in the facility, including dry storage, food raw materials, product samples and finished food products were removed from the premises. This was done in accordance with FDA regulations. Records documenting the removal and disposition were provided to a representative of FDA.

Phase 3 – Environmental Remediation

The remediation phase of the project included an intense cleaning and sanitation of the entire facility, including food processing areas, dry storage areas, freezers, coolers, offices, research facilities, labs, maintenance areas and adjoining warehouses. The cleaning and sanitation initiative was performed by a professional remediation crew and included the application of PURE Hard Surface disinfectant/sanitizer (Pure Bioscience, Inc., San Diego, CA).

Phase 4 – Air Conditioning Units and Air Handling Systems

All air conditioning units were tested to determine possible *Listeria* contamination sites. Each unit was treated using gas phase ozone (RGF Environmental, Riviera Beach, FL) and sanitized with PURE Hard Surface disinfectant/sanitizer (Pure Bioscience, Inc., San Diego, CA).

Phase 5 – Decontamination of Processing and Packaging Equipment

All food processing and packaging equipment in the facility was cleaned and sanitized with PURE Hard Surface disinfectant/sanitizer (Pure Bioscience, Inc., San Diego, CA).

Phase 6 – Systematic Decontamination Using Gas Phase Ozone

All non-food processing areas of the facility – room by room – were decontaminated using Turbo Ozone generators (RGF Environmental, Riviera Beach, FL). This process was done to assure that all non-food processing areas of the plant were exposed to a lethal treatment for *Listeria*. In addition, fork trucks and ancillary equipment were treated with PURE Hard Surface disinfectant/sanitizer (Pure Bioscience, Inc., San Diego, CA).

Phase 7 – Verification

After the completion of Phases 1 -6, a second microbiological mapping study was conducted to assure that *Listeria* contamination was fully addressed.

Phase 8 – Maintenance of Decontamination Systems for Non-Processing Areas

A plan was submitted to the owners of the facility and the FDA outlining a documented preventative maintenance and sanitization schedule to assure that all decontamination systems are operative. The plan includes twice annual microbiological mapping studies.

Implementation of the Decontamination Plan

Decontamination efforts were focused on the two operational areas of the plant where the microbiological issues were localized: 1) the manufacturing (processing) area and 2) the packaging area. These two areas totaled approximately 45,000 square feet. The two areas were directly adjacent to each other and separated by a wall with three (3) double doors between the two rooms. Ceiling height was 24 feet, the walls were constructed of an acceptable cleanable surface, and the floors were epoxy sloped properly to the drains. Air handling units in each room were suspended below the ceiling within the operations areas.



Figure 1: Manufacturing and packaging at Wheeling, IL facility where *Listeria* contamination was identified.

Processing Room:

Operations typically performed in this area were:

1. Immediate storage of raw materials to be batched and processed.
2. Batch weigh out and raw material preparation.
3. Raw material processing into finished products by a single batch process.
4. Finished bulk product was placed into transport bins for transfer to the packaging area.

Equipment consistent with a batch processing operations were located in the room including: Scales and scale tables, stainless steel work tables, multiple Staphan and Urschel sizers, grinders and mixers, as well as transport bins and totes for raw materials, WIP and finished products.

Packaging Room:

The packaging room contained 4 large and 2 small packaging lines. Operations typically performed in this area were:

1. Finished bulk product transferred into the packaging room from the processing area.
2. Finished bulk product transferred from product bins and totes into surge hoppers on packaging lines.
3. Finished bulk product, cold filled, non-vacuumed packed into retail-ready containers.
4. Packaging of retail-ready unit case packs which were transferred into cold storage areas adjacent to the packaging room.

Equipment consistent with cold non-vacuumed packed retail ready food products were located in the room including: Conveyors (plastic and stainless steel), stainless steel feed hoppers, volumetric fillers, packaging feed mechanisms, metal detectors and pack off tables.

Equipment Decontamination:

All processing and packaging equipment in the plant had been disassembled and cleaned prior to implementation of the reconditioning plan. As outlined in the decontamination plan, the processing and packaging equipment was treated with PURE Hard Surface disinfectant/sanitizer using the following spray equipment:

1. Foam-It Model #SP-5N: Portable 5 gallon sprayer, equipped with a fine mist nozzle;
2. Foam-It Model #SP-2SL: Portable 2 liter sprayer: Equipped with a fine mist nozzle

Application Protocol: On the afternoon of the first day the equipment, tables and all parts in both the processing and packaging rooms were sprayed using the Foam-It Model #SP-2SL, portable 2 liter sprayer. The surfaces were sprayed enough to assure homogeneous coverage without over-spraying. The following morning, PURE Hard Surface was again applied to the processing and packaging equipment using the Foam-It Model #SP-5N, portable 5 gallon sprayer attached to a compressed air source supplying 70 PSI incoming pressure. Again, the surfaces were sprayed using the fine mist nozzle

until there was homogeneous coverage without over-spraying, and allowed to air dry. Microbiological samples were taken for *Listeria* analysis after treatment.

Processing and Packaging Room Decontamination:

All areas of the processing and packaging rooms were treated with PURE Hi-Foam Multipurpose Cleaner and PURE Hard Surface disinfectant/sanitizer using the following spray equipment:

1. Foam-It Model #SP-5N: Portable 5 gallon sprayer, equipped with a fine mist nozzle;
2. Foam-It Model #SP-5N: Portable 5 gallon foaming sprayer, equipped with a foaming nozzle

Application Protocol: All surfaces of the room (floors, walls, tables, drains, equipment, and air handling units) were sprayed with a 1:50 dilution of PURE Hi-Foam Multipurpose Cleaner using the Foam-It Model #SP-5N, portable 5 gallon foaming sprayer attached to a compressed air source supplying 70 PSI incoming pressure. The equipment was set to allow for thick foam to cover all treated surfaces. The cleaner was completely rinsed using a potable water source and all surfaces were allowed to air dry.

All surfaces of the room were then treated with PURE Hard Surface disinfectant/sanitizer using the Foam-It Model #SP-5N, portable 5 gallon sprayer attached to a compressed air source supplying 70 PSI incoming pressure and allowed to air dry. Microbiological samples were taken for *Listeria* analysis after treatment.

Results and Discussion

The microbiological samples that were taken prior to and after the decontamination project were analyzed by an independent, certified laboratory, Deibel Labs in Lincolnwood, IL. Initial testing found three positive results for *Listeria*: Two of the positives were on processing equipment and the third was in a floor drain.

After the completion of the decontamination project, no positives for *Listeria* were reported in 300 environmental samples taken from the facility. Microbiological sampling included virtually every piece of processing and packaging equipment in the facility and every room and area of the plant. It also included every drain in the processing and packaging rooms.

The results of the microbiological testing show that the PURE Hard Surface disinfectant was effective at eliminating *Listeria* from equipment and from the plant environment. The U.S. FDA issued two letters to the owners of the facility releasing the equipment and facility for manufacturing of FDA regulated product based upon the successful eradication of the pathogen from the facility.