**Blue Bell Creameries Inc.**
**Summary of Root Cause Assessment**
**Broken Arrow, Oklahoma, Facility**

After the discovery of *Listeria monocytogenes* (*Lm*) in certain ice cream products manufactured by our company at our Broken Arrow facility, we began investigatory, sampling and remediation efforts to control the situation, ultimately choosing to voluntarily shut down operations. With operations voluntarily suspended, we focused on identifying potential sources of *Listeria*. We worked closely with our outside experts to investigate potential avenues of *Listeria*, using the results of that investigation to inform our corrective actions and updated procedures. We conducted this investigation in parallel with ongoing remediation efforts with the goal of controlling and eliminating potential sources of *Listeria* in all of our facilities.

We identified or learned about several lots of finished product produced at our Broken Arrow facility that tested positive for the presence of *Lm*. We recalled affected product, ultimately recalling all product produced at the Broken Arrow facility and suspending operations at this facility. Working with our outside experts, we investigated the facility and equipment and collected extensive samples from equipment and other surfaces in an effort to understand how *Listeria* may have become present and how it could be prevented in the future. Equipment was disassembled and carefully tested. The vast majority of these samples came back negative for *Lm*, but some tested presumptive positive for *Listeria species*, *Lm*, or both. We focused critical attention on any equipment associated with presumptive positive environmental findings or finished product, as well as on equipment and facility design and employee practices.

During our investigation, we determined that cleaned equipment that contacts product after pasteurization was being stored in a small room outside the sanitary production area. Equipment was being stored in this room after it was sanitized. This room had a drain in the floor. We learned that it was possible for particles capable of potentially carrying *Listeria* to be emitted from this drain. The drains from the facility ultimately empty into the same system to which this drain was connected, creating the potential for *Listeria* in the plant environment to be washed into the drains to be re-released into the storage room. We believe that this mechanism—particles emitted from a drain—was the most likely source of *Listeria.* We also identified potential sources associated with two pieces of filling equipment, although these samples were identified after some construction had been underway in the plant environment, making it unclear whether these samples reflected prior operating conditions. Employee hygienic practices and equipment design may have been contributing factors.

Based on this analysis, we identified and implemented specific corrective actions to address the likely source of *Listeria* as well as facility-wide programs to enhance our overall ability to prevent reintroduction of *Listeria* into the environment. As reported to FDA, we removed the equipment from the storage room in question and no longer use that room for equipment storage. We have removed the drain, filled and sealed the hole in the floor, and replaced the floor with a new (b) (4) floor. We now use this space as an employee smock room. We identified and implemented corrective actions to enhance (b) (4). We also disassembled each piece of equipment, cleaning and sanitizing it before putting it back into operation, making modifications as necessary along the way. We tested equipment after sanitizing it to verify that any *Listeria* had been eradicated.

We also took broad corrective actions, incorporating learnings from our investigation post-shutdown and from our other facilities. We enhanced and refined our cleaning and sanitation programs and retrained employees on the enhanced procedures. For example, we reviewed our procedures to ensure we are using the appropriate water temperature and sanitizer concentration during cleaning and sanitation activities. We also reviewed and enhanced our Good Manufacturing Practices (GMPs), focusing on ensuring that employees follow good hygienic practices and handle equipment and product appropriately. We shared these and other learnings across our facilities.

Further, we (b) (4) in our Broken Arrow facility. The (b) (4) (b) (4) capable of destroying *Listeria,* and we validated its effectiveness. We view our daily cleaning and sanitation programs and employee GMPs as the first line of defense in preventing the reintroduction of *Listeria*, and we periodically (b) (4) equipment to ensure that hard-to-clean areas are disinfected to reinforce our routine sanitation efforts. Moreover, recognizing the potential for *Listeria* to become established in a wide range of environments, prior to restarting production we (b) (4) our Broken Arrow facility and administered a (b) (4) treatment validated to destroy *Listeria* to key areas of the processing and production areas of the facility before resuming production, providing us a clean slate from which to begin operations. We conducted extensive environmental testing post-treatment to verifying its effectiveness.

We also reviewed and enhanced our environmental and product testing programs. We implemented an enhanced environmental monitoring program to verify that our cleaning and sanitation procedures, and other control measures are effective and to direct additional attention to any presumptive positive findings to prevent reintroduction of *Listeria*. We developed a food contact surface and finished product testing program, which we use as our test and hold program on all finished ice cream product. Lots of ice cream are not released unless all relevant food contact surface and finished product testing returns negative for *Lm*. Finally, working with our outside experts, we put into place an enhanced ingredient oversight program so that key suppliers are appropriately qualified and critical ingredients are subject to a testing regimen.

In sum, we believe that *Listeria* likely entered the facility through various potential sources and eventually became present in the drain system. The *Listeria* then may have been released into the air from the drain, thereby coming into contact with equipment and traffic into and out of the storage room. We therefore directed our efforts at identifying a more appropriate storage location for equipment, cleaning and sanitizing the production and processing areas of our facility, and equipment, and enhancing our sanitation procedures and testing programs to protect against reintroduction of *Listeria*. We believe that these enhanced programs are enabling us to effectively control for *Listeria* in our Broken Arrow facility.