

**Blue Bell Creameries Inc.  
Summary of Root Cause Assessment  
Brenham, Texas, Facility**

After the discovery of *Listeria monocytogenes* (*Lm*) in certain ice cream products manufactured by our company at our Brenham 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*.<sup>1/</sup> 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 our facilities.

We identified or learned about several lots of finished product produced at our Brenham facility that tested positive for the presence of *Lm*. We recalled affected product, ultimately recalling all product produced at the Brenham facility and suspending operations. Our main Brenham facility is our largest facility with the most production lines, making investigating and eliminating potential sources of *Listeria* an especially complex process. Working with our outside experts, we collected extensive samples from equipment and other surfaces in an effort to understand how *Listeria* may have become present in the facility and on product 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, presumptive positive for *Lm*, or both. We focused critical attention on the presumptive positive findings as well as on equipment and facility design and employee practices.

We identified several potential or likely sources of *Listeria* to the product based on our investigation, sampling and analyses. These potential sources varied by production line and included equipment such as (b) (4) and specific pieces of equipment, such as the (b) (4) and the (b) (4) machine. Individual pieces of equipment were addressed—some were disassembled and thoroughly cleaned, others were taken out of commission and removed from the facility. Although we took remedial action on individual pieces of equipment, it became evident that we would not be able to identify a single source to our entire Brenham facility, turning our focus to facility-wide remediation efforts intended to prevent the reintroduction and reestablishment of *Listeria* in our facility.

We identified several key corrective actions, which we have already shared with FDA and fully implemented. In Area (b) (4) we identified the (b) (4) machine and (b) (4) as likely sources of *Listeria*. We evaluated the (b) (4) machine and concluded that its design made it difficult to clean using our enhanced cleaning and sanitation programs. We therefore decided to permanently decommission the (b) (4) machine and removed it from the production building. We felt the (b) (4) (b) (4) without jeopardizing other remediation efforts, so we (b) (4) (b) (4). Before (b) (4) we cleaned and sanitized the (b) (4) and tested it for *Listeria*, receiving negative results. We have no plans to (b) (4)

---

<sup>1/</sup> For the Brenham facility, our review focused on the main ice cream manufacturing facility. The nearby small facility known as the “snack plant” (b) (4) (b) (4). This root cause discussion addresses our main facility exclusively.

(b) (4). We have also taken the (b) (4) equipment out of operation (some pieces have been removed from the production area; others have been left in place and regularly cleaned and sanitized) and currently do not have plans to use the equipment in the immediate future, but will reevaluate that later this year. We concluded we could keep other equipment (subject to our new and enhanced cleaning procedures), sometimes with modifications based on our analysis. We disassembled this equipment and sanitized 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 corrective actions more broadly, incorporating learnings from our investigation post-shutdown. Recognizing that *Listeria* could have entered the facility from various sources and established harborage sites on the equipment, 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 Brenham 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) key processing and production and related areas of our Brenham facility and administered a (b) (4) treatment validated to destroy *Listeria*, 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, equipment, and product testing programs. We implemented an enhanced environmental monitoring program to verify that our cleaning, sanitation, and other microbial control procedures are effective and to direct additional attention to any presumptive positive findings to prevent reintroduction of *Listeria*. We also 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 all, we believe that *Listeria* likely entered the facility from various potential sources and established harborages on some pieces of equipment. We could not identify a single common source of *Listeria* in the facility. Accordingly, we directed our corrective actions toward addressing individual pieces of equipment that returned presumptive positive test results, cleaning and sanitizing our entire 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 Brenham facility.